provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (air).
tolerance for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops. Agtrol International 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 phosphorous acid and its ammonium, sodium and potassium salts.

DATES: This regulation is effective October 5, 2000. Objections and requests for hearings, identified by docket control number (OPP±301030), must be received by EPA, on or before December 4, 2000.

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±301030 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Driss Benmhend, 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) 308–9525; and e-mail address: benmhend.driss @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:

<table>
<thead>
<tr>
<th>Categories</th>
<th>NAICS codes</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>111</td>
<td>Crop production</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>Animal production</td>
</tr>
<tr>
<td></td>
<td>311</td>
<td>Food manufacturing</td>
</tr>
<tr>
<td></td>
<td>32532</td>
<td>Pesticide manufacturing</td>
</tr>
</tbody>
</table>

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/fedreg/.

2. In person. The Agency has established an official record for this action under docket control number OPP–301030. 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) 305–5803.

II. Background and Statutory Findings

In the Federal Register of December 16, 1999 (64 FR 70255) (FRL–6393–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by Agtrol International, 7322 Southwest Freeway, Suite 1400, Houston, TX 77074. This notice included a summary of the petition prepared by the petitioner Agtrol International.

EPA received a comment from Aventis CropScience that requested EPA deny the waiver for residue chemistry data requirements for phosphorous acid. Aventis claims that phosphorous acid does not degrade rapidly in the environment, and that significant residues of phosphorous acid are expected to be found in or on raw agricultural commodities treated with products containing the active ingredient phosphorous acid. These residues of phosphorous acid according to Aventis, in or on food crops, cannot be considered to be negligible. EPA reviewed the data submitted by Aventis and concluded the following:

1. Phosphorous acid and its salts are important fertilizer compounds and used in significant quantities in this country. Tests performed using the Agtrol product showed an LD₅₀ of greater than 5,000 milligrams per kilogram of bodyweight. Human toxicity from consumption of crops treated with phosphorous acid fertilizers would be well known, if it occurred. The lack of reported dietary toxicity from consumption of crops treated with phosphorous acid fertilizers is further supporting evidence that use of phosphorous acid applications as a fungicide should not result in dietary toxicity. EPA does not require residue chemistry data in cases where the toxicity is so low and the use pattern will result in exposures much lower than the highest dose tested without an effect.

2. The Agency does note that the information provided by Aventis on the dissociation of phosphorous acid actually supports the tolerance exemption request. Further details on the dissociation of phosphorous acid at a pH of 7 indicates that the equilibrium ratio of acid phosphate ion to undissolved phosphorous acid is 500,000 to 1, and that the ratio of phosphate ion to acid phosphate ion is 2 to 1. This indicates the presence of almost no undissociated phosphorous acid.

3. Phosphorous is a required substance in the human body in the form of phosphates. This and the above are among the reasons why EPA does not regulate residues of phosphorous acid arising from the application of another pesticide which dissociates to phosphorous acid and is produced by Aventis. Also included were toxicological information provided by Aventis which proved to EPA there was no need to monitor the phosphorous acid residue.
As a result, EPA does not believe phosphorous acid and its salts should be denied the exemption from the requirement of a tolerance because of the reasons given by Aventis CropScience.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of phosphorous acid.

III. Risk Assessment

New section 408(c)(2)(A)(ii) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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

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.

1. Acute toxicity. Phosphorous acid is of high acute toxicity through the oral, dermal, and inhalation routes of exposure. Phosphorous acid is corrosive to eyes and skin. However, results of studies conducted on Agri-Phositol Agricultural Fungicide, the end-use product for which Agrot International has applied for registration, demonstrate that this product has a low order of toxicity. The acute oral LD₅₀ in the rat was greater than 5,000 milligrams per kilograms of bodyweight. The acute dermal LD₅₀ in the rat was greater than 5,000 milligrams per kilogram of bodyweight. The acute inhalation LC₅₀ in the rat was greater than 2.06 milligrams per liter. The product was found slightly irritating to the skin of guinea pigs and produced irritation to the eyes of rabbits that cleared within 48 hours. The product was not positive in guinea pigs for skin sensitization.

2. Developmental/reproductive effects, chronic effects and carcinogenicity. There is adequate information available from literature sources to characterize the toxicity of phosphorous acid. Phosphorous acid can affect human health through inhalation of mist, ingestion, and contact with the skin and eyes. It will cause corrosive effects (burns or irreversible damage) to the eyes, skin, throat, digestive tract, upper respiratory tract and nose. Signs of overexposure to this chemical are severe burning of eyes and skin, possible nausea and vomiting, coughing, burning and tightness of the chest and shortness of breath. Based on corrosiveness and the current use patterns for the mineral acids, EPA did not require these studies as part of the Reregistration Eligibility Decision (RED) on the Mineral Acids (EPA 738-R-029; December 1993).

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).

1. Dietary exposure. No dietary exposure is expected. When phosphorous acid is applied to growing crops in the environment, it rapidly dissociates to form hydrogen and phosphite ions.

2. Drinking water exposure. No significant exposure is expected to result from phosphorous acid because it is likely to be degraded in the terrestrial and aquatic environments to hydrogen and phosphate ions. The effects on humans resulting from anticipated concentrations to these ions due to agricultural uses will be moderated by natural means. Moreover, there is no potential for either ion to be significantly accumulated by the biota. Phosphorous acid is not regulated under the Safe Drinking Water Act; therefore, no maximum contaminant level (MCL) has been established for it.

3. Other non-occupational exposure. The primary non-pesticidal uses of phosphorous acid are industrial in closed production systems. There are no residential, indoor, school or day care uses proposed for this product. The proposed use pattern is for agricultural food crops. Therefore, there is no potential for non-occupational exposure to the general population.

Dermal inhalation exposures are expected to be minimal to applicators because of the label mitigating language.

VI. Cumulative Effects

Agri-Phositol Agricultural Fungicide may share a common metabolic mechanism with other salts of phosphorous acid (such as calcium); however, due to the lack of toxicity of Agri-Phositol Agricultural Fungicide and lack of reported dietary toxicity associated with the use of phosphorous fertilizers on crops, no cumulative effect from the use of Agri-Phositol Agricultural Fungicide is expected.

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

1. U.S. general population. Aggregate exposure to phosphorous acid is expected to be minimal. There is very little potential for exposure to phosphorous acid in drinking water and from non-dietary, non-occupational exposures. This chemical will be applied to agricultural food crops by commercial applicators. Once released into the environment, the chemical rapidly dissociates to form hydrogen and phosphite ions. The hydrogen ions affect pH, but this is moderated by natural means. Many phosphate salts are generally recognized as safe (GRAS). Therefore, the health risk to humans is negligible based on the low toxicity of these ions and a low application rate for the active ingredient, and one can conclude that there is a reasonable certainty that no harm will result from aggregate exposure to phosphorous acid.

2. Infants and children. Aggregate exposure to phosphorous acid is expected to be minimal. There is very little potential for exposure to phosphorous acid in drinking water and from non-dietary, non-occupational...
exposures. This chemical will be applied to agricultural food crops. Once released into the environment, the chemical rapidly dissociates to form hydrogen and phosphate ions. The hydrogen ions affect pH, but this is moderated by natural means. Many phosphate salts are “GRAS.” Therefore, the health risk to humans is negligible based on the low toxicity of Phostrol™ Agricultural Fungicide and these ions and a low application rate for the active ingredient. One can conclude that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to phosphorous acid residues.

VIII. Other Considerations

Phosphorous acid and its salts are rapidly dissociated in the environment to yield hydrogen and phosphate ions. Release of hydrogen ions will increase the pH of the plant’s surface, which will be moderated by the amount of neutralizing ions present, the buffering capacity, and the amount of dilution possible. Phosphate ions are available for uptake by plants usually in the form of ammonium, calcium, and potassium and sodium phosphates (phosphate salts).

A. Endocrine Disruption

Phosphorous acid does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Further, Agtrol International is not aware of any evidence that phosphorous acid has any effect on endocrine function. Last, there is no evidence that phosphorous acid bioaccumulates in the environment.

B. Analytical Method

Agtrol International has not submitted a practical analytical method for the detection and measurement of pesticide chemical residues. Phosphorous acid per se is not expected to be found in or on raw agricultural commodities, because once this chemical is released into the environment it dissociates rapidly to form the less toxic compounds, hydrogen and phosphate ions.

C. Codex Maximum Residue Level

No maximum residue levels (MRLs) have been established for phosphorous acid by the Codex Alimentarius Commission (CODEX).

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 that it “Tolerance Petition Fees.”

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–301030, 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 file format 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). 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 prior consultation as specified by Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12989, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or require 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. 276 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance 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).

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.


Susan B. Hazen,
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 180.1210 is added to subpart D to read as follows:

§ 180.1210 Phosphorous acid, exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of phosphorous acid and its ammonium, sodium and potassium salts in or on all food commodities when used as an agricultural fungicide on food crops.