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## II. Background and Statutory Findings

In the **Federal Register** of July 9, 2003 (68 FR 40939) (FRL-7314-1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP 2E6419, PP 1E6306, PP 1E6270, PP 1E6337, PP 9E5082, PP 0E6199, and PP 1E6292) by IR-4, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by the registrant, HACO, Inc., P.O. Box 7190, Madison, WI 53707. The Agency received a number of comments on the notice of filing published on July 9, 2003 (68 FR 40939). All comments were in favor of establishing the food tolerances proposed in the notice.

The petitions requested that 40 CFR 180.284 be amended by establishing tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide, in or on alfalfa, forage and alfalfa, hay at 0.1 parts per million (ppm); barley, grain and barley, hay at 0.05 ppm, and barley, straw at 0.2 ppm; bean, dry at 0.05 ppm; beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.2 ppm; potato at 0.05 ppm; timothy, forage and timothy, hay at 0.05 ppm; and wheat, grain, wheat, hay, and wheat, straw at 0.05 ppm.

EPA is also deleting several established tolerances in § 180.284(b) that are no longer needed, as a result of this action. The tolerance deletions are time-limited tolerances established under section 18 emergency exemptions that are superceded by the establishment of general tolerances for zinc phosphide under § 180.284(a).

The following deletions to § 180.284(b) are replaced in § 180.284(a):

1. Delete the time-limited tolerances for barley, grain at 0.01 ppm, barley, hay at 0.20 ppm, and barley straw at 0.02 ppm. Tolerances for barley, grain at 0.05 ppm, barley, hay at 0.2 ppm, and barley, straw at 0.2 ppm are established by this action under § 180.284(a).

2. Delete the time-limited tolerances for beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.1 ppm. Tolerances for sugar, beet, roots are established at 0.05 ppm and sugar, beet, tops at 0.2 ppm under § 180.284(a).

3. Delete the time-limited tolerance for potato at 0.05 ppm. A tolerance for potato is established at 0.05 ppm under § 180.284(a).

4. Delete the time-limited tolerances for timothy, forage and timothy, hay at 0.1 ppm. Tolerances for timothy, forage and timothy, hay are established at 0.5 ppm under § 180.284(a).

5. Delete the time-limited tolerances for wheat, grain, wheat, hay and wheat, straw at 0.01 ppm. Tolerances for wheat, grain, wheat, hay, wheat, straw, and wheat, forage are established at 0.05 ppm under § 180.284(a).

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) of the FFDCA 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) of the FFDCA 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 of the FFDCA 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).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide on alfalfa, forage and alfalfa, hay at 0.2 ppm; barley, grain at 0.05; barley, hay at 0.2 ppm; barley, straw at 0.2 ppm; bean, dry, seed at 0.05 ppm; beet, sugar, roots at 0.05 ppm; beet, sugar, tops at 0.2 ppm; potato at 0.05 ppm; timothy, forage and timothy, hay at 0.5 ppm; and wheat, forage, wheat, grain, wheat hay, and wheat, straw at 0.05 ppm. EPA's assessment of 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 in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 0.1 milligram/kilogram/day (mg/kg/day) LOAEL = 1.0 mg/kg/day based on increased mortality and kidney hydronephrosis in male rats
870.3150	90-Day oral toxicity in nonrodents	Waived
870.3200	21/28-Day dermal toxicity	Waived