

exposure has been identified, no dermal penetration data were required. The requirement for an acute inhalation study has been waived; thus, zinc phosphide has been placed in Toxicity Category I for acute inhalation exposure.

5. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for zinc phosphide at 0.0001 mg/kg/day. This RfD is based on a subchronic oral study in rats with a NOAEL of 0.1 mg/kg/day and an uncertainty factor (UF) of 1,000 based on increased mortality, increase in absolute and relative liver weight and hematological changes at the LOAEL of 1 mg/kg/day. An uncertainty factor of 100 was applied to account for both the interspecies extrapolation and intraspecies variability. An additional UF of 10 was applied to account for the lack of reproductive data, and the lack of chronic toxicity data in a non-rodent species (65 FR 49936).

6. *Animal metabolism.* Since residues are expected to be minimal or nonexistent, the requirement for a metabolism study with zinc phosphide has been waived. If new uses result in detectable residues, then this requirement will be reinstated.

7. *Metabolite toxicity.* Since residues are expected to be minimal or nonexistent, the requirement for a metabolism study with zinc phosphide has been waived.

8. *Carcinogenicity.* The requirement for carcinogenicity studies has been waived for zinc phosphide because chronic exposure is expected to be negligible.

9. *Endocrine disruption.* There are no data available to suggest that zinc phosphide will adversely affect the immune or endocrine systems.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.284) for the residues of phosphine resulting from the use of zinc phosphide, in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm in or on grapes to 0.1 ppm in or on grasses (rangeland). Zinc phosphide uses on grapes, pasture, and rangeland grasses, sugar beets, and sugar cane are classified as food uses. Currently registered uses on alfalfa, barley, wheat, and timothy are classified as non-food uses. The recently submitted petitions seek to amend the method of applications for these crops as follows:

i. Alfalfa; from underground or in burrow builder, or bait box use to above ground broadcast application. The proposed application would limit the timing of application to the period during dormant season (Idaho), or

following removal of all cut alfalfa and prior to new growth obtaining 2 to 3 inches (California and Idaho),

ii. Barley and wheat; from dormant season use (underground or in burrow builders) to above ground broadcast application prior to grain head formation.

iii. Timothy; from dormant season use, with no animal grazing, to use during crop dormancy but permitting livestock grazing after 158 days. These types of applications are classified as food uses; therefore, a tolerance is required. There is no reasonable expectation of secondary residues in meat, milk, poultry, or eggs. Any residues of zinc phosphide ingested by livestock would be metabolized to naturally occurring phosphorous compounds. Risk assessments were conducted by EPA to assess dietary exposures and risks from zinc phosphide applied as non-food use as follows: Acute and chronic 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 1-day or single exposure. Currently, it is not known whether the proposed use of zinc phosphide on the subject crops will result in acute or chronic human dietary exposure to zinc phosphide.

However, the petitioner notes the following:

i. Zinc phosphide is not systemic (i.e., it will not move to other portions of the plant such as roots and affect a root crop such as potatoes or sugar beets).

ii. Residues of phosphine are less than the limit of quantification (0.05) in wheat and barley grain, in dry beans, in potatoes, in sugar beet roots, and in timothy hay.

iii. The grain and sugar beet roots will be processed prior to human consumption.

iv. There is no expectation of secondary residues in meat, milk, poultry, and eggs as a result of the registered and proposed uses.

2. *From drinking water.* Zinc phosphide degrades rapidly to phosphine and zinc ions both of which adsorb strongly to soil and are common nutrients in soil. Zinc phosphide and its degradation products appear to have low potential for ground water and surface water contamination. Therefore, dietary exposure is not expected from either ground water or surface water fed drinking water.

3. *From non-dietary exposure.* Zinc phosphide is currently registered for use on residential non-food sites. A detailed residential exposure assessment is contained in the RED for zinc

phosphide (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). The residential exposure assessment evaluated exposure from accidental ingestion of zinc phosphide. No other residential exposure assessment was required. It is stated in the RED that the Agency believes that "accidental ingestion" of zinc phosphide baits should not be included in the FQPA determination for tolerance setting.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Zinc phosphide, aluminum phosphide, and magnesium phosphide all generate phosphine gas. However, the toxicity from phosphine gas is an acute effect and is readily eliminated from the body. Aluminum and magnesium phosphide, unlike zinc phosphide which is a bait, are used in fumigations. Exposure to phosphine gas from both bait and fumigation treatments is highly unlikely. It is unclear 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, where a cumulative risk approach is based on a common mechanism of toxicity, zinc phosphide does not appear to produce a toxic metabolite produced by other substances.

C. Aggregate Exposure

1. *Acute and chronic risk.* There are currently no drinking water, residential, or dietary components to acute and chronic aggregate exposure to zinc phosphide residues. Thus, acute and chronic aggregate exposure assessments were not required in the RED (Zinc Phosphide, EPA 738-R-98-006, July 1998).

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. No short- or intermediate-term dermal, oral or inhalation toxicological endpoints were identified for zinc phosphide. Thus, no short- or intermediate-term risk assessments were required in the RED (Zinc Phosphide, EPA 738-R-98-006, July 1998).

3. *Aggregate cancer risk for U.S. population.* Although zinc phosphide is registered for use on food crops, no chronic toxicity or carcinogenicity