

studies were required because chronic exposure to zinc phosphide or its byproducts were considered to be negligible. Thus, data are not available to classify zinc phosphide in terms of carcinogenicity and a cancer risk assessment was not performed.

D. Determination of Safety

1. *U.S. population.* The RED set the RfD at 0.0001. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health.

2. *Infants and children.* The available data base for zinc phosphide does not indicate a potential for an increased sensitivity to infants or children; however it does not include a two-generation reproductive toxicity study in rats or a developmental toxicity study for a non-rodent species. The available data provided no indication of increased sensitivity of fetal rats to *in utero* exposure to zinc phosphide. The prenatal exposure developmental toxicity study in rats demonstrated no developmental effects at the highest dose tested (4.0 mg/kg/day) which was maternally toxic. There was no assessment of *in utero* exposure to non-rodents (rabbits), nor was there an assessment of early postnatal exposure. The EPA did not require these studies because exposure from food sources is expected to be minimal to non-existent. The additional uncertainty factor (referred to in Section A.5.) will also accommodate the inability to assess the potential for increased sensitivity of infants and children, because of the lack of sufficient animal data on *in utero* and early postnatal exposure to zinc phosphide (a prenatal developmental toxicity study in rabbits and a two-generation reproductive toxicity study in rats). Although residue studies show there were quantifiable residues in sugarcane, sugar beets, and grasses, these commodities are not direct human foods and no dietary consumption is expected. EPA has determined that there is no likelihood of residues of zinc phosphide occurring in any processed commodities. Also, there is no likelihood of residues of zinc phosphide or phosphine being found through transfer of residues on grasses to meat and milk.

Based upon the likelihood that residues of zinc phosphide will not occur in processed commodities, milk and meat, there is a reasonable certainty that no harm will result from aggregate exposure to zinc phosphide residues.

E. Other Considerations

1. *Metabolism in plants and animals.* The nature of the residue in plants is adequately understood. The residue of concern is zinc phosphide measured as phosphine. There is no expectation of secondary residues in meat, milk, poultry, and eggs as a result of the registered uses. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorous compounds.

2. *Analytical enforcement methodology.* Adequate enforcement methodology (colorimetric and GLC/FPD) is available (Pesticide Analytical Method II under aluminum phosphide) to enforce the tolerance expression. Residues were less than the limit of quantification in all raw agricultural commodities except for sugar beet tops (0.05 ppm for alfalfa, barley, grain and hay, dry beans, potatoes, sugar beet roots, timothy and wheat; 0.1 for barley straw),

i. Barley grown in the state of Idaho was treated with two applications of zinc phosphide at approximately 0.12 lb a.i./A per application, 23 to 28 days apart, and were harvested 50 or 60 days after the last application. Barley was also harvested 50 days following two applications at 0.96 lb a.i./A (8X the proposed application rate). Residues were less than the limit of quantification for barley grain and hay (0.05 ppm) and straw (0.1). Because no residues were found in samples treated at the 8X rate, no processing study is needed.

ii. Dry beans grown in the state of Idaho were treated with one application of zinc phosphide at approximately 0.12 lb a.i./A, and were harvested 31 days after the application and allowed to dry in the field. Seven days after harvesting the beans were thrashed and samples taken. Residues were less than the limit of quantification (0.05 ppm) on this commodity.

iii. Potatoes grown in the state of Idaho were treated with one application of zinc phosphide at approximately 0.2 lb a.i./A, and were harvested 28 to 31 days later. Potatoes were also harvested 28 to 31 days later following an application at 1.0 lb a.i./A (5x the proposed application rate). Residues were less than the limit of quantification (0.05 ppm) on this commodity. Because no residues were found in samples treated at the 5X rate, no processing study is needed.

iv. Sugar beets grown in the state of Idaho were harvested 27 to 29 days following two treatments of zinc phosphide at approximately 0.2 lb a.i./A. Sugar beets were also harvested 27 to

29 days following two treatments of zinc phosphide at approximately 4 lb a.i./A (20X the proposed application rate). Residues were less than the limit of quantification (0.05 ppm) on sugar beet roots. Sugar beet tops contained some residue and a tolerance of 0.2 ppm is being proposed for sugar beet tops. Because no residues were found in roots treated at the exaggerated rate, there is no need for data from processed roots. (OPPTS Harmonized Guideline 860.1520(f)(3)(iii)).

v. Timothy hay grown in the state of Washington was harvested 117 days following two treatments of zinc phosphide. The first treatment was at approximately 0.2 lb a.i./A and the second treatment was at approximately 0.4 lb a.i./A (due to applicator error). The hay was allowed to dry in the field after harvest. Residues were less than the limit of quantification (0.05 ppm) on timothy hay and timothy forage at harvest.

vi. Wheat grown in the state of Idaho was treated with two applications of zinc phosphide at approximately 0.12 lb a.i./A per application, 22 to 28 days apart, and were harvested 56 to 60 days after the last application. Wheat was also harvested 56 days following two applications at 0.96 lb a.i./A (8X the proposed application rate). Residues were less than the limit of quantification (0.05 ppm) for wheat grain, hay and straw. Because no residues were found in samples treated at the 8X rate, no processing study is needed.

vii. Fresh alfalfa grown in the state of California was harvested 32 days following one treatment of zinc phosphide at approximately 0.2 lb a.i./A. Fresh alfalfa was also harvested 32 days following one treatment of zinc phosphide at approximate 0.4 lbs a.i./A (2X the proposed application rate). Residues were less than the limit of quantification (0.05 ppm) on fresh alfalfa.

viii. Alfalfa hay and fresh alfalfa grown in the state of Nebraska were harvested 21 days following one treatment of zinc phosphide at approximately 0.2 lbs a.i./A. Residues were less than the limit of quantification (0.05 ppm) on alfalfa hay and fresh alfalfa.

ix. Alfalfa hay and alfalfa forage grown in the state of Idaho were harvested three times: 28–32 days, 78–83 days, and 121–129 days following the second of two treatments of zinc phosphide at approximately 0.2 lbs a.i./A. Residues were less than the limit of quantification (0.05 ppm) on alfalfa hay and alfalfa forage. (Petition for residue tolerance for alfalfa use in Idaho soon to be submitted.)