List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: September 18, 2003.

Deborah Jordon,

Acting Regional Administrator, Region IX.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(317) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(317) Amended regulation for the following APCD was submitted on August 19, 2003, by the Governor's designee.

(i) Incorporation by reference.

(A) San Joaquin Valley Unified Air Pollution Control District.

(*1*) Rule 4901, adopted on July 15, 1993 and amended on July 17, 2003.

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[FR Doc. 03–24772 Filed 9–29–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0311; FRL–7327–6]

Vinclozolin; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on succulent beans at 2.0 parts per million (ppm); canola at 1.0 ppm; eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance for succulent beans will expire on September 30, 2005 and the canola, eggs, milk, meat and meat-by-product tolerances will expire on November 30, 2008.

DATES: This regulation is effective September 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0311, must be received on or before December 1, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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, pesticide manufacturer or formulator. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112
- Food manufacturer (NAICS 311)
- Pesticide manufacturer (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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0311. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 26, 2003 (68 FR 14628) (FRL–7289–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6278) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709–3528. This notice included a summary of the petition prepared by BASF Corporation, the registrant. The Agency received comments from North Williamette Research and Extension Center at Oregon State University, Norpac Foods,

Inc., Washington State University Tri-Cities, Northern Canola Growers Association, and Earthjustice on behalf of the Northwest Coalition for Alternatives to Pesticides, the Natural Resources Defense Council and Farmworker Justice Fund. The comments from outside parties are summarized in Unit V. followed by the Agency's response.

The petition requested that 40 CFR 180.380 be amended by extending the tolerances for the combined residues of the fungicide vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety, in or on succulent beans at 2.0 ppm for two years. The petition also requested that 40 CFR 180.380 be amended by making the tolerances permanent for canola at 1.0 ppm; eggs, milk, and meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm.

Several recent regulatory actions by EPA are pertinent to this petition. In the **Federal Register** of July 18, 2000 (65 FR 44453) (FRL–6594–8), EPA established time-limited tolerances at the levels identified in Unit II. for use of vinclozolin on succulent beans, canola, eggs, milk, meat and meat-by products of cattle, goats, hogs, horses, sheep, and poultry. These tolerances were made time-limited because of the need for a developmental neurotoxicity study to determine whether vinclozolin which causes antiandrogenic effects shares a common mode of toxicity with other members of the imide group of the dicarboximide class of fungicides which are considered antiandrogenic and with other compounds outside of this class of fungicides that may also be considered antiandrogenic.

The tolerances established July 18, 2000, were approved taking into consideration BASF's May 31, 2000 request to EPA to amend its vinclozolin registration to cancel uses on onions, raspberries, and ornamental plants immediately and to delete uses on kiwi, chicory, lettuce, and succulent beans over the following four years. *See* the **Federal Register** notice of September 20, 2000 (65 FR 56894)(FRL–6744–2). As later approved by EPA these use cancellations contained an existing stocks provision which permitted legal use of vinclozolin on succulent beans until September 30, 2005. Id.

Objections to the tolerances established in July, 2000, were filed on behalf of the Natural Resources Defense Council, the Environmental Working Group, the Pineros Campesinos Unidos del Noroeste, and the Northwest Coalition for Alternatives to Pesticides by Earthjustice Legal Defense Fund. These objections were withdrawn after EPA approved BASF's use cancellation request and EPA agreed to notify the objecting parties if any future requests were made for uses of vinclozolin under an emergency exemption from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and consider the objecting parties comments on any such request.

Also as part of BASF's May 31, 2000 cancellation request, BASF asked EPA to revoke tolerances permitting vinclozolin residues in cucumbers and peppers. *See* the **Federal Register** final rule of June 12, 2002 (67 FR 40185)(FRL–6835–6). Earlier, in 1998, BASF had requested that EPA cancel vinclozolin use on strawberries and stonefruit. Id. Consistent with these two actions by BASF, EPA, on June 12, 2002, revoked tolerances for strawberries, stone fruit, cucumbers, and peppers, 67 FR 40185 (June 12, 2002). This present rulemaking further implements September, 2000 cancellation order by extending the vinclozolin succulent bean tolerance through the date as to which use remains legal on succulent beans, September 30, 2005. Extending the succulent bean tolerance in this manner means that vinclozolin which is legally used on succulent beans pursuant to the cancellation order will not render the treated crops adulterated as a matter of law. *See* 21 U.S.C. 346a(l)(5). In a future action, EPA will be proposing to revoke the tolerances for vinclozolin on onions and raspberries given that those uses are now cancelled.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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. Section 408(b)(2)(C) of the FFDCA 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. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for the combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on succulent beans at 2.0 ppm; canola at 1.0 ppm; eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm.

EPA completed a full risk assessment for vinclozolin as part of the July 18, 2000 tolerance action. July 18, 2000 (65 FR 44453). This risk assessment was updated later that year in connection with the release of the Reregistration Eligibility Document (RED) for vinclozolin. U.S. EPA, Reregistration Eligibility Document Vinclozolin (October 2000) (available at *http://www.epa.gov/REDs/2740red.pdf)*. In its July 18, 2000 tolerance decision, EPA concluded that the time-limited tolerances met FFDCA section 408's safety standard. (65 FR 44462). Since that time risks from vinclozolin exposure have declined as the strawberry and stone fruit tolerances have been revoked and the last date for legal use on raspberries and onions has passed by almost 2 years. The registration of vinclozolin for use on succulent beans and lettuce will be canceled on July 15, 2004 with the last legal use of existing stocks established as September 30, 2005. At that point, the only remaining uses for vinclozolin will be on belgian endive, canola, and wine grapes. Taking into account the risk assessments done in conjunction with the July 18, 2000 tolerance action and the vinclozolin RED and the reduction in exposure that has occurred as a result of the cancellations of use on strawberries, stone fruit, onions, and raspberries and the tolerance revocations for cucumbers and peppers,

EPA concludes that extending the succulent bean tolerance until September 30, 2005, and the canola tolerance until November 30, 2008 meets the section 408 safety standard that is, there is a reasonable certainty of no harm to the general public, including infants and children, from aggregate exposure to vinclozolin.

EPA has retained a time limitation on the canola tolerance because a developmental neurotoxicity study assessing anti-androgenic and neuro-endocrine endpoints has not been conducted. Completion of such a DNT study has been delayed both because EPA needs to investigate anti-androgenic and neuro-endocrine endpoints, endpoints not previously examined in DNT studies, and because the results of the DNT study are critical to assessing whether vinclozolin shares a common mechanism of toxicity with other pesticides which may affect androgens. The Agency currently has no guidance for how this modified DNT study should be conducted, and what specific toxicity endpoints should be evaluated to capture anti-androgenic and neuro-endocrine effects. The Agency is currently examining the vinclozolin data base, as well as data for other chemicals which may effect the androgens. This data analysis extends to both data available in-house and in the literature. When this data analysis is complete, it may be necessary to present this information to the Agency's FIFRA Science Advisory Panel (SAP) to gain insight into whether the chemicals share a common mode of action, whether and how they should be considered in a cumulative risk assessment, and how a DNT study can help the Agency understand this common mechanism question. The data analysis, together with the SAP comments, will be useful in designing the required modified DNT study so that all pertinent toxicological endpoints are measured, and the study is properly conducted. Because the DNT study has not been conducted, EPA has retained the additional 10X FQPA safety factor for the protection of infants and children.

IV. Comments

The Agency received five comments summarized below. The Agency's responses are at the conclusion of the comments.

Comment 1. The North Williamette Research and Extension Center (NWR&EC) of Oregon State University expressed support for extending the tolerance for use of vinclozolin on succulent beans for two years. NWR&EC indicated that the additional time is needed in order to fully evaluate the efficacy of the potential replacement fungicides (fluazinam and BAS 510) in controlling *Sclerotinia sclerotiorum* under conditions of high disease pressure. Additionally, NWR&EC states that the consequences could be disastrous for a currently financially precarious agricultural industry if adequate time is not allowed for large scale testing of alternative fungicides to ensure efficacy comparable to vinclozolin.

Comment 2. Norpac Foods Inc. (NFI) expressed support for extending the tolerance for use on succulent bean for two years. NFI indicated that vinclozolin has been very effective in controlling white mold (*Sclerotinia sp.*) on succulent beans and has significantly reduced the economic impact of the disease upon the industry. NFI believes that extension of the existing tolerance would allow the industry time to pursue alternative control measures that are currently undergoing evaluation.

Comment 3. The Washington State Pest Management Resource Service (WSPMRS) of the Washington State University Tri-Cities expressed support for extending the tolerance for use of vinclozolin on succulent beans, and discussed the economic significance of succulent bean production to the state of Oregon. WSPMRS indicated that while there have been efforts to register alternative fungicides, researchers believe that field data gathered thus far has not been adequate to assure that the proposed replacement fungicides will prove as efficacious as vinclozolin in controlling white and gray mold.

Comment 4. The Northern Canola Growers Association (NCGA)expressed support for making permanent the tolerances for use of vinclozolin on canola. NCGA discussed the economic importance of canola production to North Dakota, and noted that vinclozolin is a critical tool used by canola growers to combat the devastating effects of *Sclerotinia sclerotiorum*.

Comment 5. Earthjustice commented on behalf of the Northwest Coalition for Alternatives to Pesticides, Natural Resources Defense Council, and Farmwork Justice Fund. Earthjustice discussed in detail three concerns. First, Earthjustice expressed concern that vinclozolin is an endocrine-disrupting chemical and a probable human carcinogen. Second, Earthjustice expressed concern that the notice of filing published in the **Federal Register** on March 26, 2003 did not describe the Agency's duty to cancel vinclozolin's tolerances for succulent beans. Earthjustice asserts that EPA should describe its legal obligations with vinclozolin in the final **Federal Register** notice responding to the registrant's petition. Third, Earthjustice states that EPA should fill data gaps before taking any regulatory action on vinclozolin. Earthjustice further states that the current data gaps are an extension of decades of data gaps, that EPA appears to be giving up on collecting or analyzing the required data, that EPA has failed to collect data on risks to drinking water, and that EPA admits to numerous other data gaps. Earthjustice concludes their comment by stating that EPA should only finalize the proposed tolerances after collecting required data, making the required findings and fully informing the public about the Agency's regulatory duties for vinclozolin.

Agency response to comments 1–3. Considerations related to the beneficial impacts of a pesticide are cognizable under the FFDCA only in very narrow circumstances. *See* 21 U.S.C. 346a(b)(2)(B). Those circumstances have not been argued to be present here.

Agency response to comment 4. Given the outstanding data, the Agency has decided not to make the vinclozolin tolerances on canola and the associated egg, milk, meat and meat-by-product tolerances permanent but instead has placed a 5 year time limitation on these tolerances. The Agency will reevaluate this issue after the data as identified in the October 2000 Vinclozolin Registration Eligibility Document are received and sufficiently evaluated.

Agency response to comment 5. The Agency agrees with Earthjustice's discussion of the hazard assessment for vinclozolin in that it is an anti-androgen, and a Group C possible human carcinogen, an effect related to its anti-androgenic properties. These effects, however, were fully considered in the risk assessments conducted for the chemical. The Agency also agrees with Earthjustice that additional data are needed to fully characterize vinclozolin's hazard potential. These data were required as part of the October 2000 Vinclozolin Registration Eligibility Document. In order to account for the data deficiencies, the 10X FQPA safety factor was retained for vinclozolin risk assessments. This 10X factor results in a total safety factor of 1000X.

As noted, the major data deficiency for vinclozolin is the modified developmental neurotoxicity (DNT) study in which antiandrogenic and neuroendocrine endpoints must be assessed. The design and execution of this study presents a host of difficult science issues, including how the study can be conducted in a manner to explore common mechanism questions

involving anti-androgenic chemicals. Significant work on this issue has been done. Although EPA in 2000 thought this issue could be resolved relatively quickly, that has not proven correct. Since 2000 EPA has completed a significant amount of work, some of which is currently ongoing. The Agency has completed an updated review of literature data for vinclozolin, and is currently examining in-house data for other chemicals, both those whose major toxic effects are related to androgen hormones, and those which have other major effects, but which still may be appropriate for inclusion in a cumulative risk assessment for androgen-related toxicity. Additional review of literature data for these chemicals is still required. The Office of Pesticide Programs (OPP) has also consulted with researchers in EPA's Office of Research and Development (ORD) who are conducting work for OPP in two areas. First, ORD is conducting experiments to determine whether the androgen-related toxicity of compounds whose effects are caused by different molecular mechanisms are additive, synergistic, or neither. Secondly, ORD is doing both experimental work and mathematical modeling to support a Physiologically Based Pharmacokinetic (PBPK) model for anti-androgenic compounds to support a cumulative risk assessment. Much of the work being done in ORD has been completed, although some remains ongoing. These data are important in assuring that the cumulative risk assessment for these chemicals is scientifically sound.

With regard to the presence of vinclozolin metabolites in drinking water, on February 14, 2001 the Agency issued a data call-in notice to BASF Corporation. The data call-in notice required the submission of a small prospective ground water monitoring study and a surface water monitoring study. These studies are required to be submitted by March 7, 2005 and March 8, 2004, respectively. The studies require that data be collected on vinclozolin and major degradation products. Additionally, on December 20, 2000, the Agency issued a data-call-in notice to BASF for an aerobic soil metabolism study and a soil column leaching/adsorption/desorption study to gain additional data on the persistence, biodegradation, and migration of vinclozolin in soil profile. These studies have been submitted to the Agency and are under review.

Finally, Earthjustice alleges that EPA admitted to many other data gaps in publishing the Notice of Filing (NOF) pertaining to these tolerances. The language cited by NRDC, however, is merely the boilerplate added by EPA to all NOFs to indicate that EPA has not yet finished its review of the petition at the time the NOF is published.

In response to Earthjustice's assertion that the Agency should fully describe the cancellation status of vinclozolin uses, EPA would note that the NOF for this tolerance action was prepared by the petitioner, BASF Corporation, as the statute requires. In this rulemaking document, EPA has fully and accurately described the status of the 2000 cancellation order and the agreement regarding NRDC's withdrawal of its objections to the 2000 tolerance action.

V. Conclusion

Therefore, the tolerances are established for combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety, in or on succulent beans at 2.0 ppm; canola at 1.0 ppm; eggs, milk, and the meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. The tolerance for succulent beans will expire on September 30, 2005, and the canola, eggs, milk, meat and meat-by-product tolerances will expire on November 30, 2008.

VI. 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), 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–2003–0311 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 December 1, 2003.

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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.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.1. Mail your copies, identified by docket ID number OPP–2003–0311, 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 Unit I.B.1. 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).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 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. 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.

VIII. 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: September 24, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.380 is amended by revising the expiration date for the following commodities in the table in paragraph (a) to read as follows:

§ 180.380 Vinclozolin; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Bean, succulent ...	2.0	9/30/05
* * *	* *	* *
Canola	1.0	11/30/08
Cattle, fat	0.05	11/30/08
Cattle, meat byproducts	0.05	11/30/08
Cattle, meat	0.05	11/30/08
* * *	* *	* *
Egg	0.05	11/30/08
Goat, fat ..	0.05	11/30/08
Goat, meat byproducts	0.05	11/30/08
Goat, meat	0.05	11/30/08
Hog, fat ...	0.05	11/30/08
Hog, meat byproducts	0.05	11/30/08
Hog, meat	0.05	11/30/08
Horse, fat	0.05	11/30/08
Horse, meat byproducts	0.05	11/30/08
Horse, meat	0.05	11/30/08
* * *	* *	* *
Milk	0.05	11/30/08
* * *	* *	* *
Poultry	0.1	11/30/08
Poultry, meat byproducts	0.1	11/30/08
Poultry, meat	0.1	11/30/08
* * *	* *	* *
Sheep, fat	0.05	11/30/08
Sheep, meat byproducts	0.05	11/30/08
Sheep, meat	0.05	11/30/08

* * * * *

[FR Doc. 03–24782 Filed 9–29–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0319; FRL–7329–9]

Zinc Phosphide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on alfalfa, forage; alfalfa hay; barley, grain; barley, hay; barley, straw; bean, dry, seed; beet, sugar, roots; beet, sugar, tops; potato; timothy, forage; timothy, hay; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 30, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0319, must be received on or before December 1, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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. 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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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. 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0319. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access*. 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 *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/*