

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

Commodity	Parts per million	Expiration/Revocation Date
Sheep, meat	0.05	11/30/08

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[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.html/>.

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 July 9, 2003 (68 FR 40939) (FRL-7314-1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP 2E6419, PP 1E6306, PP 1E6270, PP 1E6337, PP 9E5082, PP 0E6199, and PP 1E6292) by IR-4, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by the registrant, HACO, Inc., P.O. Box 7190, Madison, WI 53707. The Agency received a number of comments on the notice of filing published on July 9, 2003 (68 FR 40939). All comments were in favor of establishing the food tolerances proposed in the notice.

The petitions requested that 40 CFR 180.284 be amended by establishing tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide, in or on alfalfa, forage and alfalfa, hay at 0.1 parts per million (ppm); barley, grain and barley, hay at 0.05 ppm, and barley, straw at 0.2 ppm; bean, dry at 0.05 ppm; beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.2 ppm; potato at 0.05 ppm; timothy, forage and timothy, hay at 0.05 ppm; and wheat, grain, wheat, hay, and wheat, straw at 0.05 ppm.

EPA is also deleting several established tolerances in § 180.284(b) that are no longer needed, as a result of this action. The tolerance deletions are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for zinc phosphide under § 180.284(a).

The following deletions to § 180.284(b) are replaced in § 180.284(a):

1. Delete the time-limited tolerances for barley, grain at 0.01 ppm, barley, hay at 0.20 ppm, and barley straw at 0.02 ppm. Tolerances for barley, grain at 0.05 ppm, barley, hay at 0.2 ppm, and barley, straw at 0.2 ppm are established by this action under § 180.284(a).

2. Delete the time-limited tolerances for beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.1 ppm. Tolerances for sugar, beet, roots are established at 0.05 ppm and sugar, beet, tops at 0.2 ppm under § 180.284(a).

3. Delete the time-limited tolerance for potato at 0.05 ppm. A tolerance for potato is established at 0.05 ppm under § 180.284(a).

4. Delete the time-limited tolerances for timothy, forage and timothy, hay at 0.1 ppm. Tolerances for timothy, forage and timothy, hay are established at 0.5 ppm under § 180.284(a).

5. Delete the time-limited tolerances for wheat, grain, wheat, hay and wheat, straw at 0.01 ppm. Tolerances for wheat, grain, wheat, hay, wheat, straw, and wheat, forage are established at 0.05 ppm under § 180.284(a).

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 residues of phosphine resulting from the use of the rodenticide zinc phosphide on alfalfa, forage and alfalfa, hay at 0.2 ppm; barley, grain at 0.05; barley, hay at 0.2 ppm; barley, straw at 0.2 ppm; bean, dry, seed at 0.05 ppm; beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 0.2 ppm; potato at 0.05 ppm; timothy, forage and timothy, hay at 0.5 ppm; and wheat, forage, wheat, grain, wheat hay, and wheat, straw at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. The nature of the toxic effects caused by zinc phosphide are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 0.1 milligram/kilogram/day (mg/kg/day) LOAEL = 1.0 mg/kg/day based on increased mortality and kidney hydronephrosis in male rats
870.3150	90-Day oral toxicity in nonrodents	Waived
870.3200	21/28-Day dermal toxicity	Waived

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 2.0 mg/kg/day Maternal LOAEL = 4.0 mg/kg/day based on mortality Developmental NOAEL = >4.0 mg/kg/day Developmental LOAEL = not established
870.370	Prenatal developmental in non-rodents	Waived
870.3800	Reproduction and fertility effects	Waived
870.4100	Chronic toxicity rodents	Waived
870.4100	Chronic toxicity dogs	Waived
870.4200	Carcinogenicity rats	Waived
870.4300	Carcinogenicity mice	Waived
870.5375	Mutagenicity-mouse lymphoma	Positive for gene mutation, with and without S9 mammalian metabolic mutation
870.5385	Chromosomal aberration	Negative for gene mutation
870.5500	Mutagenicity-Ames	Negative for gene mutation, with and without S9 mammalian metabolic mutation
870.620	Acute neurotoxicity screening battery	NOAEL = >10 mg/kg/day LOAEL = not established
870.6200	Subchronic neurotoxicity screening battery	NOAEL = 0.1 mg/kg/day LOAEL = 2.0 mg/kg/day based on clinical toxicity (not neurotoxicity)

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where

the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach

assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for zinc phosphide used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ZINC PHOSPHIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 2.0 mg/kg/day UF = 100 Acute RfD = 0.02 mg/kg/day	Developmental Toxicity Study-Rat LOAEL = 4.0 mg/kg/day based on maternal deaths on gestation day 10 (i.e., after 4 doses) though day 16
Chronic dietary (all populations)	NOAEL = 0.1 g/kg/day UF = 1,000 Chronic RfD = 0.0001 mg/kg/day	90-Day Oral Toxicity Study-Rats LOAEL = 1.0 mg/kg/day based on increased mortality, increased absolute and relative liver weight, and hematological alterations
Short-term dermal (1 to 7 days) Intermediate-term (1 week to several months) Long-term dermal (several months to lifetime) (Residential)	Not applicable	Dermal exposure is not expected since baits are not absorbable and Zn phosphide powder is too polar to be absorbed through the skin
Short-term inhalation (1 to 7 days) Intermediate-term inhalation (1 week to several months) Long-term inhalation (several months to lifetime) (Residential)	Not applicable	Inhalation exposure is not expected. End-use baits are not powdery or respirable
Cancer (oral, dermal, inhalation)	Not applicable	Not applicable

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.284(a)) for residues of phosphine resulting from the use of zinc phosphide, in or on a variety of raw agricultural commodities including: Grape (0.01 ppm), grass (rangeland) (0.1 ppm), and sugarcane (0.01 ppm). Tolerances with regional registration are established 40 CFR 180.284(c) for zinc phosphide residues in or on globe artichokes (0.01 ppm), sugar beet (roots) (0.04 ppm), and sugar beet tops (0.02 ppm). Section 18 tolerances at 40 CFR 180.284(b) currently exist for zinc phosphide residues in or on: Alfalfa forage, alfalfa hay, barley grain, barley hay, barley straw, sugar beets (tops), sugar beet roots, timothy, hay, timothy, forage, potato, wheat grain, wheat hay, and wheat straw.

Based on residue data from field trials conducted in support of the subject tolerances, EPA concludes that acute and chronic dietary exposure associated with the proposed uses of zinc phosphide is unlikely. Residues were below the Level of Quantitation (LOQ) (<0.05 or <0.1 ppm) in crops, except for the livestock feed items alfalfa forage, sugar beet tops, and timothy forage. Alfalfa forage, sugar beet tops, and timothy hay are not direct human food items; rather, they are used as animal feeds. Because residues of zinc phosphide ingested by

livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds, residues of zinc phosphide in livestock feeds are not expected to result in residues of zinc phosphide in livestock commodities. Also, the act of processing and washing will not allow for unreacted zinc phosphide to remain in or on food items. In addition, residues are not expected in wheat and barley grain since zinc phosphide will be applied to barley and wheat prior to the formation of seed heads.

2. *Dietary exposure from drinking water.* No drinking water risk assessment was performed for zinc phosphide because no residues are expected in either ground water or surface water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Zinc phosphide is currently registered in pellet and bait form for use on residential non-food sites to control mammals (primarily rodents) in areas such as commercial establishments, public areas (parks), dumps, and homes. A detailed residential exposure assessment is contained in the Reregistration Eligibility Decision (RED)

Document, EPA 738-R-98-006, July 1998, for zinc phosphide.

There were no endpoints identified for zinc phosphide use in a residential assessment except for accidental ingestion. The residential exposure assessment evaluated exposure from accidental ingestion of zinc phosphide. No other residential exposure assessment was either expected or, if expected, found to have any hazard potential.

Although having considered that accidental ingestion of zinc phosphide baits may occur with respect to a very small number of children, EPA has concluded that this potential exposure is not appropriate for inclusion in evaluating the safety of aggregate exposure of consumers and major identifiable subgroups of consumers to zinc phosphide. Unlike other residential uses (such as a turf use) that potentially may result in exposures to significant groups of children, the subgroup of children that may consume baits in childproof bait stations is very tiny. This small subgroup of children would not qualify as a major identifiable subgroup of consumers.

4. *Cumulative effects from substances with a common mechanism of toxicity.* 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."

EPA does not have, at this time, available data to determine whether zinc phosphide has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to zinc phosphide and any other substances, and zinc phosphide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that zinc phosphide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCFA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

3. *Conclusion.* EPA has waived a significant portion of the data normally required in establishing a tolerance for a pesticide chemical, in evaluating the petitions for zinc phosphide. This data waiver is based on data showing that dietary exposure is unlikely to result from agricultural uses of zinc phosphide. Based on these exposure data, EPA concludes there are reliable data supporting a conclusion that no additional safety factor is necessary to protect the safety of infants and children.

E. Aggregate Risks and Determination of Safety

Zinc phosphide has both food and non-occupational uses; therefore, the considerations for aggregate exposure are those from food, drinking water, and residential (non-occupational) sources.

The Agency has concluded that there will be no human dietary exposure from the proposed or registered uses of zinc phosphide. Thus, exposure to zinc phosphide from food is not a component of the acute and chronic aggregate exposure assessment.

1. *Acute risk.* The Agency has concluded that there will be no human dietary exposure from the proposed or registered uses of zinc phosphide. Thus, exposure to zinc phosphide from food is not a component of the acute and chronic aggregate exposure assessment.

2. *Chronic risk.* The Agency has concluded that there will be no human dietary exposure from the proposed or registered uses of zinc phosphide. Exposure to zinc phosphide from food and water is not a component of the acute and chronic aggregate exposure assessment.

There are no residential uses for zinc phosphide that result in chronic residential exposure to zinc phosphide. Based on the use pattern, chronic residential exposure to residues of zinc phosphide is not expected. There is no potential for chronic dietary exposure to zinc phosphide in food and drinking water.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure levels) plus indoor and outdoor residential exposure. No short-term or intermediate-term dermal, oral or inhalation toxicological endpoints were identified for zinc phosphide.

Further, no incidental oral exposure is expected given the conditions of use. Although potentially accidental ingestion of zinc phosphide bait may occur in rare instances, the subgroup of children that are exposed in such a manner is not a major identifiable subgroup of consumers.

4. *Aggregate cancer risk for U.S. population.* Since chronic exposure and risk associated with the use of zinc phosphide is negligible, no risk of cancer is expected from the use of zinc phosphide.

5. *Determination of safety.* There is no drinking water, residential, nor dietary component to acute and chronic aggregate exposure to zinc phosphide residues. Based on these exposure assessments, EPA concludes that there

is a reasonable certainty that no harm will result to adults, infants and children from aggregate exposure to zinc phosphide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Acceptable methods are available for enforcement and data collection purposes for plant commodities. The Pesticide Analytical Manual (PAM), Vol. II lists, under aluminum phosphide, a colorimetric method and a gas liquid chromatography with flame photometric detection (GLC/FPD) method as Methods A and B, respectively. Both methods determine the level of phosphine liberated when zinc phosphide is exposed to dilute acid solutions. EPA has determined that Method A is acceptable for enforcement. Data submitted in support of the established tolerances were collected by one of these two methods. Data submitted in support of the proposed tolerances were collected by the GLC/FPD method or a similar method.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no international harmonization issues associated with this action since there are no Codex, Mexican or Canadian maximum residue levels (MRLs) or tolerances for zinc phosphide on any crop.

V. Conclusion

Therefore, the tolerances are established for residues of phosphine resulting from the use of zinc phosphide in or on alfalfa, forage and alfalfa, hay at 0.2 ppm; barley, grain, at 0.05 ppm; barley, hay and barley, straw at 0.2 ppm; bean, dry, seed at 0.05 ppm; beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.2 ppm; potato at 0.05 ppm; timothy, forage and timothy, hay at 0.5 ppm; and wheat, forage, wheat, grain, wheat hay, and wheat, straw at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, 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 FFDCFA 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 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-2003-0319 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-2003-0319, 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 FFDCFA. 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 25, 2003.

Debra Edwards,

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 180.284 is amended by adding commodities to the table in paragraph (a) and removing the following entries from the table in paragraph (b): “barley, grain,” “barley, hay,” “barley, straw,” “beet, sugar, roots,” “beet, sugar, tops,” “potato,” “timothy, forage,” “timothy, hay,” “wheat, grain,” “wheat, hay,” and “wheat, straw” to read as follows:

§ 180.284 Zinc phosphide; tolerances for residues.

(a) General. * * *

Commodity	Parts per million
Alfalfa, forage	0.2
Alfalfa, hay	0.2
Barley, grain	0.05
Barley, hay	0.2
Barley, straw	0.2
Bean, dry, seed	0.05
Beet, sugar, roots	0.05
Beet, sugar, tops	0.2
Potato	0.05
Timothy, hay	0.5
Timothy, forage	0.5
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

* * * * *

[FR Doc. 03-24844 Filed 9-26-03; 11:11 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL-7564-9]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion for the Celtor Chemical Works Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region IX is issuing a Notice of Deletion for the Celtor Chemical Works Superfund Site (Site) located in Hoopa, California, from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. The EPA, Hoopa Valley Tribe and the State of California, through the California Department of Toxic Substances Control, have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

EFFECTIVE DATE: September 30, 2003.

FOR FURTHER INFORMATION CONTACT: Debbie Schechter, Section Chief, U.S. EPA, Region IX, SFD-7-2, 75 Hawthorne Street, San Francisco, CA 94105-3901, (415) 972-3230 or (800) 231-3075.

SUPPLEMENTARY INFORMATION: The Site to be deleted from the NPL is the Celtor Chemical Works Superfund Site, in Hoopa, California.

A Notice of Intent to Delete for this Site was published in the **Federal Register** on August 18, 2003 (68 FR 49406). The closing date for comments on the Notice of Intent to Delete was September 17, 2003. A Responsiveness Summary was prepared for comments received regarding delisting of the site; those responses are part of the NOD below. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment, and it maintains the NPL as the list of those