

TABLE 36.—COMPOUND LISTS USED FOR COMPLIANCE DEMONSTRATIONS FOR ENHANCED BIOLOGICAL TREATMENT PROCESSES (SEE § 63.145(h))—Continued

List 1	List 2
	Methylene Chloride (dichloromethane). Naphthalene. Nitropropane 2 Phosgene. Propionaldehyde. Propylene Oxide. Styrene. Tetrachloroethane 1,1,2,2. TolueneTrichloroethane 1,1,1 (methyl chloroform). Trichloroethane 1,1,2. Trichloroethylene. Trimethylpentane 2,2,4. Vinyl Chloride. Vinyl Acetate. Xylene-m. Xylene-o. Xylene-p.

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5. Section I of appendix C to part 63 is revised to read as follows:

Appendix C to Part 63—Determination of the Fraction Biodegraded (F_{bio}) in a Biological Treatment Unit

I. Purpose

The purpose of this appendix is to define the procedures for an owner or operator to use to calculate the site specific fraction of organic compounds biodegraded (F_{bio}) in a biological treatment unit. If an acceptable level of organic compounds is destroyed rather than emitted to the air or remaining in the effluent, the biological treatment unit may be used to comply with the applicable treatment requirements without the unit being covered and vented through a closed vent system to an air pollution control device.

The determination of F_{bio} shall be made on a system as it would exist under the rule. The owner or operator should anticipate changes that would occur to the wastewater flow and concentration of organics, to be treated by the biological treatment unit, as a result of enclosing the collection and treatment system as required by the rule.

The forms presented in this appendix are designed to be applied to thoroughly mixed treatment units. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit. Systems that are not thoroughly mixed treatment units should be subdivided into a series of zones that have uniform characteristics within each zone. The number of zones required to characterize a biological treatment system will depend on the design and operation of the treatment system. Each zone should then be modeled as a separate unit. The amount of air emissions and biodegradation from the modeling of these separate zones can then be added to reflect the entire system.

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Appendix C [Amended]

6. Section III of appendix C of part 63, the second paragraph after (4) is revised to read as follows:

III. Procedures for Determination of f_{bio}

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(4) * * *

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Select one or more appropriate procedures from the four listed above based on the availability of site specific data. If the facility does not have site-specific data on the removal efficiency of its biological treatment unit, then Procedure 1 or Procedure 4 may be used. Procedure 1 allows the use of a bench top bioreactor to determine the first-order biodegradation rate constant. An owner or operator may elect to assume the first order biodegradation rate constant is zero for any regulated compound(s) present in the wastewater. Procedure 4 explains two types of batch tests which may be used to estimate the first order biodegradation rate constant. An owner or operator may elect to assume the first order biodegradation rate constant is zero for any regulated compound(s) present in the wastewater. Procedure 3 would be used if the facility has, or measures to determine, data on the inlet and outlet individual organic compound concentration for the biological treatment unit. Procedure 3 may only be used on a thoroughly mixed treatment unit. Procedure 2 is used if a facility has or obtains performance data on a biotreatment unit prior to and after addition of the microbial mass. An example where Procedure 2 could be used, is an activated sludge unit where measurements have been taken on inlet and exit concentration of organic compounds in the wastewater prior to seeding with the microbial mass and start-up of the unit. The flow chart in figure 1 outlines the steps to use for each of the procedures.

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7. In appendix C of part 63, section III, in the second sentence of C. Inlet and Outlet Concentration Measurements

(Procedure 3), the phrase “uniform well-mixed or completely mixed system” is revised to read “thoroughly mixed treatment unit.”

[FR Doc. 98–32567 Filed 12–8–98; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300760; FRL 6046–1]

RIN 2070–AB78

Zinc phosphide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of phosphine in or on potatoes, sugar beet (roots), and sugar beet (tops). This action is in response to EPA’s granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on potatoes and sugarbeets. This regulation establishes a maximum permissible level for residues of phosphine in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on May 1, 2000.

DATES: This regulation is effective December 9, 1998. Objections and requests for hearings must be received by EPA on or before February 8, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300760], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300760], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300760]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9364; e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(e) and (l)(6) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the rodenticide zinc phosphide, in or on potatoes and sugar beets at 0.05 part per million (ppm). These tolerances will expire and are revoked on May 1, 2000. EPA will publish a document in the

Federal Register to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL 5572-9).

New 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) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without

providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Zinc Phosphide on Potatoes and Sugar beets and FFDCA Tolerances

Potato and sugar beet growers in Idaho have experienced substantial losses in recent years due to vole and mouse damage. The only registered option available to sugar beet and potato growers in Idaho is to use zinc phosphide on non-crop land surrounding their fields. Where fields are surrounded by other crops or bare ground, there are no registered controls or other effective non-chemical methods. EPA has authorized under FIFRA section 18 the use of zinc phosphide on potatoes and sugar beets for control of voles and mice in Idaho. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of phosphine in or on potatoes and sugar beets. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on May 1, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on potatoes and sugar beets after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this

pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether zinc phosphide meets EPA's registration requirements for use on potatoes and sugar beets or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of zinc phosphide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for zinc phosphide, contact the Agency's Registration Division at the address provided above.

III. Aggregate Risk Assessment and Determination of Safety

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 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).

Consistent with section 408(b)(2)(D), 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 phosphine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of zinc phosphide on potatoes and sugar beet (roots) at 0.05 ppm and sugar beet (tops) at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 below.

1. *Acute toxicity.* No toxicology studies were identified by EPA which demonstrated the need for an acute dietary risk assessment.

2. *Short - and intermediate - term non-dietary toxicity.* Based on the acute dermal LD₅₀ study in rabbits, no appropriate toxic effects were identified for risk assessment. In that study no mortalities were observed at 5,000 milligram/kilogram mg/kg. At the lowest observed effect level (LOEL) of 2,000 mg/kg, there was a decrease in body weight. Based on the physical properties of the chemical, dermal absorption is expected to be very low, since zinc phosphide reacts with water and stomach acid to produce the toxic gas phosphine from oral, but not dermal, exposure. As no endpoint of toxicological concern for dermal exposure has been identified, no dermal penetration data were required. The requirement for an acute inhalation study has been waived, thus zinc phosphide has been placed in Toxicity Category I for acute inhalation exposure.

3. *Chronic toxicity.* EPA has established the RfD for zinc phosphide at 0.001 (mg/kg/day). However, as indicated in the Reregistration Eligibility Document (RED), a chronic dietary risk assessment is not required because exposure from food sources is expected to be minimal to non-existent. There are no detectable residues in potatoes. Furthermore potatoes are often washed and cooked before they are eaten thereby further reducing any trace of residues. Residue studies showed there were detectable residues in sugar beet roots and tops; however, these commodities are not direct human foods and no dietary consumption is expected. Sugar beet tops are fed to livestock; however, there is no likelihood of residues of zinc phosphide being found through transfer of residues to meat and milk. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds. Furthermore, the Agency believes that the refining process for sugar beets will remove any unreacted zinc phosphide from refined sugar and the data requirements for a sugar beet processing study has been waived. Therefore the Agency has determined that there is no likelihood of residues of zinc phosphide occurring in any processed commodities and no chronic dietary exposure assessment is required.

4. *Carcinogenicity.* Zinc phosphide has not been classified as to its carcinogenic potential since cancer studies have been waived. Although this

chemical has food uses, dietary exposure is expected to be minimal.

B. Exposures and Risks

1. From food and feed uses.

Tolerances have been established (40 CFR 180.284) for the residues of zinc phosphide, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from zinc phosphide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Acute dietary endpoints were not identified; thus an acute dietary risk assessment was not performed.

ii. *Chronic exposure and risk.* For the purpose of assessing chronic dietary exposure to zinc phosphide from food, EPA assumed tolerance level residues and 100% of crop treated for potatoes, sugarbeets and all other commodities having zinc phosphide tolerances. These conservative assumptions result in over estimation of human dietary exposures.

2. *From drinking water.* The EPA Safe Drinking Water Hotline has indicated (06/97) that there are no established maximum contaminant levels (MCL) for residues of zinc phosphide in drinking water. No health advisory levels for zinc phosphide in drinking water have been established. There is no entry for zinc phosphide in the "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992). Furthermore as indicated in the RED, zinc phosphide and its degradation products appear to have a low potential for ground water or surface water contamination. Therefore, dietary exposure is not expected from either ground or surface water fed drinking water and a drinking water risk assessment was not performed in the RED. Since the issuance of the RED, drinking water levels of comparison (DWLOCs) for zinc phosphide were calculated in accordance with the current Standard Operating Procedures for Drinking Water Exposure and Risk Assessments. The Agency concludes with reasonable certainty that exposure to zinc phosphide in drinking water would not result in unacceptable levels of concern.

i. *Acute exposure and risk.* Acute dietary endpoints have not been identified; therefore, a DWLOC for acute dietary exposure was not determined.

ii. *Chronic exposure and risk.* Zinc phosphide degrades rapidly to Zn²⁺ and PH₃, which sorb strongly to soil and are common nutrients in soil. Zinc

phosphide and its degradation products appear to have a low potential for ground water or surface water contamination. Therefore, EPA concludes with reasonable certainty that the residues of zinc phosphide in drinking water would not result in unacceptable levels of concern.

3. *From non-dietary exposure.* Zinc phosphide is currently registered for use on the following residential non-food sites: hand-applied bait to underground burrows in/on the following sites/settings: bulb crops, golf course turfgrass, lawns, ornamentals, nurseries, parks, homes, industrial, commercial, and agricultural buildings. Because of these residential uses, EPA has concerns about possible post-application exposures to children. A post-application exposure and risk assessment, using the method described in the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments was conducted. The margin of exposure (MOE) of 310 for post-application exposure to children at residential sites does not exceed EPA's level of concern (i.e., acceptable MOEs are ≥ 100). The dose estimates generated here are based on some central tendency (i.e., body weight) and some upper-percentile assumptions (i.e., ingestion rate of dry pesticide formulation, and maximum application rate) and are considered to be representative of high-end exposure. The uncertainties associated with this assessment stem from the use of an assumed ingestion rate of dry pesticide formulation. The dose estimates are considered to be reasonable high-end estimates based on professional judgement.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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."

Although zinc phosphide may share a common mode of toxicity (the generation of phosphine gas) with other chemicals (aluminum and magnesium phosphide), the Agency has determined that any future cumulative risk determination involving these chemicals will not include the current uses of zinc phosphide. This determination is based on the fact that exposures to phosphine from zinc phosphide in food or water are negligible due to zinc phosphide's rapid degradation and limited use patterns.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Acute dietary endpoints were not identified; thus an acute dietary risk assessment was not performed.

2. *Chronic risk.* A chronic dietary reference dose (RfD) was established for zinc phosphide at 0.0001 mg/kg/day (see Zinc Phosphide RED, 7/98). However, as indicated in the RED, a chronic dietary risk assessment is not required because exposure from food sources is expected to be minimal to non-existent. There are no detectable residues in potatoes. Furthermore potatoes are often washed and cooked before they are eaten thereby further reducing any trace of residues. Residue studies showed there were detectable residues in sugar beet (roots) and (tops); however, these commodities are not direct human foods and no dietary consumption is expected. Sugar beet (tops) are feed to livestock; however, there is no likelihood of residues of zinc phosphide being found through transfer of residues to meat and milk. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds. Furthermore, the Agency believes that the refining process or sugar beets will remove any unreacted zinc phosphide from refined sugar and the data requirements for a sugar beet processing study has been waived. Therefore the Agency has determined that there is no likelihood of residue of zinc phosphide occurring in any processed commodities and no chronic dietary exposure assessment is required.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. A short and intermediate term aggregate risk assessment is not required as a non-dietary endpoint was not identified.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zinc phosphide residues.

D. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children — i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of zinc phosphide, EPA considered data from developmental toxicity studies in the rat. The developmental toxicity studies

are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of 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. EPA believes that reliable data support using the standard 100-fold factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold safety factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental study in rats, the maternal no observed adverse effect level (NOAEL) was 2.0 mg/kg/day, based on increased mortality at the LOEL of 4.0 mg/kg/day. The developmental (fetal) NOAEL was 4.0 mg/kg/day, the highest dose tested.

iii. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for zinc phosphide is not complete. EPA is not requiring these studies because exposure from food sources is expected to be insignificant. The rat developmental toxicity data provided no indication of increased sensitivity of fetal rats to *in utero* exposure to zinc phosphide. In that study, no developmental effects were observed at the highest dose tested which was shown to be maternally toxic. An additional uncertainty factor of 10 was applied to the reference dose calculation to account for the extrapolation from subchronic to chronic exposure, the lack of reproductive toxicity data, and the lack of chronic toxicity data in a non-rodent species, this additional uncertainty factor will accommodate the inability to assess the potential for increased sensitivity of infants and children, because of the lack of animal data.

2. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to zinc phosphide residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The residue of concern is zinc phosphide *per se*, measured as phosphine. There is no expectation of secondary residues in meat, milk, poultry, and eggs as a result of the registered zinc phosphide uses.

B. Analytical Enforcement Methodology

Adequate analytical methodology (spectrophotometric) is available in PAM II (Sec. 180.284, Method A) to enforce the tolerance expression. The method determines zinc phosphide residues as phosphine gas.

C. Magnitude of Residues

Residues of phosphine resulting from the proposed use of zinc phosphide are not expected to exceed 0.05 ppm in potatoes, 0.05 ppm in sugar beet (roots), and 0.1 ppm in sugar beet (tops). Concentration of residues in potato and sugar beet processing by-products is not expected. There is no reasonable expectation of secondary residues in meat, milk, poultry, or eggs.

D. International Residue Limits

No Codex, Canadian or Mexican Maximum Residue Levels have been established for zinc phosphide.

V. Conclusion

Therefore, the tolerances are established for residues of zinc phosphide in potatoes and sugar beet (roots) at 0.05 ppm and sugar beet (tops) at 0.1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 8, 1999, file written objections to any aspect of

this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300760] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency,

Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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

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

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the

Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the

requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This 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: November 24, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In §180.284, in paragraph (b), by alphabetically adding the following commodities to the table to read as follows:

§180.284 Zinc phosphide; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Potatoes	0.05	5/1/00
Sugar beet (roots)	0.05	5/1/00
Sugar beet (tops)	0.1	5/1/00
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[FR Doc. 98-32574 Filed 12-8-98; 8:45 am]

BILLING CODE 6560-50-F