ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301212; FRL–6821–4]

RIN 2070–AB78

Lysophosphatidylethanolamine (LPE); 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 biological pesticide lysophosphatidylethanolamine (LPE) on all food commodities when applied/used in accordance with good agricultural practices. Nutra-Park, Inc. 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 LPE.

DATES: This regulation is effective April 11, 2002. Objections and requests for hearings, identified by docket control number OPP–301212, must be received by EPA, on or before June 10, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301212 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Carol E. Frazer, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8810; and e-mail address: frazer.carol@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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301212. 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 January 3, 2002 (67 FR 323) (FRL–6773–6), 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 (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (PP 1F6244) by JP BioRegulators, now called Nutra-Park Inc., 8383 Greenway Blvd., Suite 520, Middleton, WI 53562. This notice included a summary of the petition prepared by the petitioner Nutra-Park, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1199 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of lysophosphatidylethanolamine (LPE).

III. Risk Assessment

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.

EEPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

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

LPE is a phospholipid. Phospholipids are a heterogeneous group of compounds that are classed together partly because of their solubility, and partly on the basis of the ester phosphorus present in the compounds. Phospholipids are found in all cellular organisms as part of the structure of the cellular membrane.

The framework of membranes surrounding the cell and intracellular organelles is composed of a bilayer of lipid. The basic unit of the bilayer is a composite of phospholipids (phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol). LPE is derived from phosphatidylethanolamine by the enzymatic removal of one fatty acid by a phospholipase. Residues of LPE naturally occur in raw agricultural commodities and are eaten regularly. For example, LPE and *N*-acyl LPE levels are found in the following foodstuffs: 13-15 mg/100 g in corn grain, 0.5-29 mg/100 g in rice and 15-64 mg/100 g in wheat grain; and 2.1% lipid phosphorus in egg yolk. LPE plus lysophosphatidylcholine (LPC) in cow milk was 7.6% w/w and it is found in human breast milk (Ref. 1). Residues of LPE will not be significantly increased in raw agricultural commodities through the use of this product. For example, using reasonably foreseeable residue levels based on application rates, the level of LPE applied to apples would be approximately 0.06% greater than that found naturally in apple pulp (Ref. 2).

Toxicity studies submitted in support of this tolerance exemption are referenced below. More detailed analyses of these studies can be found in the specific Agency reviews of the studies (Refs. 3 and 4). In addition, a substantial body of information on LPE is published and selected copies are included in this reference (Ref. 5).

Two toxicity studies using the same protocol were submitted for each category captioned below one for the technical (LPE E94T) and one for the end-use product (LPE-94 10% Aqueous Growth Regulator). The results of study reviews are combined in the summaries that follow. LPE E94T is covered first. Next, a reduced concentration, 35% LPE, is shown as representative test material for the end-use product, although it is not as reduced as the pending end-use product concentration (10%).

1. *Acute oral toxicity (OPPTS 870.1100; 152–10; MRIDs 452740–01 and 452736–01).* Five male and five female rats were dosed with 5,000 milligrams/kilograms (mg/kg) of LPE E94T or 35% LPE and observed for 14 days. All rats survived and gained weight throughout each study. LPE E94T caused two females to exhibit liquid feces and oily urogenital areas on the day of dosing (symptoms cleared by day 1 post dosing), but the end-use product showed no abnormal symptoms. All rats appeared normal during the study. Based on the data, the acute oral LD_{50} for rats was >5,000 mg/kg. Classification: Acceptable; Toxicity Category IV.

2. *Acute dermal toxicity (OPPTS 870.1200; 152–11; MRIDs 452740–02 and 454361–01).* Five male and five female rabbits were given 2,000 mg/kg LPE E94T or 35% LPE dermally for 24 hours and observed for the following 14 days. All rabbits survived and gained weight throughout the study. LPE E94T caused erythema, edema, atonia, fissuring, and/or desquamation on some rabbits during the study, but all symptoms cleared by day 14. Some of the 35% LPE rabbits also exhibited very slight to well-defined erythema and/or desquamation symptoms that cleared by day 14. One female had very slight erythema by day 7 through day 10 and desquamation by day 7 through the end of the study. The acute dermal LD_{50} for rabbits was >2,000 mg/kg. Classification: Acceptable; Toxicity Category III.

3. *Acute inhalation toxicity (OPPTS 870.1300; 152–12; MRIDs 452740–05 and 452736–04).* In the first study, five male and five female rats were exposed for four hours to nominal atmospheric concentrations of 91.21 mg/L LPE E94T and observed for 14 days. In the second study, the same number and mix of animals were exposed to atmospheric concentrations of 35% LPE for 4 hours and observed for 14 days. All rats survived the study. After an initial post-exposure weight loss, all rats gained weight through the remainder of the study. All rats had wet stained fur and two males and one female had red/brown staining around the nose on day 1 in the LPE E94T study, while two males and one female had staining around the eyes on the day of exposure to the 35% LPE, but symptoms cleared by day 2 in both studies. One male in the 35% LPE study had a sore on his neck on days 2-7 and days 13-15. Gross necropsies in the LPE E94T study indicated that the lungs were unaffected, but certain other abnormalities were noted in some rats. The abnormalities were not likely the result of exposure to the test substance, and are commonly noted in lab animals. No abnormalities occurred in the 35% LPE study. The inhalation LC_{50}'s for rats was >2.50 milligram/liter (mg/L) for the LPE E94T and >4.63 for the 35% LPE. Classification; Acceptable; Toxicity Category IV.

4. *Primary eye irritation (OPPTS 870.2400; 152–13; MRIDs 452740–04 and 452736–03).* In the first study, three adult rabbits administered 29 mg LPE E94T mixed in 0.1 mL water into the everted right eyelid, then observed for 72 hours. No corneal opacity was noted on any rabbit. All rabbits in the group had iritis and conjunctivitis one hour after instillation of LPE; all symptoms cleared by 48-hours post-instillation. In the second study, three adult rabbits administered 0.1 mL of undiluted test substance 35% LPE into the everted right eyelid, then observed for 72 hours. No corneal opacity was noted on any rabbit. One rabbit exhibited very mild conjunctivitis at 1–hour post-instillation, but symptoms cleared by 24 hours. Based on the data, LPE E94T was considered a minimal irritant. Classification: Acceptable; Toxicity Category III. Based on the data for 35% LPE, this compound was practically non-irritating. Classification: Acceptable; Toxicity Category IV.

5. *Primary dermal irritation (OPPTS 870.2500; 152-14; MRIDs 452740–03 and 452736–02).* Three each adult rabbits were treated with 0.5 g of LPE E94T mixed with 0.95 mL water or 35% LPE dermally for 4 hours and observed for the following 72 hours. No irritation was noted on any rabbit. LPE E94T and 35% LPE were non-irritants. Classification: Acceptable; Toxicity Category IV.

6. *Hypersensitivity (OPPTS 870.2600; 152–15; MRIDs 454357–01 and 452736–*

05). Thirty-eight each adult male guinea pigs were used to test the potential for dermal sensitization of LPE E94T or 35% LPE by a Magnusson and Kligman maximization method. All animals survived and gained weight throughout the studies. Mild to moderate erythema and edema reactions with scab formation at the injection sites were noted on all test and control animals throughout the observation period. Following challenge, all treated test animals showed scattered mild redness to intense redness and swelling on the right side. The left side, treated with sterile water, showed no irritation after challenge. None of the control animals in either study showed irritation on either side 24 and 48 hours after challenge. Both LPE E94T and 35% LPE were extreme dermal sensitizers.

Data Waivers (Ref. 6) were requested for the following studies:

Studies to detect genotoxicity (OPPTS 870.5300)

Immune response (OPPTS 880.3800)

Mammalian mutagenicity test (OPPTS 870.5195)

90-Day feeding (1 species) (OPPTS 870.3100)

90-Day dermal (1 species) (OPPTS 870.3250)

90-Day inhalation (1 species) (OPPTS 870.3465)

Teratogenicity (1 species) (OPPTS 870.3700)

Chronic exposure (OPPTS 870.4100) (Tier III)

Oncogencity (OPPTS 870.4200) (Tier III)

The registrant submitted additional information to support waivers from the data requirements for additional acute toxicity testing, subchronic toxicity testing, and chronic toxicity testing (Ref. 6). The registrant's rationale to support the waivers is that LPE is ubiquitous in nature and this and related phospholipids are synthesized by microorganisms, plants, and animals. These compounds are also ubiquitous in the human diet. Also, phospholipids have specific roles in cellular functions and in maintaining the integrity of cell membranes. Much of these data regarding LPE and related phospholipids were submitted in support of similar waivers in conjunction with a temporary tolerance exemption (see 40 CFR 180.1199) (Ref. 5) for the use of this active ingredient under an Experimental Use Permit (EPA Reg. No. 70515–EUP–1). See also memo from Russell Jones, Ph.D. to Sheila Moats, Ph.D., October 8, 1997 (Ref. 7). The aforementioned data may be bridged to support the current waiver requests. In addition, there is a long history of consumption by humans of lipids in food and the Agency knows of no instance where lipids have been associated with any toxic effects related to the consumption of food. Due to this knowledge of LPE's presence and function in the human system (Ref. 1) and the recent acute testing, EPA believes LPE is unlikely to be carcinogenic or have other long-term toxic effects.

V. 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.* Because LPE is a naturally occurring fat present in all living organisms, there is a great likelihood of exposure to naturally occurring LPE for most, if not all individuals, including infants and children. As mentioned above, LPE is found in human breast milk, cow milk, corn grain, starch, oats and plant tissues and high quantities are found in both egg yolk and meats (Ref. 1). Thus, LPE is a normal part of the human diet. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to LPE. A gallon of end-use product can be produced from the LPE equivalent to that found in six eggs (Ref. 5). The product would then be diluted to achieve the 25-400 ppm of LPE proposed for final spray or dip use. Even if there is a significant increase in exposure to LPE due to its use as a pesticide, the battery of acute toxicity studies submitted by the registrant demonstrating very low mammalian toxicity (Toxicity Categories III and IV) indicates that risk associated with acute exposures by the oral, dermal and inhalation routes would be low to non-existent.

2. *Drinking water exposure.* LPE may get into surface water during run-off, but dissipation of LPE in the environment will, in all likelihood, be through microbial mediated degradation which will rapidly remove the residues (Ref. 1). The levels of residues that might get into ground or surface water used for drinking water will not be high compared to the exposure from naturally occurring residues of LPE.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to LPE pesticide residues for the general population, including infants and children, is unlikely because potential use sites are commercial, agricultural, and horticultural. However, because LPE is a natural fat present in all cellular organisms, there is a great likelihood of prior exposure for most, if not all, individuals. LPE is a normal part of the human diet and the increased exposure due to this proposed product would be negligible.

VI. Cumulative Effects

The Agency has considered the cumulative effects of LPE and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. There is no indication of mammalian toxicity at the maximum doses tested, of this or other products containing LPE.

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

1. *U.S. population.* There is reasonable certainty that no harm will result from aggregate exposure to residues of LPE to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV) associated with LPE and the long history of safe use and consumption of LPE.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that LPE is practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. As a result, EPA has not used a margin of exposure

(safety) approach to assess the safety of LPE.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen- and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program(EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, LPE may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of LPE. It is a naturally occurring residue in raw agricultural food, feed commodities and processed food. To date, there is no evidence to suggest that LPE affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including LPE's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for LPE.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues of LPE.

IX. Conclusions

Based on the toxicology data submitted, there is reasonable certainty no harm will result from aggregate exposure of residues of LPE to the U.S. population, including infants and children, when the proposed product is used in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on data submitted demonstrating no toxicity at the maximum doses tested and the long history of safe use and consumption of naturally occurring LPE. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of LPE in or on all food commodities.

X. 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–301212 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 June 10, 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 IX.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 number OPP–301212, 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).

XI. References

1. JP BioRegulators, Inc. A Review on Lysophosphatidylethanolamine and Related Phospholipids, 2000.

2. Nutra-Park Inc. Effect of LPE Applications, 2002.

3. USEPA. Science review in support of registration of LPE E94T Technical and LPE–94 20% Aqueous Growth Regulator; Memo from Jones, Russell S., Ph.D., September 13, 2001.

4. USEPA. Data Evaluation Record: Skin Sensitization (MRID 454357–01), Reilly, Sheryl K., Ph.D., January 21, 2002.

5. Palta, Jiwan, Ph.D. and Hartman, Christina L., Ph.D.: Phospholipid Safety Data in Support of a Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Phospholipid for Use in Grapes, Tomatoes, Apples, Pear, Peaches, Nectarines, Citrus, Cranberries, and Strawberries, 1997 (MRID 443399–05).

6. JP BioRegulators, Inc.: Waiver Request from Biochemical Pesticides Toxicology Data Requirements, 2000.

7. USEPA. An Experimental Use Permit (EUP) and Petition for a Temporary Tolerance Exemption for Phospholipid; Memo from Jones, Russell S., Ph.D. to Sheila Moats, Ph.D., October 8, 1997.

XII. 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 other 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.

XIII. 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: March 26, 2002.

James Jones,

Acting Director, 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 371.

2. Section 180.1199 is revised to read as follows:

§ 180.1199 Lysophosphatidylethanolamine (LPE); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide lysophosphatidylethanolamine in or on all food commodities.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7168–8]

Washington: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Washington applied to the United States Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has reached a final determination that these changes to the Washington hazardous waste program satisfy all requirements needed to qualify for final authorization. Thus, with respect to these revisions, EPA is granting final authorization to the State to operate its program subject to the limitations on its authority retained by EPA in accordance with RCRA, including the Hazardous and Solid Waste Amendments of 1984.

EFFECTIVE DATE: Final authorization for the revisions to Washington's hazardous waste management program shall be effective at 1 p.m. on April 11, 2002.

FOR FURTHER INFORMATION CONTACT: Nina Kocourek, U.S. EPA, Region 10, Office of Waste and Chemicals Management, 1200 Sixth Avenue, Mail Stop WCM–122, Seattle, Washington 98101, phone (206) 553–6502.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to and consistent with the Federal program. States are required to have enforcement authority which is adequate to enforce compliance with the requirements of the hazardous waste program. Under RCRA section 3009, States are not allowed to impose any requirements which are less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in Title 40 of the Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

Washington initially received final authorization on January 30, 1986, effective January 31, 1986 (51 FR 3782), to implement the State's dangerous waste management program. EPA also granted authorization for changes to Washington's program on September 22, 1987, effective on November 23, 1987 (52 FR 35556); August 17, 1990, effective October 16, 1990 (55 FR 33695); November 4, 1994, effective November 4, 1994 (59 FR 55322); February 29, 1996, effective April 29, 1996 (61 FR 7736); September 22, 1998, effective October 22, 1998 (63 FR 50531); and on October 12, 1999, effective January 11, 2000 (64 FR 55142). On August 2, 2001, Washington submitted a final program revision application to EPA in accordance with 40 CFR 271.21 seeking authorization of changes to the State program. On January 15, 2002, EPA published its preliminary decision announcing its intent to grant Washington final authorization for revisions to its federally authorized hazardous waste program. Further background on the tentative determination to grant authorization appears at 67 FR 1931–1937 (January 15, 2002).

B. What Were the Comments and Responses to EPA's Proposal?

Along with the tentative determination in EPA's proposal, EPA also announced the availability of the authorization revision application for public comment. The public comment period ended on February 14, 2002. EPA received one written comment during the public comment period. The significant issues raised by the commenter are summarized and responded to below.

The commenter asserts that the Washington Commercial Fertilizer Act, Chapter 15.54 RCW, acts to circumvent and knowingly violate the Washington Dangerous Waste Regulations, WAC 173–303. EPA reviewed the Washington Commercial Fertilizer Act, also known as the fertilizer registration act, to determine the validity of the commenter's assertion. Although implemented by the Washington Department of Agriculture, the legislative intent of the fertilizer registration act, as stated in RCW 15.54.265, is to ensure that all fertilizers in Washington meet standards for allowable metals, that fertilizer purchasers and users know about the contents of fertilizer products in Washington, that the oversight authority of the Washington Department of Ecology (Ecology) over waste-derived fertilizers be clarified, and that better information be provided to the Washington public on fertilizers, soils, and potential health effects. EPA found nothing in the fertilizer registration act, per se, to circumvent or knowingly violate the Washington Dangerous Waste regulations.

The fertilizer registration act, at RCW 15.54.270(34), defines waste-derived fertilizers as commercial fertilizers derived in whole or in part from solid waste as defined in chapter 70.95 or 70.105 RCW, or rules adopted thereunder, excluding biosolids regulated under chapter 70.95J RCW or wastewaters regulated under chapter 90.48 RCW. Before the Washington Department of Agriculture can register a waste-derived fertilizer or micronutrient fertilizer, it must obtain written approval from Ecology as provided by RCW 15.54.820. For waste-derived fertilizers, Ecology must evaluate