

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4,

1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 21, 1997.

James Jones,
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. 346a and 371.

2. In § 180.438, by adding paragraph (b) to read as follows:

§ 180.438 Lambda-cyhalothrin tolerance for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the insecticide lambda-cyhalothrin (a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
barley bran	0.2	8/30/98
barley grain	0.05	8/30/98
barley hay	2	8/30/98
barley straw	2	8/30/98
canola seed	0.1	8/30/98
sugarcane	0.03	8/30/98

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300564; FRL-5749-2]

RIN 2070-AB78

Ferric Phosphate; Establishment of an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of ferric phosphate, when used as a molluscicide in or on all food commodities. W. Neudorff GmbH KG submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this molluscicide in or on all food commodities.

DATES: This regulation is effective on October 29, 1997. Objections and requests for hearings must be received by December 29, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300564], 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-300564], 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. 1132, CM #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@epamail.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 number [OPP-300564]. 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: Sheryl K. Reilly, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail address: CS1 Rm. 5-W31, 2800 Crystal Drive, Arlington, VA, 703-308-8265, e-mail: reilly.sheryl@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: W. Neudorff GmbH KG, c/o Walter G. Telarek, PC, 1008 Riva Ridge Drive, Great Falls, VA, has requested in pesticide petition PP 7F4804 the establishment of an exemption from the requirement of a tolerance for residues of the molluscicide iron (ferric) phosphate. A notice of filing (FRL-5721-6) was published in the **Federal Register** (62 FR 32331-32336) on June 13, 1997, and the notice announced that the comment period would end on July 13, 1997; no comments were received.

This exemption from the requirement of a tolerance will permit the marketing of raw agricultural commodities when treated in accordance with EPA Reg No. 67702-3, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136).

The data submitted in the petition and all other relevant material have been evaluated. The following is a summary of EPA's findings regarding this petition.

I. Product Identity

NEU 1165M Slug and Snail Bait (EPA file symbol No. 067702-G) is the first pesticide product containing the active ingredient ferric phosphate (FePO₄, CAS# 11045-86-0). The product contains the active ingredient at a concentration of 1% incorporated into a solid matrix, which is odorless, and has a white-to-buff color.

II. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(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(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***." EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the scientific data and other relevant information in support of this action and considered its validity, completeness, reliability, and relationship 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.

A battery of acute toxicity studies place NEU 1165M Slug and Snail Bait in the following Toxicity Categories: Acute Oral (Toxicity Category IV); Acute Dermal (Toxicity Category IV); Primary Eye Irritation (Toxicity Category III); and Primary Dermal Irritation (Toxicity

Category IV). (MRIDs 440427-04, -05, -06, and -07)

Data waivers were requested for acute inhalation toxicity, dermal sensitization, genotoxicity, reproductive and developmental toxicity, subchronic (90-day) oral toxicity, and chronic toxicity. The waivers were accepted based on the long history of use of iron and iron salts by humans without any indication of deleterious effects, and on the following:

The toxicity of ferric phosphate is low; ferric phosphate occurs naturally as a mineral, and is added to food, such as bread, for nutritional fortification. Iron is an essential nutrient for humans and all other vertebrates; the average human diet contains 10-15 mg of iron a day. Ferric phosphate is also sometimes used as a fertilizer. In addition, iron is found in abundance in nature; the low water-solubility of ferric phosphate limits its absorption across the intestinal epithelium.

IV. Residue Chemistry

A waiver was requested and granted for magnitude of the residue anticipated at the time of harvest and method used to determine the residue data requirements based on ferric phosphate's (1) low toxicity, (2) natural occurrence, (3) abundance in the environment, (4) widespread use as human nutrient and dietary supplements and in infant formula, (5) status at FDA as "generally recognized as safe" (GRAS), and (6) data available in the open literature.

V. Aggregate Exposure

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. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* Dietary exposure of ferric phosphate via food or water exists due to its use as a nutritional supplement and its ubiquitous presence in nature. Residues from use of the biochemical pesticide, ferric phosphate, will not significantly add to the current dietary exposures.

2. *Non-dietary, non-occupational exposure.* Increased non-dietary exposure of ferric phosphate via non-commercial greenhouse, home lawn and garden or ornamental use will be minimal. Exposure by the inhalation route would be non-existent because

ferric phosphate is not volatile and the formulation of the product is a solid matrix of non-respirable size. In summary, the potential aggregate exposure, derived from non-dietary and non-occupational exposure should be minimal.

VI. Cumulative Effects

Ferric phosphate has a very low toxicity to humans. Because of its low toxicity, low rate of application, and use patterns, the Agency believes that there is no reason to expect any cumulative effects from ferric phosphate and other substances.

VII. Endocrine Disruptors

The Agency has no information to suggest that ferric phosphate has any effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. Nevertheless, the above discussion on exposure from all sources combined with the low toxicity of ferric phosphate would indicate such testing would not be necessary.

VIII. Safety Determination for U.S. Population, Infants and Children

Based on the information discussed above, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of ferric phosphate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, the toxicity of ferric phosphate to mammals is very low and under reasonably foreseeable circumstances it does not pose a risk.

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 pre- and post-natal toxicity and the completeness of the database, 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, the Agency believes there is reliable data to support the conclusion that ferric phosphate is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects, and EPA has not used a margin of exposure (safety) approach to assess the safety of

ferric phosphate. As a result, the provision requiring an additional margin of exposure (safety) does not apply.

IX. Other Considerations

1. *Analytical method.* The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for ferric phosphate residues.

2. *Codex maximum residue level.* There are no CODEX tolerances nor international tolerance exemptions for ferric phosphate at this time.

X. Conclusion

Based on the information discussed above, EPA establishes an exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for ferric phosphate.

This exemption from the requirement of a tolerance will be revoked if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

XI. Objections and Hearing Requests

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

Any person adversely affected by this regulation may, on or before December 29, 1997, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(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 genuine and substantial issue of fact; there is 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 issue(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.

XII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300564] (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 1132 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 Highway, Arlington, VA.

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

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

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which

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

XIII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerance 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.

XIV. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory

Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 21, 1997.

Stephen L. Johnson,

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. 346a and 371

2. Section 180.1191 is added to subpart D to read as follows:

§ 180.1191 Ferric phosphate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, ferric phosphate (FePO₄, CAS No. 11045-86-0) in or on all food commodities.

[FR Doc. 97-28657 Filed 10-28-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-5914-3]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Bowers Landfill Superfund Site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Bowers Landfill Superfund Site in Ohio from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. This action is being taken by EPA and the State of Ohio, because it has been determined that Responsible Parties have implemented all appropriate response actions required. Moreover, EPA and the State of Ohio have determined that remedial actions conducted at the site to date remain protective of public health, welfare, and the environment.

EFFECTIVE DATE: October 29, 1997.

FOR FURTHER INFORMATION CONTACT: David Wilson (312) 886-1476 (SR-6J), Remedial Project Manager or Gladys Beard at (312) 886-7253, Associate Remedial Project Manager, Superfund Division, U.S. EPA—Region V, 77 West Jackson Blvd., Chicago, IL 60604. Information on the site is available at the local information repository located at: Pickaway County Public Library, 165 E. Main Street, Circleville, OH 43113. Requests for comprehensive copies of documents should be directed formally to the Regional Docket Office. The contact for the Regional Docket Office is Jan Pfundheller (H-7J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353-5821.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Bowers Landfill Superfund Site located in Pickaway County, Ohio. A Notice of Intent to Delete for this site was published September 10, 1997 (62 FR 47619). The closing date for comments on the Notice of Intent to Delete was October 9, 1997. EPA received no comments and therefore no Responsiveness Summary was prepared.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund (Fund-) financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL in the unlikely event that conditions at the site warrant such action. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous