estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate or to the private sector. This Federal action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not subject to E.O. 13045 because this is not an economically significant regulatory action as defined by E.O. 12866, and it implements a previously promulgated health or safety-based Federal standard.

E. Executive Order 12875: Enhancing the Intergovernmental Partnership

Under E.O. 12875, 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, or EPA consults with those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to OMB a description of the extent of EPA's prior consultation with representatives of the 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, E.O. 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 proposed rule does not create a mandate on State, local or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

F. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under E.O. 13084, 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, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to 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, E.O. 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 proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The identified areas are not located in tribal lands, and this proposed action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

G. Paperwork Reduction Act

This proposal does not contain any information collection requirements which requires OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

H. Executive Order 12898: Environmental Justice

Under E.O. 12898, each Federal agency must make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. Today's proposed action (identifying additional ozone areas where the 1-hour standard is no longer applicable) does not adversely affect minorities and low-income populations because the new, more stringent 8-hour ozone standard is in effect and provides increased protection to the public, especially children and other at-risk populations.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing new regulations. To comply with NTTAA, the EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this proposed action. Today's proposed action does not require the public to perform activities conducive to the use of VCS.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Issued in Washington, D.C. on May 12, 1999.

Carol M. Browner,

Administrator.

[FR Doc. 99–14596 Filed 6–7–99; 10:42 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300865; FRL–6082–4]

RIN 2070–AB78

Phosphine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Tolerances are being revised and consolidated for residues of phosphine in or on certain agricultural commodities and animal feeds. None of these proposed tolerances are new, although this change would facilitate new application methods. The Agency is merely changing the tolerance expression to eliminate references

concerning how the phosphine gas is generated.

DATES: Comments, identified by the docket control number [OPP–300865], must be received on or before July 9, 1999.

ADDRESSES: By mail, submit written comments 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, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit VI. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Interested persons are invited to submit comments on the proposed regulation. Comments must bear a notation indicating the docket control number [OPP–300865].

FOR FURTHER INFORMATION CONTACT: By mail: Dennis McNeilly, 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) 308-6742, e-mail: McNeilly.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 1998, (FRL–6053–6), EPA announced the availability of the Reregistration Eligibility Decision (RED) for aluminum and magnesium phosphide, which was signed on September 30, 1998. This document discusses in detail the Agency's risk assessment for these two very similar pesticides.

Current tolerances established for aluminum and magnesium phosphide are expressed in terms of residues of the fumigant phosphine resulting from the use of aluminum and/or magnesium phosphide, respectively. Both of these chemicals have very similar use patterns, chemical properties and both result in the same residue (hydrogen phosphide), both qualitatively and quantitatively. In fact, due to the high reactivity and volatility of these two compounds the detection of finite residues is not expected and the residue data indicate non- detectable levels of phosphine, when label directions concerning aeration for 48 hours before entering into commerce are followed. The Agency has decided to revise the current tolerance expressions because it does not matter from a safety or practical standpoint, i.e. tolerance enforcement purposes, whether residues of phosphine result from treatment with aluminum phosphide or magnesium phosphide. In fact, having tolerances expressed in this manner precludes treatment of the food and/or feed commodities with phosphine gas delivered or generated via different technology. Different application techniques involving direct application of phosphine gas have the potential to reduce worker exposure because fumigators would not need to enter the facility being fumigated.

The aluminum and magnesium phosphide RED states that the tolerances listed under 40 CFR 180.225 (a) and (b), 185.200, and 186.200 and tolerances for magnesium phosphine listed under 40 CFR 180.375 (a) and (b), 185.3800, and 186.3800 should be amended to consolidate all of these tolerances in the Code of Federal Regulations. Following passage of the Food Quality Protection Act (FQPA), tolerances for pesticide residues in all types of food (raw or processed) are set under the same provision of the law and EPA is including all such tolerances in part 180 of the Code of Federal Regulations. The Agency will list all aluminum phosphide and magnesium phosphide tolerances under 40 CFR 180.225 and be subdivided into paragraphs (a)(1), (a)(2), (a)(3), and (a)(4). Tolerances in the new paragraph (a)(1) concern residues resulting in or on Raw Agricultural Commodities (RACs) from post-harvest fumigation uses. Tolerances in paragraph (a)(2) concern residues in or on RACs from preharvest treatment of pest burrows in agricultural and non-crop land areas. The Agency notes that this use involves control of vector borne disease, especially in the southwestern United States. Paragraph (a)(3) concerns residues resulting from fumigation of processed foods. Finally, paragraph (a)(4) concerns residues resulting from fumigation of animal feeds. There are no tolerances established, nor are there any uses registered, for the direct treatment of any field crop or greenhouse-grown food commodity.

The Agency recently updated the list of raw agricultural and processed commodities and foodstuffs derived from crops (Table 1 OPPTS GLN 860.1000). As a result of changes to this table, commodity definitions used in the CFR also need to be updated. For example, instead of a tolerance expressed as corn, it should now specify corn, grain or corn, forage, etc. Further, since the tolerances for phosphide will be combined under a single tolerance expression for phosphine, several commodities with tolerances currently listed under both aluminum and magnesium phosphide would need only one tolerance. The Agency notes that it is impossible for a laboratory to determine from strictly analytical methods whether phosphine residues resulted from Al or Mg phosphide application and for risk assessment it is irrelevant. In addition, with the required 48-hour aeration period required on all labels, finite residues are not expected in/on any food commodity.

I. Risk Assessment and Statutory Findings

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. . . .''

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).

II. 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 phosphine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for residues of phosphine in or on almond, nutmeat at 0.1 parts per million (ppm); avocadoes at 0.01 ppm; bananas at 0.01 ppm; barley, grain at 0.1 ppm; Brazil nut at 0.1 ppm; Cabbage,Chinese at 0.01 ppm; cacao, bean at 0.1 ppm; cashews at 0.1 ppm; citrus, citron at 0.01 ppm; coffee, bean, green at 0.1 ppm; corn, field, grain at 0.1 ppm; corn, pop, grain at 0.1 ppm; cotton, seed, undelinted at 0.1 ppm; date, dried at 0.1 ppm; eggplants at 0.01 ppm; endive (escarole) at 0.01 ppm; filbert at 0.1 ppm; grapefruit at 0.01 ppm; kumquats at 0.01 ppm; Legume vegetables succulent or dried group(excluding soybeans) at 0.0 1 ppm; lemons at 0.01 ppm; lettuce at 0.01 ppm; limes at 0.01 ppm; mangoes at 0.01 ppm; millet, grain at 0.1 ppm; mushrooms at 0.01 ppm; oats, grain at 0.1 ppm; oranges at 0.01 ppm; papayas at 0.01 ppm; peanut, nutmeat at 0.1 ppm; pecans at 0.1 ppm; peppers at 0.01 ppm; persimmons at 0.0 1 ppm; pistachios at 0.1 ppm; rice, grain at 0.1 ppm; rye at 0.1 ppm; safflower seed at 0.1 ppm; salsify tops at 0.01 ppm; sesame seed at 0.1 ppm; sorghum grain at 0.1 ppm; soybeans at 0.1 ppm; sunflower, seed at 0.1 ppm; sweet potatoes at 0.01 ppm; tangelos at 0.01 ppm; tangerines at 0.01 ppm; tomatoes at 0.01 ppm; walnuts at 0.1 ppm; wheat, grain at 0.1 ppm; all Raw Agricultural Commodities (RAC) resulting from preharvest treatment of pest burrows in agricultural and non-cropland areas, 0.01 ppm; phosphine residues resulting from fumigation of processed foods, 0.01 ppm; and phosphine residues resulting from fumigation of animal feeds, 0.01 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.

The Agency does not normally use inhalation studies for oral (dietary) risk assessments. However, inhalation studies were used for these chemicals because: (1) Use of an inhalation ''dose'' provides a conservative approach for oral risk assessments; (2) these studies enable the Agency to quantify the dosage of phosphine exposed to laboratory animals; (3) the Agency required inhalation studies (rather than oral studies) for this chemical because exposure to this chemical via inhalation is much more likely for those individuals who would have occupational exposure.

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 phosphine are discussed below.

1. *Acute toxicity*. A rat acute inhalation study on phosphine indicated an LC_{50} greater than 11 ppm, the highest dose tested (HDT). This puts phosphine in Toxicity Category I, i.e., Highly Toxic.

Given aluminum and magnesium phosphide's use patterns and chemical characteristics, the other acute toxicity 81-series guideline studies used to establish precautionary labeling were waived for these chemicals as they would not change the Toxicity Category or effect protective clothing requirements. The material of concern is phosphine gas which is the material with pesticidal properties, when either aluminum or magnesium phosphide are used.

2. *Subchronic toxicity*. In a 90 day rat inhalation study, Fischer 344 rats (10/sex/dose) were exposed to phosphine 6 hours/day, 5 days/week for 13 weeks at levels of 0, 0.3, 1.0 or 3.0 ppm. Additional groups (3-5/sex/group) were exposed at 0 or 10 ppm starting at week 8, and 0 or 5 ppm starting at week 12. Recovery groups were included in the study at each dose level and sacrificed after 4 weeks of post-exposure observations. In the groups exposed at levels up to 3.0 ppm, there was a transient decrease in body weight gain accompanied by decreased food consumption. Red blood cell counts, hemoglobin concentration, and hematocrit values were slightly decreased in males exposed at 3.0 ppm (at 4 weeks only), but no effects were observed in these males at 13 weeks or in females at either interval. No exposure-related gross or histologic findings were observed at levels up to and including 3.0 ppm. Exposure at 10 ppm for 3 days caused 40% mortality in females but no mortality in males. Exposure at 10 ppm for 4 weeks caused 80% death in females. Both males and females exposed at 10 ppm had coagulative necrosis in the tubules of the kidneys and pulmonary congestion was observed in the females that died. No histologic findings related to dosing were apparent in the rats exposed for 2 weeks at 5 ppm; an increase in the BUN and alkaline phosphatase were observed in males but not females exposed at 5 ppm. An LEL for subchronic exposure (13 weeks) was not established in this study. The no-observed adverse effect level (NOAEL) for 13 weeks was 3 ppm (HDT). An LEL of 10 ppm for 4 weeks was based on lethality (4/5 deaths for females) due to the sharp dose-response curve.

3. *Chronic toxicity/carcinogenity*. In a 2-year rat feeding study, diets were treated with Phostoxin pellets at 48 and 90 gm/metric ton, fumigated for 48 hours and 72 hours, mixed for 2 hours, and then aerated for one hour. The feed was then stored frozen in small sealed containers until used as laboratory rat feed. Sixteen separate batches of feed were treated utilizing this methodology over the 2-year period. Samples of diet were taken to determine phosphine at the time the feed was removed from the freezer. Phosphine levels ranged from 0.2 to 7.5 ppm and averaged approximately 1 ppm. The amounts of phosphine that remained in the feed offered to the rats as food was not measured (but would be expected to be less because of dissipation). Therefore, the actual dosages in this study are unknown. Two groups of 60 rats each (30 males and 30 females) were used, one as treatment group and other as controls. The rats were observed for the effects on growth, food consumption, survival, morbidity, hematology, blood chemistry and gross and microscopic pathology. No differences were seen between the controls and the treated animals for any toxicity parameter. No increased oncogenicity resulted from fumigation residues. The study was not considered guideline since toxicity, secondary to phosphine residues, is not possible when aeration is adequate. However, the study shows that toxic levels of residues were not achieved even with the excessive fumigation treatment rates.

In a chronic/oncogenicity study, Charles River Fischer CDF Rats (60/sex/group) were exposed, under dynamic chamber conditions, to 0, 0.3, 1 and 3 ppm of phosphine. The rats were kept under standard laboratory conditions, observed twice daily and sacrificed (10/sex/group) during week 52 of the study. Body weights; food consumption; routine hematologic, serum biochemical and urinary analyses were all comparable to control animals. There were no adverse effects observed for the initial 12 month period. Body weights;

food consumption; routine hematologic, serum biochemical and urinary analyses were all comparable to control animals. Ophthalmological observations, gross pathology, organ weights and histopathology indicated no adverse effects from the phosphine exposures. The NOAEL for the 52 week period was 3.0 ppm, the HDT.

4. *Mutagencity*. In a *Salmonella typhimurium* reverse gene mutation assay, the test was negative with hydrogen phosphide (PH_3) in all strains up to cytotoxic concentrations (≥488 ppm/plate +/-S9).

i. *Chromosome aberrations*. In an *in vitro* cytogenetic assay with Chinese hamster ovary (CHO) cells phosphine was positive at 2,500 and 5,000 ppm without S9 activation. This resulted in a significant but not dose-related increases in the frequency of cells with structural chromosome aberrations. Significant clastogenic effects were also noted at 2,500 ppm with S9 activation but not at the HDT (5,000 ppm).

ii. *Other genotoxic mechanisms*. In an *in vivo* unscheduled DNA Synthesis (UDS) in primary rat hepatocytes, the test was negative in male Fischer rats exposed via inhalation to PH_3 doses of 0, 4.8, 13, 18 or 23 ppm (equiv. to 0, 11.4, 30.8, 42.6 or 54.5 mg/m^3, respectively) for 6 hours. Overt toxicity (*i.e.*, difficulty in breathing) but no target cell cytotoxicity was observed at the HTD.

Based on the findings reported by Garry *et al.*, (1989) that pesticide applicators exposed to phosphine had increased levels of chromosome damage, the USEPA sponsored a series of acute (Kligerman *et al.*,1994a) and subacute (Kligerman *et al.*, 1994b) inhalation cytogenetic studies with phosphine. A summary of these studies are as follows:

(a) Phosphine was negative for the induction of micronucleated polychromatic erythrocytes (MPE) in bone marrow cells and splenocytes and negative for the induction of sister chromatid exchange or chromosomal aberrations in splenocytes of CD-1 male mice exposed by inhalation to 0, 5, 10 or 15 ppm for 6 hours. Overt toxicity, manifested as lethargy and shallow breathing was seen at the HDT. There was a dose-related and significant reduction of splenocyte cell cycling at all levels, which indicates that phosphine was cytotoxic to splenocytes. There was, however, no adverse effect on bone marrow cells (Kligerman, *et al.*, 1994).

(b) Male B6C3F1 mice and male F344 rats were exposed by inhalation to 0, 1.25, 2.5 or 5.0 ppm phosphine, 6 hours/day, 5 days/week over an 11-day period. Bone marrow cells and/or peripheral blood lymphocytes were harvested and examined for sister chromatid exchanges and chromosomal aberrations (mouse and rat peripheral blood lymphocytes) and for MPEs (rat bone marrow and mouse bone marrow and peripheral blood lymphocytes). In addition, B6C3F1 males were exposed via inhalation to 0 or 5 ppm as above over a 12-day period and mated with untreated females in a dominant lethal assay. Results show that phosphine was not genotoxic at any endpoint.

iii. Additional *in vivo* data summarized below were available for review:

(a) Following subchronic inhalation exposure (0, 0.3, 1.0 or 4.5 ppm, 6 hours/ day, 5 days/week for 13 weeks) but not acute inhalation exposure (0 or 5.5 ppm, 2 weeks, 6 hours/day, 5 days/ week for 2 weeks), phosphine at 4.5 ppm caused a statistically significant increase in micronucleus induction in the spleen lymphocytes and bone marrow cells of Balb-c male and female mice. There was, however, no increase in gene mutations at the hypoxanthine guanine phosphoribosyl transferase locus in the recovered spleen lymphocytes.

(b) After 6 hours of inhalation exposure, phosphine, at the HDT (19 ppm) induced a significant increase in chromosomal aberrations in the bone marrow of Sprague Dawley male rats but not in the female rats. The effect is considered equivocal because increased chromosomal aberration frequencies were only seen in high-dose males with severely reduced mitotic indices (MIs). Females did not show increased chromosome aberrations and did not have decreased MIs. There was also no effect on peripheral lymphocytes.

(c) In an Australian study of workers exposed to phosphine, 31 phosphine fumigators and 21 controls, all employed at the New South Wales Grain Corporation, were examined for micronucleus incidence in peripheral blood lymphocytes and their concentrated urine was assessed for mutagenicity in TA100 and TA98 strains of *S. typhimurium*. In addition, serum bile acids were measured. The subjects, all males, were matched for medication, X-ray exposure within the past year and smoking habits. There was no indication how often the fumigators were exposed, or the most recent exposure date or the length of the various fumigators employed. No individual data were presented to identify if certain individuals showed unusually high micronuclei incidence, or presence of mutagens in the urine.

Urine samples were concentrated 75-fold and the procedure of Yamaski and Ames (1977) was used to test mutagenicity to TA100 and TA98 in the presence or absence of metabolic activation (S9). There was no increase in the mutagenicity of urine from the fumigators (N-27) vs controls (N=-19) in this assay.

Serum bile acids showed no changes related to phosphine exposure. Cholesterol and some liver enzymes (gamma-glutamyl transferase were elevated in the exposed group. Micronuclei formation was measured in isolated peripheral blood lymphocytes cultured for 44 hours in the presence of phytohemagglutinin to stimulate mitosis, arrested at metaphase with cytochalasin-B and harvested by cytocentrifugation after 72 hours in culture. The micronucleus incidence was comparable among the fumigators and the control groups (overall MI for fumigators = 6.9 vs 7.1 for controls).

Phosphine is not mutagenic in bacteria but is clastogenic *in vitro*. Both the negative Ames test and the positive CHO cell chromosome assay are consistent with the *in vitro* test results for zinc phosphide. Studies conducted *in vivo* indicate that phosphine is not clastogenic in mice or rats and does not cause dominant lethal mutations in mice following acute exposures for up to 2 weeks. There is, however, evidence that inhalation exposures of phosphine for up to 13 weeks induced significant clastogenic and/or an euploidogenic effects in male and female mice. The biological relevance of this finding can not be fully ascertained until the results of the 2-year rat inhalation study currently underway are submitted and reviewed.

5. *Neurotoxicity*. In an acute neurotoxicity study, 11 Crl:CD®BR VAF/Plus® rats/sex/exposure group were exposed to 0, 20, 30, or 40 ppm of phosphine (1% a.i. in nitrogen) for four hours. Each treatment group was exposed on a different day, with the first exposure occurring six days prior to the final exposure. 11 rats/sex/exposure group were selected for functional observational battery (FOB) and motor activity (MA) testing prior to and following exposure, and on days 7 and 14 post-exposure; six rats/sex/exposure group were perfused for neuropathology. All animals survived to scheduled termination. There were no exposure-related clinical signs. FOB and MA parameters were characterized by variability both within and among control and exposed groups; this variability (which may be partly due to the unbalanced treatment schedule) confounded interpretation of some of

the results. Palpebral closure was noted in some exposed groups on day 1 and was significant in females exposed to 30 and 40 ppm and in males at 20 and 40 ppm. Body temperatures were significantly lowered for males and females on day 1 in all exposure groups. The remainder of the differences in the FOB parameters were random statistical variations that occurred both pre- and post-test, were not dose related, and were not consistent between the sexes. Motor activity (horizontal, vertical, total distance, and stereotypic time) was decreased at 20, 30, and 40 ppm, primarily during the 10 and 20 minute post-exposure time intervals (data comparing motor activity for the entire 30-minute assessment period was neither presented nor analyzed). With one exception, these reductions no longer occurred at 7 or 14 days after exposure. For males during the first 10-minute post-exposure interval, horizontal activity decreased significantly by 76.4, 71.7 and 83.8% in the 20, 30, and 40 ppm groups, respectively. Males in the 20 ppm group had the following decreases in horizontal activity: 76.4%, 77.6% (both statistically significant), and 89.4% (non-statistically significant) during the 10, 20, and 30 minute intervals, respectively. For females during the first 10-minute post-exposure interval, horizontal activity decreased significantly by 71.3, 48.0, and 83.5% in the 20, 30, and 40 ppm groups, respectively. Females in the 20 ppm group had the following decreases in horizontal activity: 71.3%, 85.8% (both significant), and 54.1% (non-statistically significant) during the 10, 20, and 30 minute intervals, respectively. Similar decreases occurred for both sexes for vertical activity, total distance, and stereotypic time. No phosphine-related neuropathological changes were observed in any exposure group. Significant increases in absolute and relative (body and brain weights) adrenal gland weights in males from the 40 ppm group were of questionable biological significance and did not show a concentration-response relationship. The significant decrease in temperature and motor activity, seen at all exposure levels in spite of the flaws in the study, are considered treatment-related. The LOEL for neurobehavioral findings is 20 ppm based on decreased body temperatures and decreased motor activity in males and females. The NOAEL is <20 ppm. Based on lack of systemic toxicity, the NOAEL for systemic toxicity is 40 ppm. It must be noted that the Agency has asked for additional information regarding this study and has not accepted the study until the requested data are submitted and reviewed.

In a subchronic inhalation neurotoxicity study, 16 Crl:CD®BE VAF/Plus® rats/sex/exposure group were exposed to phosphine (1% a.i. in nitrogen) for six hours/day, 5 days/week for approximately 90 days at 0, 0.3, 1, or 3 ppm. An additional six rats/sex were assigned to the 0 and 3 ppm groups for a 2-week recovery group. Eleven rats/sex/exposure group were assigned for neurobehavioral evaluations. Six of the eleven rats/sex/exposure group were designated for neuropathological evaluations. No exposure-related deaths occurred in this study. Body weights were slightly higher in high-concentration males (2.4%) and females (1.2%) after 13 weeks of treatment, and became equal or less than the control body weights after the 2 week recovery period. Palpebral closure was consistently increased in high-concentration animals compared to controls. The increase was significant ($p \leq 0.05$) in high-concentration males at week 4 and was exposure related. The increased palpebral closure in high-concentration females was not significantly different from the control group. The incidence of high-concentration males found sleeping was consistently higher than the controls and was significantly higher ($p \geq 0.05$) at week 4. The sleep incidence in males showed an exposure effect at weeks 4 and 13. A similar trend was observed in females, but the differences were not statistically significant. Body temperatures of high-concentration males were consistently lower than the controls and reached statistical significance ($p \geq 0.05$) at week 13. The decreased body temperature was exposure- related at weeks 4 and 13. Females did not show a treatment-related change in body temperature. The horizontal and vertical motor activities were significantly lower in high-concentration males than the control group at week 13, and were consistently, but not significantly lower at other time intervals. Motor activity measurements in females were compromised by high variations and significant decreases in the high-concentration group at the pretest interval. There were no treatment-related findings at necropsy or during the neurohistopathological examination of collected tissues. The effects seen in high-concentration males that could be treatment-related are slight, but are consistent and mutually supportive. The effects in females either did not occur, were not statistically significant, or were compromised by variations in pretest measurements. Due to the equivocal nature of the effects seen in high-concentration males, and the lack of effects seen in females, the tentative NOAEL for systemic/neurobehavioral findings is 3.0 ppm for males and females, a LOEL was not determined in this study. Since the procedures used in this study have not been validated, and since positive effects may be obscured by insensitive methods, the NOAEL is tentative and will be re-evaluated upon receipt of information requested from the sponsor. It must be noted that the Agency has asked for additional information regarding this study and has not accepted the study until the requested data are submitted and reviewed.

B. Toxicological Endpoints

1. *Acute toxicity*. The acute dietary endpoint is based upon the results of the 90-day inhalation study. The dose and endpoint for risk assessment was 5 ppm or 1.8 milligrams/kilogram/day (mg/kg/day) based on the lack of treatment-related effects following 15 days of exposure. This includes a 100 fold Uf to account for inter and intra species variation.

2. *Short - and intermediate - term toxicity*. Based on the use pattern and the fact that phosphine is a gas, an end-point and risk assessment were not conducted for short- and intermediate-term, oral or dermal exposures.

3. *Chronic toxicity*. EPA has established the chronic reference dose (RfD) for phosphine at 0.0113 mg/kg/day. This RfD is based on an interim report (one year) for a 2-year chronic/oncogenicity inhalation toxicity in rats. The dose for the risk assessment was a NOAEL=3 ppm = 0.004 mg/L=1.13 mg/kg/day. A 100 fold Uf was applied to account for inter and intra species variation.

4. *Carcinogenicity*. The results of a non-guideline 2-year rat feeding study did not indicate a carcinogenic concern. Additionally, an interim (one year) report for a 2-year inhalation carcinogenicity study has been reviewed and does not indicate a carcinogenic concern. The final report was submitted to the Agency in November, 1998 and is being reviewed; however, it is unlikely to change the Agency's evaluation of phosphine's carcinogenic potential.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established under (40 CFR 180.225 (a) and (b), 185.200, 186.200, 180.375, 185.3800, and 186.3800) for the residues of phosphine, in or on a variety of raw agricultural

commodities at either 0.01 ppm or 0.1 ppm level including food and feed tolerances. This rule does not propose any new tolerances but rather changes the existing tolerance expressions and eliminates reference to the source of the phosphine gas, i.e., generated from either aluminum or magnesium phosphide. Tolerances are set at 0.01 ppm for those commodities for which direct treatment is not permitted. Tolerances of 0.1 ppm were established for those commodities listed above for which aluminum and magnesium are allowed to come into direct contact, e.g., tablets are added directly to corn grain as it is stored in silos . The Agency does not expect finite residues at the consumer's dinner plate, even for those commodities with a 0.1 ppm tolerance. This is because these commodities are aerated for 48 hours, cooked, shelled, washed, or otherwise prepared in some other way before they are actually consumed. For example, nuts are shelled and further processed before reaching the consumer. Other commodities such as dates are washed and graded for packaging which would remove any unreacted phosphine residue. The Agency has residue data from numerous studies on a wide variety of raw agricultural commodities and processed foods that confirm, with adequate aeration (48 hours is required) there will not be finite residues in or on food commodities. Still the FDA does at times sample RACs before the further processing described above occurs and there is the potential that small amounts of unreacted phosphine residues of up to 0.1 ppm could be observed in one of the RACs listed. All aluminum and magnesium phosphide product labels are carefully reviewed to restrict direct addition of the fumigant to commodities that are further processed in a manner that it would preclude the possibility of unreacted fumigant being in or on the food supply presented to the consumer. Risk assessments were conducted by EPA to assess dietary exposures and risks from phosphine 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. Dietary exposure to aluminum and magnesium phosphide can potentially occur via residues of phosphine gas remaining in treated commodities. A large number of studies involving numerous types of raw agricultural commodities and processed commodities submitted to the Agency for establishment of food tolerances indicate that residues of phosphine gas will be non- detectable with adequate aeration. One of these studies involved the analysis of 49 different processed foods, with all residues being <0.004 ppm (limit of detection for this study). There are many other studies cited in the Registration Standard (PB87-117172) that support the conclusion that residues will typically be non-detectable with adequate aeration, i.e., <0.004 ppm. Tolerances were established based on the limits of quantification of the analytical method for phosphine gas for those commodities that may not come into direct contact phosphine during the fumigation procedure. Tolerances of 0.1 ppm were established for those commodities for which aluminum and magnesium are allowed to come in direct contact. This tolerance level allows for any small amount of unreacted product compound left in the food or feed that would be removed later during processing. Direct addition (with it's 0.1 ppm tolerance) is not allowed for processed commodities, and is strictly prohibited by the product use manuals.

Anticipated residues, were used for both the chronic and acute dietary exposure analysis. The Agency conducted a Dietary Exposure Evaluation Model (DEEM) analysis, for both acute and chronic exposure scenarios, making the very conservative assumption (protective of human health) that all food contained in the DEEM consumption database (except meat/milk/poultry/eggs), i.e., the food consumed by an individual in a given day, would contain residues of phosphine gas at the anticipated residue level of 0.006 ppm. This was the highest limit of detection for any of the residue studies in the Agency's tolerance petition files and was used for both the acute and chronic analysis. The Agency considers this to be a ''worst-case'' scenario. Acute dietary exposure from food does not exceed the Agency's level of concern. The percent of the acute RfD occupied, at the 99.9th percentile, is less than 30% for the population subgroups examined. The Agency again notes that tolerances are based upon non-detectable residues in residue field trials. Because phosphine gas will dissipate into the atmosphere, especially as foods are cooked (heated) or prepared, residues are unlikely to be found on food at the time of consumption.

TABLE 1. ACUTE DIETARY (FOOD) EXPOSURE AT THE 99.9TH PERCENTILE

Population Subgroup	Exposure (mg/kg/day)	Percent Acute RfD
U.S. Population	0.003872	22
Non-nursing Infants (<1 yr old)	0.004943	27
Children (1-6 yr old)	0.004440	25

In addition, the acute dietary endpoint is based on a NOAEL which is the highest dose in the study. The true NOAEL may well be higher than that observed in the study. Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure and risk.* The results of the DEEM chronic exposure analysis for exposure are summarized in Table 2. Chronic exposure does not exceed the Agency's level of concern. The percent of the chronic RfD occupied, is less than 10% for the population subgroups examined.

These estimates of exposure are partially refined, yet still conservative in that it was assumed that all food (except meat/milk/poultry/eggs) consumed by an individual would contain phosphine gas residues at 0.006 ppm. This anticipated residue level is based on the highest limit of detection reported in tolerance petitions. The Agency again notes that all tolerances are based upon non-detectable residues in residue field trials. Because phosphine gas will dissipate into the atmosphere, especially as foods are cooked (heated) or prepared, residues are unlikely to be found on food at the time of consumption.

TABLE 2. CHRONIC DIETARY (FOOD) EXPOSURE

Population Subgroup	Exposure (mg/kg/day)	Percent Chronic RfD
U.S. Population	0.000261	2
Non-nursing Infants (<1 yr old)	0.001004	9
Children (1-6 yr old)	0.000474	4

Chronic aggregate dietary exposure (food and water) does not exceed HED's level of concern. Using conservative assumptions, chronic risk estimates from exposure in food were less than 10% for all population subgroups examined. In fact, due to the rapid dissipation of gaseous phosphine, the Agency does not expect finite residues on treated commodities at all if used according to label directions. Therefore, the Agency concludes that there is a reasonable certainty of no harm from chronic dietary exposure.

Section 408(b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemical that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified or left in effect demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate as required by section 408(b)(2)(E). EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than five years from the date of issuance of this tolerance.

2. *From drinking water.* Phosphine degrades in days (half-life is estimated to be 5 hours) and has a low exposure potential for contaminating ground and surface water because it is a gas. Therefore, EPA believes these uses will not result in any exposure through ground or surface water. Therefore, aggregate exposure is limited only to food. If new uses are added in the future, the Agency will reassess the potential impacts of phosphine on drinking water as a part of the aggregate risk assessment process. Due to the nature of these insecticides, addition of crop or residential uses is not likely.

3. *From non-dietary exposure.* Phosphine is restricted use pesticide that is used to fumigate grains and other non-food commodities. Phosphine is also used to control rodents in burrows. It has no residential uses. Residential exposure is not expected; therefore, no risk assessment for these scenarios were conducted.

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 phosphine 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, phosphine 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 phosphine has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The aggregate acute risk reflects food source risk only, therefore an additional aggregate risk assessment is not needed (see Unit II.C.2 in the preamble of this document). The use patterns associated with aluminum and magnesium phosphide are not expected to impact water resources through labeled uses; therefore, exposure to humans through drinking water is not expected. In addition, all aluminum and magnesium phosphide products are restricted use pesticides, which have no indoor residential uses; therefore, residential exposure is not expected for these restricted use products (which do not have residential use other that rodent control in burrows). The acute risk from food exposure to phosphine is 22% of the RfD, which indicates an adequate margin of safety.

2. *Chronic risk.* Using the anticipated residues and 100% crop treated exposure assumptions described above, EPA has concluded that aggregate exposure to phosphine from food will utilize less than 10% of the RfD for the U.S. population. The subgroup with the highest aggregate exposure is 9% for Non-nursing infants (<1 year 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. The potential residues

in drinking water are considered to be zero; therefore, the combined exposure of chronic food and drinking water exposure to phosphine would be no greater than less than 10% of the RfD for children or the general U.S. Population. Due to the nature of the non-dietary use, EPA believes that the commercial use of phosphine as a fumigant and in pest burrows will not result in any significant residential exposure. Therefore the chronic risk is based on food only.

3. *Short- and intermediate-term risk*. Short- and intermediate- term risks are assessed in tolerance actions where a pesticide has the potential for residential exposure through a route other than the diet. No such potential exists for phosphine. The acute and chronic risk assessments fully capture the risks associated with this tolerance action.

4. *Aggregate cancer risk for U.S. population*. EPA has determined that there is no evidence of carcinogenicity in the available studies. Based upon this determination it can be concluded that phosphine does not pose a cancer risk.

5. *Conclusion*. The Agency concludes that there is reasonable certainty that no harm will result from aggregate exposure to phosphine residues.

E. Aggregate Risks and Determination of Safety for Infants and Children and the General Population

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of phosphine, EPA considered data from a prenatal inhalation developmental toxicity study in rats.

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.

ii. *Developmental toxicity studies*. In a developmental study, CD derived Sprague Dawley mated female rats (24-27/dosage group) were exposed in inhalation chambers to concentrations of phosphine gas at 0, 0.03, 0.3, 3.0, 5.0 and 7.5 ppm, 6 hours per day on gestation days 6 through 15. The highest dose group was terminated after 10 days of exposures due to high mortalities (14/24). The treated females were observed twice daily for toxicity, and body weights and food consumption were monitored throughout the study. At day 20 post-coitus, the females were sacrificed and examined for corpora lutea, implantations, live and dead fetuses and early and late resorptions. Pups were identified, sexed and examined for external malformations and visceral and skeletal defects. The females and their fetuses from the high dose group were not examined for developmental effects. The only abnormalities observed were increased resorptions in liters (16 litters, 76 pups). Increased resorptions were not seen in the 0.3, 3.0 or 5.0 ppm groups. All other observations were comparable to the control females and pups. The maternal NOAEL was 5 ppm and the maternal LEL was 7.5 ppm based on the high incidence of maternal deaths. The reproductive NOAEL is 5 ppm and the developmental NOAEL was 5 ppm.

iii. *Reproductive toxicity study*. This study was not required for aluminum and magnesium phosphide. The complete toxicology data requirements for food- use chemicals are not required for aluminum and magnesium phosphide since little phosphine exposure is expected from use on foods as a fumigant. In fact, the Agency does not routinely require the standard toxicological data base for a food use chemical for fumigants. Fumigants are gases, which dissipate rapidly and provide for no residual control. Phosphine diffuses rapidly through the stored product because it is a small molecule and does not absorb to most commodities. Dietary exposure to this gas is not expected, tolerances are established to prevent misuse of the fumigants. It is for this reason, lack of exposure, that the Agency does not routinely require the complete battery of testing required for a food-use chemical, for fumigants. The very nature of the chemicals used for fumigation (very high volatility) make dietary exposure an unlikely scenario. The Agency reevaluated all previously waived food-use data requirements while reassessing these fumigants and determined that, based on lack of expected exposure, the data were not required. The only exception to this is the 2-year combined cancer-chronic study because there were specific concerns regarding chronic effects from low level exposure in grain workers.

iv. *Pre- and post-natal sensitivity*. The available toxicology data indicate no increased susceptibility in utero and/or postnatal exposure to phosphine. Aluminum/magnesium phosphide developmental toxicity to the offspring occurred at equivalent or higher doses than maternal toxicity.

v. *Conclusion*. The data base is considered complete, with respect to the usual data requirements for fumigants (See section E1iii above). There are no data gaps. The toxicity data for phosphine does not indicate increased susceptibility in utero or postnatal. Exposure assessments do not indicate a concern of potential risk to children because phosphine residues are not expected in food or drinking water and there is only a minor use of phosphine near residential sites, i.e., control of rodents in burrows. In addition, the Agency conducted a very conservative exposure assessment, i.e., protective of human health. It is for all these reasons that the Agency concludes that the additional safety factor of 10 can be removed.

Based on these risks EPA concludes that there is reasonable certainty that no harm will result to infants and children or the general population from aggregate exposure to phosphine residues.

III. Other Considerations

A. Metabolism In Plants and Animals

Based on the limited use pattern of aluminum and magnesium phosphide, plant and animal metabolism data were not required. The residue of concern is phosphine. The Agency has determined that decomposition products of phosphine are toxicologically insignificant at the levels found in treated commodities.

B. Analytical Enforcement Methodology

The Pesticide Analytical Manual (PAM) Vol. II lists, under aluminum phosphide, a colorimetric method (LOD = 0.01) and a GLC method with a flame photometric detection (LOD = 0.001 ppm) as Method A and B, respectively, for the enforcement of tolerances. The residue of concern is phosphine. It is noted that Method A remains a lettered method because of variable recoveries observed in an Agency method try-out. However, the method has been determined to be acceptable for enforcement because phosphine is highly reactive, and finite residues are

not expected. Data submitted in support of the established tolerances were collected by one of these two methods. The original Reregistration Standards for aluminum and magnesium phosphide reserved the requirements for human health studies until certain uncharacterized residues which resulted from the treatment of food were characterized and evaluated. Subsequent to the issuance of the Reregistration Standards, the Agency received information which identified these formerly unknown residues as oxidation products of phosphine. Having reviewed these data, the Agency has concluded that these decomposition products of phosphine are toxicologically insignificant at the levels found in the treated commodities.

Because aluminum and magnesium phosphide are inorganic compounds, recovery of residues using FDA Multiresidue Protocols is not expected, and the requirement for such data is waived.

C. Magnitude of Residues

Residue data reflecting registered postharvest treatments of stored raw agricultural and processed commodities indicate that, with adequate aeration or further processing after treatment, residues of phosphine dissipate to nondetectable levels (all <0.01 ppm). Residue data also indicate that the phosphine release from registered aluminum and magnesium phosphide products are not significantly different. Since aluminum and magnesium phosphide have essentially identical use patterns, the available residue data for aluminum phosphide has been translated to magnesium phosphide. Existing tolerances reflect a 48-hour aeration period.

D. International Residue Limits

The following tolerances for phosphine residues have been established by the CODEX Alimentary Commission: Cereal grains, 0.1 ppm; cocoa beans, 0.01 ppm; dried fruits, 0.01 ppm; dried vegetables, 0.01 ppm; peanuts, 0.01 ppm; spices, 0.01 ppm; tree nuts, 0.01 ppm. These tolerance levels are at or below the equivalent U.S. tolerances levels. The U.S. has no tolerances for use on spices or a broad tolerance for use on cereal grains; however, use on specific grains are registered uses in the U.S.. No U.S. registrants are apparently interested in obtaining such a tolerance for the Cereal Grains Crop Group (Crop Group 15) or an import tolerance for residues in/on spices. The lower tolerances probably reflects CODEX tolerances that do not allow direct addition of the fumigant to the raw agricultural commodity. Provided that one of the registrants submits a petition, with the supporting CODEX residue data and any corresponding use restriction, requesting that the higher U.S. tolerances (0.1 ppm) be reduced to 0.01 ppm, the Agency anticipates that harmonization for all commodities would be possible. The Agency notes that by changing the tolerance expression, new application technology could be registered that would eliminate the possibility of unreacted residues resulting from direct addition of the fumigant to raw agricultural commodities.

E. Rotational Crop Restrictions

Rotational crop restrictions are not needed as these insecticides are not used on agricultural crops.

IV. Conclusion

Tolerances are being revised and consolidated for residues of phosphine in the food commodities as outlined in the tables below. None of these proposed tolerances are new, the Agency is merely changing the tolerance expression to eliminate references concerning how the phosphine gas is generated.

V. Public Comment Procedures

EPA invites interested persons to submit written comments, information, or data in response to this proposed rule. After consideration of comments, EPA may issue a final rule. Such rule will be subject to objections. Failure to file an objection within the appointed period will constitute waiver of the right to raise in further proceedings issues resolved in the final rule.

Although the standard comment period on tolerance proposals issued by EPA is 60 days, EPA finds for good cause that it would be in the public interest to have a comment period of only 30 days on this proposal. This proposed tolerance will allow registration under the Federal Insecticide, Fungicide, and Rodenticide Act of phosphine gas as an insecticide. Currently, phosphine gas is used as a insecticide but only when applied by means of the registered pesticides magnesium phosphide or aluminum phosphide. Application of phosphine gas directly will serve as a replacement for the use of methyl bromide as a fumigant. Methyl bromide use is generally being phased out in the United States and worldwide under the Montreal Protocol due to concerns with ozone depleting compounds. Finding replacements for methyl bromide's insecticidal uses is a top priority for EPA. Additionally, use of phosphine gas directly may reduce risks to workers.

VI. Public Docket and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300865] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300865]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

VII. 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 subject to approval under 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 mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), or require prior consultation 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).

Pursuant to the requirements of the Regulatory Flexibility Act (Public Law 96–354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A

certification statement explaining the factual basis for this determination was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

A. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (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 the Office of Management and Budget (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 proposed 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.

B. 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 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 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 proposed 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.

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

40 CFR Part 186

Environmental protection, Animal feeds, Pesticides and pests.

Dated: May 25, 1999.

James Jones

Director, Registration Division.

Therefore, it is proposed that 40 CFR chapter 1 be amended as follows.

PART 180—[AMENDED]

1. In part 180:

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

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

b. Section 180.225 is revised to read as follows:

§ 180.225 Phosphine; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide phosphine in or on the following raw agricultural commodities resulting from post-harvest fumigation:

Commodity	Parts per million
Almond, nutmeat	0.1
Avocadoes	0.01
Bananas (includes Plantains)	0.01
Barley, grain	0.1
Brazil nuts	0.1
Cabbage, Chinese	0.01
Cacao bean	0.1
Cashews	0.1
Citrus citron	0.01
Cocoa bean	0.1
Coffee, bean, green	0.1
Corn, field, grain	0.1
Corn, pop, grain	0.1
Cotton, seed, undelinted	0.1
Date, dried	0.1
Eggplants	0.01
Endive/Ecarole	0.01
Filberts	0.1
Grapefruit	0.01
Kumquats	0.01
Lemons	0.01
Lettuce	0.01
Limes	0.01
Mangoes	0.01
Legume vegetables (succulent or dried group, excluding soybeans)	0.01
Millet, grain	0.1
Mushrooms	0.01
Oats	0.1
Oranges	0.01
Papayas	0.01
Peanut, nutmeat	0.1
Pecans	0.1
Peppers	0.01
Persimmons	0.01
Pimentos	0.01
Pistachio	0.1
Rice, grain	0.1
Rye, grain	0.1
Safflower, seed	0.1
Salsify tops	0.01
Sesame, seed	0.1
Sorghum, grain	0.1
Soybeans	0.1
Sunflower, seed	0.1
Sweet potatoes	0.01
Tangelos	0.01
Tangerines	0.01
Tomatoes	0.01
Walnuts	0.1
Wheat	0.1

(2) Tolerances are established for residues of the fumigant phosphine in or on all raw agricultural commodities (RAC) resulting from preharvest treatment of pest burrows in agricultural and non-crop land areas as listed in the following table:

Commodity	Parts per million
All RACs resulting from preharvest treatment of pest burrows	0.01

(3) Residues resulting from fumigation of processed foods:

Commodity	Parts per million
Processed foods	0.01

(4) Residues resulting from fumigation of animal feeds:

Commodity	Parts per million
Animal feeds	0.01

(5) To assure safe use of this pesticide, it must be used in compliance with the labeling conforming to that registered by the U.S. Environmental Protection Agency (EPA) under FIFRA. Labeling shall bear a restriction to aerate the finished food for 48 hours before it is offered to the consumer, unless EPA specifically determines that a different time period is appropriate. Where appropriate, a warning shall state that under no condition should any formulation containing aluminum or magnesium phosphide be used so that it will come in contact with any processed food, except processed brewer's rice, malt, and corn grits stored in breweries for use in the manufacture of beer.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

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

§ 180.375 [Removed]

b. Section 180.375 is removed.

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.200 [Removed]

b. Section 185.200 is removed.

§ 185.3800 [Removed]

c. Section 185.3800 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 371.

§ 186.200 [Removed]

b. Section 186.200 is removed.

§ 186.3800 [Removed]

c. Section 186.3800 is removed.

[FR Doc. 99–14069 Filed 6–8–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[CC Docket Nos. 96–45 and 96–262; FCC 99–119]

Federal-State Joint Board on Universal Service; Access Charge Reform

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission has adopted the principles of a federal support mechanism that conforms to the *Second Recommended Decision,* however, the Commission does not believe that an adequate record yet exists to make determinations regarding some of the specific elements of the support methodology. Accordingly, the Commission has issued this document seeking comment on several specific implementation issues. In conjunction with our actions to implement an explicit high-cost support mechanism based on forward-looking costs, we also take action and seek comment on additional issues to permit us to identify implicit support remaining in interstate access charges by January 1, 2000.

DATES: Comments are due on or before July 2, 1999 and reply comments are due on or before July 16, 1999. Written comments by the public on the proposed information collections are due on or before July 2, 1999 and reply comments are due on or before July 16, 1999. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed information collections on or before August 9, 1999.

ADDRESSES: Parties who choose to file by paper must file an original and four copies of each filing. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, 445 Twelfth Street, S.W., TW–A325, Washington, D.C. 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 Twelfth Street, S.W., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725—17th Street, N.W., Washington, DC 20503 or via the Internet to fain__t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Jack Zinman, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418–7400. For additional information concerning the information collections contained in this Further Notice of Proposed Rulemaking contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document released on May 28, 1999. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 Twelfth Street, S.W., Washington, D.C., 20554.

Initial Paperwork Reduction Act Analysis

1. This Further Notice of Proposed Rulemaking contains a proposed information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collections contained in this Further Notice of Proposed Rulemaking, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due at the same time as other comments on this Further Notice of Proposed Rulemaking; OMB notification of action is due August 9, 1999. Comments should address: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other form of information technology.

OMB Approval Number: None.

Title: Notification to High Cost Subscriber Lines and Certification Letter Accounting for Receipt of Federal Support (Proposals).

Form No.: N/A.

Type of Review: New collection.

Respondents: Business or Other for Profit and State, Local or Tribal Government.