

§ 52.570 Identification of plan.

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(c) * * *

(49) Addition of NO_x RACT permits to specify RACT for specific sources, submitted on November 15, 1994, and March 19, 1998.

(i) Incorporation by reference.

(A) The following source specific NO_x RACT permits of the Georgia Department of Natural Resources, Chapter 391-3-1, Air Quality Control, effective on December 27, 1995.

NO_x RACT Permits:

Permit 4911-033-5037-0 Plant

McDonough conditions 10 through 22

Permit 4911-038-4838-0 Plant Yates

conditions 19 through 32

Permit 4911-038-4839-0 Plant Yates

conditions 16 through 29

Permit 4911-038-4840-0 Plant Yates

conditions 16 through 29

Permit 4911-038-4841-0 Plant Yates

conditions 16 through 29

(B) The following source specific NO_x

RACT permits of the Georgia

Department of Natural Resources,

Chapter 391-3-1, Air Quality Control,

effective on November 15, 1994.

NO_x RACT Permits:

Permit 4911-033-1321-0 Plant

Atkinson conditions 8 through 13

Permit 4911-033-1322-0 Plant

Atkinson conditions 8 through 13

Permit 4911-033-6949 Plant Atkinson

conditions 5 through 10

Permit 4911-033-1320-0 Plant

Atkinson conditions 8 through 13

Permit 4911-033-1319-0 Plant

Atkinson conditions 8 through 13

Permit 4911-033-6951 Plant

McDonough conditions 5 through 10

Permit 4922-028-10902 Atlanta Gas

Light Company conditions 20 and 21

Permit 4922-031-10912 Atlanta Gas

Light Company conditions 27 and 28

Permit 2631-033-11436 Austell Box

Board Corp. conditions 1 through 5

Permit 8922-044-10094 Emory

University conditions 19 through 26

Permit 3711-044-11453 General Motors

Corporation conditions 1 through 6

and Attachment A

Permit 2077-058-11226 Georgia

Proteins Company conditions 16

through 23 and Attachment A

Permit 3221-060-10576 Owens-

Brockway Glass Container, Inc.

conditions 26 through 28 and

Attachment A

Permit 3296-060-10079 Owens-Corning

Fiberglass Corporation conditions 25

through 29

Permit 3354-038-6686-0 William L.

Bonnell Co. conditions 17 through 30

Permit 4922-075-10217

Transcontinental Gas Pipe Line

Corporation conditions 21 through 24

Permit 9711-033-11456 Lockheed-

Georgia Company conditions 1

through 11

Permit 3241-060-8670 Blue Circle

Incorporated conditions 48 through

54

(ii) Other material None.

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300696; FRL-6021-6]

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 timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay). 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 timothy or timothy-alfalfa, clover stands in Washington. 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 February 1, 2000.

DATES: This regulation is effective August 25, 1998. Objections and requests for hearings must be received by EPA on or before October 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300696], 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-300696], 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 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-300696]. 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 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 tolerances for 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 are revoked on February 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 tolerance 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 Timothy and Timothy-Alfalfa/Clover and FFDCa Tolerances

A potential population of 500 voles per acre would result in significant economic loss. The currently available methods of control, including the use of zinc phosphide bait boxes and flood irrigation, are inadequate and impractical. EPA has authorized under FIFRA section 18 the use of zinc phosphide on timothy and timothy-alfalfa/clover for control of vole complex in Washington. 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 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 be consistent with the new 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 these tolerances will expire and are revoked on February 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 timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) 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 these tolerances at the time of that application. 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.

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 timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) 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 Washington to use this pesticide on these crops under section 18 of FIFRA without following all provisions of 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. 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. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the "no-observed effect level" or "NOEL").

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. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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 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.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include "acute," "short-term," "intermediate term," and "chronic" risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enactment of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when

reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). 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. In evaluating food exposures, EPA takes

into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. 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.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (children 1-6 years old) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

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 zinc phosphide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for phosphine resulting from the use of the rodenticide zinc phosphide of zinc phosphide on timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) at 0.1 ppm. EPA's assessment of the dietary 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 below.

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

2. *Short- and intermediate-term toxicity.* Since 10% zinc phosphide tracking powder has been classified in Toxicity Category IV ($LC_{50} > 19.6$ mg/L), inhalation exposure resulting from this section 18 action is not considered toxicologically significant. For short-term and intermediate dermal MOE calculations, Health Effects Division (HED), OPP recommended use of the adjusted acute dermal LD_{50} NOEL of 1,000 milligrams/kilogram (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 lowest effect level (LEL) of 2,000 mg/kg in the rabbit dermal LD_{50} 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.

3. *Chronic toxicity.* EPA has established the RfD for zinc phosphide at 0.003 (mg/kg/day). This RfD is based on an 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 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.

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. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40

CFR 180.284(a) and (b)) for residues of the phosphine resulting from the use of the rodenticide zinc phosphide in or on a variety of raw agricultural commodities. There is no reasonable expectation of secondary residues in meat, milk, poultry, or eggs (Category 3 of 40 CFR 180.6(a)). 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 these tolerances. 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.

ii. *Chronic exposure and risk.* 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 overestimation of human dietary exposures.

2. *From drinking water.* Zinc phosphide degrades rapidly to Zn^{2+} and phosphine gas which absorb strongly to soil and are common nutrients in soil. Zinc phosphide and its degradation products appear to have a low potential for ground water and surface water contamination. There is no information on zinc phosphide (phosphine) residues in ground water and runoff in the 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.

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.

These registrations could result in non-occupational exposure and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational, non-dietary exposure scenarios. At this time, the Agency has insufficient information to assess the potential risks from such exposure.

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." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other

substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether zinc phosphide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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.

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

1. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to zinc phosphide from food will utilize 27.5% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years old "discussed below." EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to zinc phosphide from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zinc phosphide residues.

2. *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.

D. Aggregate Cancer Risk for U.S. Population

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.

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

1. *Safety factor for infants and children—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 and mouse. 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 MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty 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.

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 pre-natal sensitivities for infants and children. OPP has waived teratogenicity in the rabbit and the 2-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. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to zinc phosphide from food will utilize from 6.8% of the RfD for nursing infants (<1 year old) and up to 59.9% children 1 to 6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to zinc phosphide from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to zinc phosphide residues.

V. Other Considerations

A. Metabolism In Plants and Animals

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.

B. Analytical Enforcement Methodology

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 as phosphine gas are described in PAM, Vol. II, as Method A.

C. Magnitude of Residues

Residues of phosphine resulting from this use of zinc phosphide in timothy (seed, forage, hay), alfalfa (forage, hay) and clover (forage, hay) will not exceed 0.1 part per million (ppm).

D. International Residue Limits

There are no Codex tolerances for timothy (seed, forage, hay), alfalfa (forage, hay) and clover (forage, hay).

VI. Conclusion

Therefore, these tolerances are established for phosphine resulting from the use of the rodenticide zinc phosphide in timothy (seed, forage,

hay), alfalfa (forage, hay), and clover (forage, hay) at 0.1 ppm.

VII. Objections and Hearing Requests

The new FFDC 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 October 26, 1998, 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300696] (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.

IX. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDC section 408(d) 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). 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 these tolerances and exemptions that are established under FFDC 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.

X. 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: August 11, 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. Section 180.284 is revised to read as follows:

§ 180.284 Zinc phosphide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the phosphine resulting from the use of the rodenticide zinc phosphide in or on the raw agricultural commodities as follows:

Commodity	Parts per million
Grapes	0.01
Grasses (rangeland)	0.1
Sugarcane	0.01

(b) *Section 18 emergency exemptions.* 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	02/01/00
Alfalfa (hay)	0.1	02/01/00
Clover (forage)	0.1	02/01/00
Clover (hay)	0.1	02/01/00
Timothy (forage)	0.1	02/01/00
Timothy (hay)	0.1	02/01/00
Timothy (seed) ..	0.1	02/01/00

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of phosphine resulting from the use of the rodenticide

zinc phosphide in or on the following raw agricultural commodities as follows:

Commodity	Parts per million
Artichoke (globe)	0.01
Sugar beet (roots)	0.04
Sugar beet (tops)	0.02

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98-22787 Filed 8-24-98; 8:45 am] BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97-26, RM-8968, RM-9089, RM-9090; MM Docket No. 97-91, RM-8854, RM-9221]

Radio Broadcasting Services; Detroit, Howe, Jacksboro, Lewisville, Gainesville, Robinson, Corsicana, Mineral Wells TX, Antlers, Hugo, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document consolidates MM Docket No. 97-26 and MM Docket No. 97-91. In doing so, it allots Channel 294C2 to Detroit, Texas, and Channel 222C2 to Antlers, Oklahoma. In addition, this document also substitutes Channel 300C1 for Channel 300C2 at Gainesville, Texas, reallots Channel 300C1 to Lewisville, Texas, and modifies the Station KECS construction permit to specify operation on Channel 300C1 at Lewisville, Texas, and substitutes Channel 300A for Channel 300C1 at Corsicana, Texas, reallots Channel 300A to Robinson, Texas, and modifies the Station KICI license to specify operation on Channel 300A at Robinson, Texas. In order to accommodate these reallotments, this document substitutes Channel 237A for Channel 299A at Jacksboro, Texas, and modifies the construction permit of Station KJKB, Jacksboro, Texas, to specify operation on Channel 237A. See 62 FR 4223, January 29, 1997; 62 FR 14091, March 25, 1997. The reference coordinates for Channel 294C2 at Detroit, Texas, are 33-49-16 and 95-24-16. The reference coordinates for Channel 222C2 at Antlers, Oklahoma, are 34-12-45 and 95-42-13. The reference coordinates for Channel 300C1 at Lewisville, Texas, are 33-17-33 and 97-13-46. The reference coordinates for

Channel 300A at Robinson, Texas, are 31-26-58 and 97-07-27. The reference coordinates for Channel 237A at Jacksboro, Texas, are 33-13-06 and 98-09-48. With this action, the proceeding is terminated.

EFFECTIVE DATE: October 6, 1998.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau (202) 418-2177

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order* adopted August 12, 1998, and released August 21, 1998. The full text of this decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3805, 1231 M Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 294C2 at Detroit.

3. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by adding Channel 222C2 at Antlers.

4. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 300C2 at Gainesville, and adding Channel 300C1 at Lewisville.

5. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 300C1 at Corsicana, and adding Channel 300A at Robinson.

6. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Channel 299A and adding Channel 237A at Jacksboro.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 98-22807 Filed 8-24-98; 8:45 am]

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