this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, 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 by Executive Order 13175 (65 FR 67249, November 6, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 3, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2))

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 18, 2005.

Julie M. Hagensen,

Acting Regional Administrator, Region 10.

■ Chapter I, title 40 of the Code of Federal Regulations is corrected by making the following correcting amendment:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart MM—Oregon

■ 2. Section 52.1970 is amended by revising paragraph (c)(143)(i)(A) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * *

(143) * * *

(i) * * *

(A) The following sections of the Oregon Administrative Rules 340: 232–0010 and 232–0030, as effective December 26, 2001.

* * * * *

[FR Doc. 05–15338 Filed 8–2–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0154; FRL–7717–2]

Acetic Acid; 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 acetic acid when used as a preservative for post-harvest stored grains and hay intended for animal feed. Eastman Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of acetic acid for this use.

DATES: This regulation is effective August 3, 2005. Objections and requests for hearings must be received on or before October 3, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0154. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy

form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *Benmhend.driss@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 11, 2003 (68 FR 34955) (FRL–7308–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6516) by Eastman Chemical Company, P.O. Box 511, Kingsport, TN 37662. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid. This notice included a summary of the petition prepared by the petitioner, Eastman Chemical Company. There were no comments received in response to the notice of filing.

Acetic acid was previously registered by EPA and was exempt from the requirement of a tolerance when used as a hay and grain preservative under 40 CFR 180.1029. However, the registration was canceled and the tolerance was revoked due to failure by the registrant to respond to a January 1987 generic Data Call-In, and also for failure to submit the required annual pesticide registration maintenance fees (58 FR 47214, September 8, 1993).

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid when used as a preservative for post-harvest stored grains and hay intended for animal feed.

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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA 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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require 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) of the FFDCA 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 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 the 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.

Acetic acid is a naturally occurring substance found in all plants, animals, and humans. An intermediate produced in aerobic metabolism of foods during digestion (FDA, 1977), acetic acid has a long history of safe use as a food additive, and when diluted, is most commonly used and referred to as vinegar. It is a natural component of apple cider vinegar and other fruit and distilled vinegars, at a concentration ranging from 4-8%. This rule supports the use of acetic acid as the active ingredient in pesticide products that will be used as a preservative for post-harvest stored grains and hay intended for animal feed. The application rate will be based on the moisture content of the commodity, but concentrations of acetic acid as applied will be between 1% on hay and about 1.5% on grain. Any resulting residues of acetic acid will be less than those that result from the use of vinegar in or on foods.

In support of this tolerance exemption, data waivers were requested for the required mammalian toxicity studies, including acute toxicity and other toxicological studies used to determine risk to human health, based on the lack of toxicity associated with acetic acid in commonly consumed food and information available from the public literature. Additionally, acetic acid is considered GRAS (Generally Recognized As Safe) by the Food and Drug Administration when applied directly to foods (21 CFR 184.1005).

Data waivers were sought and granted for the following toxicity studies based

on information from the open scientific literature:

- Acute Oral Toxicity (OPPTS 870.1100)
- Acute Dermal Toxicity (OPPTS 870.1200)
- Acute Inhalation Toxicity (OPPTS 870.1300)
- Primary Eye Irritation (OPPTS 870.2400)
- Primary Dermal Irritation (OPPTS 870.2500)

Acetic acid is a commonly known food material that has been tested and written about for years. As a result, a lot of toxicity studies about aa are found in the public literature. As demonstrated in the public literature supplied by the applicant, acetic acid has a low pH (pH 2.4) and low corrosivity. Indeed, the effects on targeted microbial pest species are due to the low pH. Similarly, primary eye irritation and primary dermal irritation testing was not deemed necessary due to the low pH and low corrosivity of the active ingredient. As a result, the Agency concluded that additional acute oral, acute dermal, and acute inhalation toxicity testings are not necessary.

1. *Hypersensitivity* (OPPTS 870.2600). The potential for repeated contact of the product with human skin is a concern only to applicators of the end-use products. However, the risk to applicators from exposure is mitigated as they are required to wear protective chemical-resistant gloves, aprons, and footwear. There are no reports of dermal sensitization to low concentrations of acetic acid at concentrations such as those found in vinegars. Accordingly, a hypersensitivity study is not required for registration of this product (per 40 CFR 158.690(c)(2)(iii)).

The registrant has reported no hypersensitivity incidents to date (OPPTS Guideline 885.3400). Nonetheless, pursuant to FIFRA section 6(a)(2), the registrant is required to report to the Agency any future incidents of hypersensitivity associated with acetic acid.

2. *Genotoxicity* (OPPTS 870.5100 and 870.5375). In lieu of guideline studies, the registrant submitted a waiver request with supporting studies/data/information from the open technical literature (Master Record Identification Number (MRID) 457691–06)). Two non-guideline gene mutation studies in bacteria (Ames test) were conducted as part of a larger screening study of large numbers of chemicals. Reviews of these studies showed that this compound is not anticipated to induce mutagenic responses. Moreover, acetic acid is not structurally related to any known mutagens. As a result, the agency approved the waiver request for genotoxicity studies.

3. *Immune response* (OPPTS 870.7800). The registrant requested a waiver for this study, and submitted supporting studies/data/information from the open technical literature. EPA's review concluded that acetic acid is a common component of the diet in humans and is a naturally-occurring metabolite found in all plants and animals (including humans). Acetic acid is non-toxic at levels (4%-8%) consumed by humans in or on foods. With no known incidences of allergic responses to acetic acid, there is reasonable evidence that acetic acid would not induce adverse immune responses in humans, particularly at the very low levels anticipated from the proposed pesticidal uses. As a result, the agency approved the waiver request for the Immune Response study.

4. *90–Day feeding* (OPPTS 870.3100). Data waivers were sought and granted for this study. The conditions of potential exposure requiring this study are not triggered. Acetic acid is a food acid and is naturally occurring. Acetic acid is absorbed from the gastrointestinal tract and through the lungs and is readily, although not completely, oxidized in the organism. Acetic acid is proposed to be used as a hay and grain preservative at low concentrations and for animal food only. When the product is applied according to label directions, the treated hay and grains will contain less than 2% of acetic acid. After consumption by the animal, AA will then be rapidly metabolized. Moreover, acetic acid is consumed (by humans) at higher concentrations found in commercially available vinegar (4%-8%), without any reported negative effects. Therefore, there would be no expected subchronic effects from the use of acetic acid in products intended for hay and grain treatment.

5. *90–Day dermal* (OPPTS 870.3250). A data waiver was sought and granted for this study. The active ingredient acetic acid is intended for use as a preservative on stored grain and hay used as animal feed. There will be no intentional application to human skin and there will be no prolonged human dermal exposure. Acetic acid is not expected to be metabolized differently by the dermal route of exposure.

6. *90–Day inhalation* (OPPTS 870.3465). A data waiver was sought and granted for this study. Repeated inhalation exposure to acetic acid is not expected because application will occur seasonally and the product is rapidly diluted in the air. Furthermore, the applicator/operator is separated from the point of application by 15-20 feet and is typically, but not always, within an enclosed tractor cab.

7. *Developmental toxicity* (OPPTS 870.3550). In three developmental toxicity studies (MRID 457691–07), acetic acid was administered to presumed pregnant rats, mice, and rabbits by gavage at 0, 16, 74.3, 345, or 1,600 milligrams/kilograms/day (mg/kg/day). Rats, mice, and rabbits were sacrificed for examination on days 17, 20, and 29, respectively. No treatment-related maternal deaths occurred in any species. Maternal body weights for rats and rabbits were not affected by treatment. For high-dose mice, body weights were 90% of the control level on day 11 and 88% of the controls on days 15 and 17. Therefore, the maternal toxicity lowest observed adverse effect level (LOAEL) for acetic acid is 1,600 mg/kg/day for mice based on reduced body weight; the LOAEL was not identified for rats and rabbits. The maternal toxicity no observed adverse effect level (NOAEL) was 345 mg/kg/day for mice and was ≥1,600 mg/kg/day for rats and rabbits. For all three species, the numbers of implantations, resorptions, and live fetuses per litter were similar between the treated and control groups. No effects on numbers of dead fetuses or fetal body weights were observed in rats or rabbits. In mice, a greater number of litters in the high-dose group contained dead fetuses compared with the controls (7/21 vs. 2/22 respectively). Mean fetal body weight from high-dose mice was 0.84 gram (g) compared with 0.92 g for the controls. No treatment-related external, visceral, or skeletal malformations or variations were observed in fetuses from rats, mice, or rabbits. Therefore, the developmental toxicity LOAEL for acetic acid is 1,600 mg/kg/day for mice based on an increased number of dead fetuses/litter and decreased fetal body weight; the LOAEL for rats and rabbits was not identified. The developmental toxicity NOAEL for acetic acid is 345 mg/kg/day for mice and ≥1,600 mg/kg/day for rats and rabbits. It should be noted that the highest dose tested in all three species, 1,600 mg/kg/day, is greater than the limit dose of 1,000 mg/kg/day. As a result, developmental toxicity is not expected from the use sought for acetic acid as a post-harvest grain and hay preservative.

Based on the data or data waivers submitted in accordance with the Tier I toxicology data requirements set forth in 40 CFR 158.690(c), the Tier II and Tier III toxicology data requirements also set forth therein were not triggered and, therefore, not required in connection with this action.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA 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).

Acetic acid is a common metabolite in plants and animals. It is normally produced in relatively large amounts during the digestion and metabolism of foods (FDA, 1977). It is not a known mutagen, teratogen, nor oncogen; neither is it chemically related to any known class of mutagens, teratogens, or oncogens. Moreover, the acetic acid contained in this product is intended solely for use as a post-harvest preservative on hay and grain. After the treated feed is ingested by animals, acetic acid is readily metabolized into a source of energy for the animal. As a result, the possibility of human exposure through consumption of meat or milk from these animals, is not expected.

A. Dietary Exposure

1. *Food.* When end-use products containing the active ingredient acetic acid are used in the manner intended for stored hay and grains, residues of acetic acid will not be present on the feed commodities at levels greater than 2%. While human dietary exposure from the use of this product is not expected in connection with the proposed uses, even if humans were to consume acetic acid at these levels, the dietary intake would be 2 to 3 times less than when consuming vinegar in vegetable salads and other commonly consumed foods. Moreover, human dietary exposure is also not anticipated from the consumption of meat and milk of animals that were fed treated grains and hay (see Unit IV. above).

2. *Drinking water exposure.* When used according to label directions, no dietary exposure through drinking water is expected from the use of acetic acid to treat stored hay and grains. The product is not intended for use in drinking water, nor are the approved uses likely to result in acetic acid reaching surface or ground water that might be used as drinking water. Furthermore, in the unlikely event that the use of acetic acid to treat stored hay and grains does result in acetic acid reaching water that ultimately is consumed, it would not pose any health risk due to its inherent low toxicity and ability to be metabolized just like vinegar.

B. Other Non-Occupational Exposure

Based on the proposed post-harvest use on stored hay and grains that will be used as feed only, the potential for non-occupational, non-dietary exposures to acetic acid residues by the general population, including infants and children, is unlikely. Moreover, in the unlikely event of non-occupational, non-dietary exposures to acetic acid residues as a result of the proposed post-harvest uses, no harm is expected because of acetic acid's low toxicity. Based on available data, therefore, it is highly unlikely that any adverse effects will occur to humans via use of acetic acid as a post-harvest preservative for stored hay and grains.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children. Acetic acid is used in a manner similar to propionic acid as a preservative of post-harvest hay and grain. Under aerobic conditions, propionic acid acts as a carbon source for various microbes and is metabolized to acetic acid. Propionic acid is also used on other food commodities. Certain uses of propionic acid are exempt from the requirement of a tolerance under 40 CFR 180.1023. Since there will be no dietary or non-dietary, non-occupational exposure to acetic acid when the end-use product is used according to label directions, no cumulative or incremental effects to humans are anticipated.

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

1. *U.S. population.* There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of acetic acid due to its use as a preservative for post-harvest stored grains and hay intended for animal feed. 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 function of acetic acid as a natural component of metabolism in the human body, the anticipated low acute exposure estimates from its pesticidal use, the common use of acetic acid in the human diet and its classification by the FDA as GRAS as a direct food additive.

2. *Infants and children.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (MOE) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different MOE will be safe for infants and children. Margins of exposure, which are often referred to as uncertainty (safety) factors, are incorporated into EPA risk assessments either directly, or through the use of a MOE analysis or by using uncertainty factors in calculating a dose level that poses no appreciable risk. In this instance, based on all available information, the Agency concludes that acetic acid is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when acetic acid is used as labeled, the Agency concludes that the additional MOE is not necessary to protect infants and children and that not adding any additional MOE will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of 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.'' Acetic acid is not a known endocrine disruptor nor is it related to any class of known endocrine disruptors. Thus, there is no impact via endocrine-related effects on this Agency's safety finding set forth in this final rule for acetic acid.

B. Analytical Method

Through this action, the Agency proposes to establish an exemption from the requirement of a tolerance for acetic acid when used as a preservative on post-harvest hay and grain intended for use as animal feed. For the very same reasons that support the granting of this tolerance exemption, the Agency has concluded that an analytical method is not required for enforcement purposes for these proposed uses of acetic acid.

C. Codex Maximum Residue Level

There are no codex maximum residue levels established for acetic acid.

VIII. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2005–0154 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 October 3, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0154 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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).

IX. Statutory and Executive Order Reviews

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

X. Congressional Review Act

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: July 1, 2005.

James Jones,

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), 346a and 371.

■ 2. Section 180.1258 is added to subpart D to read as follows:

§ 180.1258 Acetic acid; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide acetic acid when used as a preservative on post-harvest agricultural commodities intended for animal feed, including alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay.

[FR Doc. 05–15148 Filed 8–2–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0183; FRL–7725–6]

Alachlor, Carbaryl, Diazinon, Disulfoton, Pirimiphos-methyl, and Vinclozolin; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances for residues of the herbicide alachlor, insecticides carbaryl, diazinon, disulfoton, and pirimiphos-methyl, and the fungicide vinclozolin because these specific tolerances are no longer needed or are associated with food uses that are no longer current or registered in the United States. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. The regulatory actions in this document pertain to the revocation of 15 tolerances of which 9 count as tolerance reassessments toward the August, 2006 review deadline.

DATES: This regulation is effective August 3, 2005. Objections and requests for hearings must be received on or before October 3, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0183. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8037; e-mail address: *nevola.joseph@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.