

the levels of ECH and PO set out in current § 173.25(a)(20) are in error because those levels do not reflect the levels presently used by industry to manufacture the resin. The information in the present petition establishes that the manufacturing process and the resin composition do not differ from the process and resin composition evaluated in the original petition. Because the composition of the resin is unchanged, the exposure to the residues of ECH and PO remains unchanged. Therefore, the agency concludes that the agency's safety evaluation conducted for the original petition (FAP 6A3905) supports the safety of the amendment to § 173.25 proposed by FAP 6A4500. Accordingly, the agency concludes that a recalculation of a risk assessment performed for the original petition (FAP 6A3905) is not necessary to support this action.

Thus, FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe; (2) the additive will achieve its intended technical effect; and that therefore, (3) the regulations in § 173.25 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before March 21, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a

waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.25 is amended by revising paragraph (a)(20) to read as follows:

§ 173.25 Ion-exchange resins.

* * * * *

(a) * * *

(20) Regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then sulfonated whereby the amount of epichlorohydrin plus propylene oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose.

* * * * *

Dated: February 11, 1997.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 97-4082 Filed 2-19-97; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300453; FRL-5588-1]

RIN 2070-AB78

Zinc Phosphide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on the raw agricultural commodities timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) in connection with EPA's granting of an emergency exemption to the state of Washington under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of zinc phosphide on timothy or timothy-alfalfa, clover stands. This regulation establishes maximum permissible levels for residues of phosphine in these foods 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 on April 15, 1998.

DATES: This regulation is effective February 20, 1997. The entries in the table expire on April 15, 1998. Objections and requests for hearings must be received by EPA on or before April 21, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300453], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Room 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-300453], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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: Crystal Mall #2, Room 1132, 1921 Jefferson Davis Highway, 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300453]. 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 (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, 703-308-8326, e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the phosphine resulting from the use of the rodenticide zinc phosphide in or on timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) at 0.1 part per million (ppm). These tolerances will expire and be revoked automatically without further action by EPA on April 15, 1998.

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 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 FFDCA section 408(b)(2)(A)(i) 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." FFDCA 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, but does not include occupational exposure. FFDCA 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.

FFDCA section 408(l)(6) 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. FFDCA section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under FFDCA section 408(l)(6) and requires that the regulations be consistent with FFDCA section 408(b)(2) and (c)(2) and FIFRA section 18.

FFDCA section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of FFDCA section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the FFDCA section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new FFDCA section 408, EPA does

not intend to set precedents for the application of FFDCA section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemptions for Zinc Phosphide on Timothy and Timothy-alfalfa/clover and FFDCA Tolerances

EPA has authorized use under FIFRA section 18 of zinc phosphide on timothy and timothy-alfalfa/clover for control of the vole complex. A potential population of 500 voles per acre would mean significant economic loss during 1997. The currently available methods of control, including the use of zinc phosphide bait boxes and flood irrigation, are inadequate and impractical.

As part of its assessment of this specific exemption, EPA assessed the potential risks presented by residues of phosphine on timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay). In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for residues of phosphine will permit the marketing of timothy and timothy-alfalfa/clover treated in accordance with the provisions of the FIFRA section 18-emergency exemptions. Consistent with the need to move quickly on this emergency exemption and in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under FFDCA section 408(e) as provided in FFDCA section 408(l)(6). Although these tolerances will expire and be revoked automatically without further action by EPA on April 15, 1998, under FFDCA section 408(l)(5), residues of phosphine not in excess of the amount specified in these tolerances remaining in or on timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or

other relevant information on this pesticide indicate that the residues are not safe.

EPA has not made any decisions about whether zinc phosphide meets the requirements for registration under FIFRA section 3 for use on timothy and timothy-alfalfa/clover or whether permanent tolerances for zinc phosphide for timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) would be appropriate. This action by EPA does not serve as a basis for registration of zinc phosphide by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than Washington to use this product on these crops under FIFRA section 18 without following all provisions of FIFRA 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 in "ADDRESSES" at the beginning of this document.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, by using a dose that causes adverse effects (threshold effects) and a dose that causes no observed effect levels (NOELs).

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the reference dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children

based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low-dose extrapolations or margin of exposure (MOE) calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The theoretical maximum residue contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a "worst case" estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Zinc phosphide is already registered by EPA for outdoor residential lawn, nursery, right-of-way, recreational area, and other non-food uses, as well as several food use registrations. Phosphine is a highly reactive gas that reacts with raw agricultural commodities to form bound phosphate residues. The Agency stated in a registration standard for zinc phosphide (June 23, 1982) that a tolerance of 0.1 ppm for phosphine resulting from the use of zinc phosphide would be allowable for raw agricultural commodities, provided the bound phosphate residues can be fully characterized. At the time the registration standard was issued, the Agency identified 70% of the bound phosphate residues in treated commodities as consisting of oxyphosphorus acids, which are considered toxicologically insignificant at the levels found in treated commodities. Data have since been submitted which demonstrate that the remaining 30% of residues consists of oxidation products of phosphine (oxyphosphorus acids and/or their salts), which are also considered toxicologically insignificant at the levels found in treated commodities. EPA believes it has sufficient data to assess the hazards of zinc phosphide and to make a determination on aggregate exposure, consistent with FFDCA section 408(b)(2), for the time-limited tolerances for residues of phosphine resulting from the use of zinc phosphide in or on timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) at 0.1 part per million (ppm). EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, EPA's Office of Pesticide Programs (OPP) has established the RfD for zinc phosphide at 0.0003 milligram(mg)/kilogram(kg)/day. The RfD was established based on an lowest effect level (LEL) of 3.48 mg/kg/day from an open literature 90-day rat feeding study. Effects observed at the LEL were decreased food consumption and body weight. An uncertainty factor of 10,000 was used due to data gaps and the absence of a NOEL in the study. The Agency has recently reviewed a 90-day gavage study in rats which had a NOEL

of 0.1 mg/kg/day and a LEL of 1.0 mg/kg/day. The LEL of 1.0 mg/kg/day was based on increased mortality and kidney nephrosis in male rats.

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

3. *Short-term, non-dietary inhalation and dermal toxicity.* Since 10% zinc phosphide tracking powder has been classified in Toxicity Category IV (LC₅₀ > 19.6 mg/liter (L)), inhalation exposure resulting from this FIFRA section 18 action is not considered toxicologically significant. For short-term and intermediate dermal MOE calculations, EPA's Health Effects Division (HED), OPP recommended use of the adjusted acute dermal LD₅₀ NOEL of 1,000 mg/kg from the acute dermal toxicity study in rabbits. In the absence of other dermal toxicity data, the acute NOEL dose of 1,000 mg/kg was divided by a 100-fold uncertainty factor to approximate a 3-month dermal NOEL for worker dermal exposure. The 3-month dermal NOEL is 10 mg/kg/day. At the LEL of 2,000 mg/kg in the rabbit dermal LD₅₀ study, the animals lost weight, but no mortalities were observed up to 5,000 mg/kg highest dose tested (HDT). Actual risk from dermal exposure is likely to be significantly less, since zinc phosphide reacts with water and stomach acid to produce the toxic gas phosphine from oral, but not dermal, exposure.

4. *Carcinogenicity.* Zinc phosphide has not been reviewed for carcinogenicity. OPP has waived carcinogenicity data requirements for zinc phosphide on the basis that exposures to zinc phosphide are controlled to prevent exposures to humans. Applications to crop areas are such that the zinc phosphide will dissipate.

B. Aggregate Exposure

1. Tolerances are already established for residues of the phosphine resulting from the use of zinc phosphide on several raw agricultural commodities (40 CFR 180.284 (a) and (b)). There is no reasonable expectation of secondary residues in meat, milk, poultry, or eggs (40 CFR 180.6(a)(3)). Any residues of zinc phosphide ingested by livestock would be metabolized to naturally occurring phosphorous compounds. No human food items are derived from timothy grown for seed or mixed stands of timothy-alfalfa/clover produced for hay. Therefore, humans will receive no additional dietary exposure to phosphine as a result of establishment of this tolerance.

2. For the purpose of assessing chronic dietary exposure from zinc phosphide, EPA assumed tolerance level residues and 100% of crop treated for the proposed and existing food uses of zinc phosphide. These conservative assumptions result in over estimation of human dietary exposures.

3. Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. There is no information on zinc phosphide (phosphine) residues in ground water and runoff in the EPA's Environmental Fate and Effects Division (EFED) One-Liner Data Base. There is no established maximum concentration level (MCL) for residues of zinc phosphide (phosphine) in drinking water. No drinking water health advisory levels have been established for zinc phosphide (phosphine). There is no entry for zinc phosphide (phosphine) in the "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992). Based on the available studies used in EPA's assessment of environmental risk, EPA does not anticipate exposure to residues of zinc phosphide (phosphine) in drinking water.

4. There are residential uses of zinc phosphide and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational, non-dietary exposure scenarios. OPP has identified a toxicity endpoint for an intermediate-term residential risk assessment. However, no acceptable reliable dermal exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make its safety determination for these tolerances based on those factors which it can reasonably integrate into a risk assessment.

5. At this time, the Agency has not made a determination that zinc phosphide and other substances that may have a common mode of toxicity would have cumulative effects. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to define common mode of toxicity, the Agency will make its safety determination for these tolerances based on those factors which can reasonably integrate into a risk assessment. For purposes of these tolerances only, the Agency is considering only the potential

risks of zinc phosphide in its aggregate exposure.

C. Safety Determinations For U.S. Population

No human food items are derived from timothy grown for seed or mixed stands of timothy-alfalfa/clover produced for hay. Taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to zinc phosphide from published tolerances (including recently published time-limited tolerances for potatoes and sugar beets) will utilize 27.5% of the RfD for the U.S. population. EPA does not anticipate chronic exposure to residues of zinc phosphide (phosphine) in drinking water.

D. Determination of Safety for Infants and Children

1. There were no developmental findings in rats up to a maternally toxic dose of 4.0 mg/kg/day zinc phosphide nor in mice at 4.0 mg/kg/day HDT. A comparison of the NOEL of 0.1 mg/kg/day in the recent 90-day rat gavage study and the NOELs for developmental toxicity in rats and mice (4.0 mg/kg/day) provides a 40-fold difference, which demonstrates that there are no special prenatal sensitivities for infants and children. OPP has waived teratogenicity in the rabbit and the two-generation reproduction study in the rat data requirements for zinc phosphide on the basis that exposures to zinc phosphide are controlled to prevent exposures to humans. Applications to crop areas are such that the zinc phosphide will dissipate. Since there are no reproduction studies with zinc phosphide, the post-natal potential for effects from zinc phosphide in infants and children cannot be fully evaluated. However, the above information, together with the uncertainty factor of 10,000 utilized to calculate the RfD for zinc phosphide, is considered adequate protection for infants and children with respect to prenatal and postnatal development against dietary exposure to zinc phosphide residues, and therefore, EPA has determined that an additional 10-fold safety factor is not appropriate.

2. EPA has concluded that the percent of the RfD that will be utilized by chronic dietary exposure to residues of zinc phosphide ranges from 6.8% for nursing infants (<1 year old) up to 59.9% for children 1 to 6 years old. However, this calculation assumes tolerance level residues for all commodities and is therefore an over estimate of dietary risk. Refinement of the dietary risk assessment by using anticipated residue data would reduce dietary exposure. As mentioned before,

EPA does not expect chronic exposure from drinking water.

V. Other Considerations

The metabolism of zinc phosphide in plants and animals is adequately understood for the purposes of these tolerances. The residue of concern is unreacted zinc phosphide, measured as phosphine, that may be present. Adequate methods for purposes of data collection and enforcement of tolerances for zinc phosphide residues as phosphine gas are available. Methods for determining zinc phosphide residues of phosphine gas are described in PAM, Vol. II, as Method A. There are no Codex tolerances for timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay).

VI. Conclusion

EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to zinc phosphide based on the following considerations. First, approval of these tolerances results in no additional exposure to consumers. Second, EPA has used a 10,000-fold safety factor in assessing the risk estimate posed by zinc phosphide. Third, this pesticide is being used to address an emergency situation and EPA, therefore, must make a quick decision. Fourth, because these tolerances are for an emergency situation, extended use under these tolerances are not authorized. Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of phosphine resulting from the use of zinc phosphide in timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) at 0.1 part per million (ppm). These tolerances will expire and be automatically revoked without further action by EPA on April 15, 1998.

VII. 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 FFDCA section 408(e) and (l)(6) as was provided in the old FFDCA section 408 and 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 April 21, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given in "ADDRESSES" at the beginning of this document (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 Confidential Business Information (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.

VIII. Public Record

A record has been established for this rulemaking under docket control number [OPP-300453]. A public version of this record, 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 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency,

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

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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.

The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this rule.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 6, 1997.

Peter Caulkins,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
 Authority: 21 U.S.C. 346a and 371.

2. In §180.284, paragraph (c) is amended by revising the introductory text and adding in alphabetical order new entries to the table to read as follows:

§ 180.284 Zinc phosphide, tolerances for residues.

* * * * *

(c) Time-limited tolerances are established for residues of phosphine resulting from the use of the rodenticide zinc phosphide in connection with use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Alfalfa (forage)	0.1	April 15, 1998
Alfalfa (hay)	0.1	April 15, 1998
Clover (forage)	0.1	April 15, 1998
Clover (hay)	0.1	April 15, 1998
* * * * *	*	* * *
Timothy (forage)	0.1	April 15, 1998
Timothy (hay)	0.1	April 15, 1998
Timothy (seed)	0.1	April 15, 1998

[FR Doc. 97-3931 Filed 2-19-97; 8:45 am]
 BILLING CODE 6560-50-F

40 CFR Part 261

[SW-FRL-5690-6]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Amendment

AGENCY: Environmental Protection Agency.

ACTION: Final rule; amendment.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is amending 40 CFR part 261, appendix IX to reflect changes in ownership and name for United Technologies Automotive, Inc., Jeffersonville, Indiana. Today's amendment documents these changes.

EFFECTIVE DATE: February 20, 1997.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free at (800) 424-9346 or at (703) 412-9810. For technical information contact Ms. Judy Kleiman, Waste Management Branch (DRP-8J), Waste, Pesticides and Toxics Division, U.S. Environmental Protection Agency, 77 W. Jackson Blvd, Chicago, IL 60604, (312) 886-1482.

SUPPLEMENTARY INFORMATION: In this document EPA is amending appendix IX to part 261 to reflect changes in the ownership and name for United Technologies Automotive. The petition process under §§ 260.20 and 260.22 allows facilities to demonstrate that a specific waste from a particular generating facility should not be regulated as a hazardous waste. Based on waste specific information provided by the petitioner, EPA granted an exclusion to United Technologies Automotive on April 29, 1986, for F019 wastes at its Jeffersonville, Indiana, facility (51 FR 15888). On November 20, 1995, Region 5 received notice that ownership of the United Technologies Automotive facility in Jeffersonville, Indiana, was transferred to Profile Extrusion Company. On November 14, 1996, Region 5 received notice that ownership of Profile Extrusion Company was transferred to Alumnitec, Inc.

In this notification Alumnitec noted that no changes had been made in the management of the F019 waste excluded by the Agency, and that all conditions of the exclusion will continue to be met. Today's notice documents this change by updating Appendix IX to incorporate this change in name.

This change to 40 CFR Part 261, Appendix IX will be effective February 20, 1997. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. As described above, Alumnitec will continue to meet all conditions of United Technologies Automotive's exclusion. Therefore, a six-month delay in the effective date is not necessary in this case. This provides a basis for making this amendment effective immediately upon publication under the Administrative Procedures Act, pursuant to 5 U.S.C. 5531(d).

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Dated: January 21, 1997.
 Jo Lynn Traub,
Acting Regional Administrator, Region 5.

For the reasons set out in the preamble, 40 CFR part 261 is to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

2. 40 CFR Part 261, Appendix IX, Table 1, is amended by removing the entry for "United Technologies Automotive, Inc." and by adding in alphabetical order the entry for "Alumnitec, Inc." to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
* * * * *	* * * * *	* * * * *
Alumnitec, Inc. (formerly Profile Extrusion Co., formerly United Technologies Automotive, Inc.).	Jeffersonville, IN	Dewatered wastewater treatment sludge (EPA Hazardous Waste No. F019) generated from the chemical conversion of aluminum after April 29, 1986.
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