

alfalfa, forage and hay at 3.0 parts per million (ppm). The American Cyanamid Co. requested this regulation that establishes the maximum permissible level for residues of the herbicide in or on alfalfa.

EFFECTIVE DATE: This regulation becomes effective January 20, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 1F4013/R2101], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 36277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager (PM) 25, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 245, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-6800.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of March 11, 1992 (57 FR 8658), which announced that the American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, had submitted pesticide petition (PP) 1F4013 to EPA proposing that 40 CFR part 180 be amended by establishing a tolerance under section 408 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a, for the combined residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazo[1-2-y1]-5-ethyl-3-pyridine-carboxylic acid, as its ammonium salt and the metabolite, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, in or on alfalfa, forage and hay at 3.0 ppm.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing. The data submitted in the

petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of the tolerance.

1. Several acute toxicology studies placing technical-grade imazethapyr in Toxicity Category III.

2. An 18-month carcinogenicity study with mice fed diets containing 0, 1,000, 5,000, or 10,000 ppm with no carcinogenic effects observed under the conditions of the study at levels up to and including 10,000 ppm (1,500 mg/kg/day) (highest dose tested [HDT]), a systemic no-observed-effect level (NOEL) of 5,000 ppm (750 mg/kg/day), and a systemic LOEL of 10,000 ppm (1,500 mg/kg/day), based on decreased body weight gain in both sexes.

3. A 2-year chronic toxicity/carcinogenicity study in rats fed diets containing 0, 1,000, 5,000, or 10,000 ppm with no carcinogenic effects observed under the conditions of the study at levels up to and including 10,000 ppm (500 mg/kg/day [HDT]) and a systemic NOEL of 10,000 ppm (500 mg/kg/day [HDT]).

4. A 1-year feeding study in dogs fed diets containing 0, 1,000, 5,000, or 10,000 ppm with a NOEL of 1,000 ppm (25 mg/kg/day) and a LOEL of 5,000 ppm (125 mg/kg/day), based on decreased packed cell volume, hemoglobin, and erythrocytes in females.

5. A developmental toxicity study in rats fed dosage levels of 0, 125, 375, and 1,125 mg/kg/day, with a maternal toxicity NOEL of 375 mg/kg/day and a LOEL of 1,125 mg/kg/day (clinical signs of toxicity) and a developmental toxicity NOEL of greater than 1,125 mg/kg/day (HDT).

6. A developmental toxicity study in rabbits fed dosage levels of 0, 100, 300, and 1,000 mg/kg/day with a maternal toxicity NOEL of 300 mg/kg/day and a LOEL of 1,000 mg/kg/day (death) and a developmental toxicity NOEL of greater than 1,000 mg/kg/day (HDT).

7. A two-generation reproduction study in rats fed dietary levels of 0, 1,000, 5,000, or 10,000 ppm with a NOEL for systemic and reproductive effects of 10,000 ppm (500 mg/kg/day [HDT]).

8. A mutagenic test with *Salmonella typhimurium* (negative); an *in vitro* chromosomal aberration test in Chinese hamster ovary cells (positive without metabolic activation but at dose levels that were toxic to the cells and negative with metabolic activation); an *in vivo* chromosomal aberration test in rat bone marrow cells (negative); an unscheduled DNA synthesis study in rat hepatocytes (negative).

Based on the NOEL of 25 mg/kg bwt/day in the 1-year dog feeding study, and

using a hundredfold uncertainty factor, the acceptable daily intake (ADI) for imazethapyr is calculated to be 0.25 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) is 0.000100 mg/kg bwt/day for existing tolerances for the overall U.S. population. The current action will not increase the TMRC since no finite residues of imazethapyr are expected from meat and milk derived from animals consuming treated alfalfa. This tolerance and previously established tolerances utilize a total of 0.05 percent of the ADI for the overall U.S. population. For U.S. subgroup populations, nonnursing infants and children aged 1 to 6, the previously established tolerances utilize a total of 0.16 percent of the ADI.

A maximum Tolerated Dose (MTD) or Limit Dose (20,000 ppm) was not evaluated in the chronic toxicity/carcinogenicity study with rats. However, the highest dose tested was within 50 percent of the dose level necessary for an adequate carcinogenicity study in rats (20,000 ppm or 1,000 mg/kg/day); this chemical is structurally similar to two other pesticides (Scepter and Assert) that were not carcinogenic in rats or mice, and the genetic toxicity studies were negative for imazethapyr. For these reasons, no further carcinogenicity testing is required.

Although an analytical method is available for imazethapyr on alfalfa (confirmed by EPA), the Agency has requested that the petitioner rewrite the primary enforcement procedure to include an alternate CE buffer system as the confirmatory step and the petitioner has agreed. This pesticide is useful for the purposes for which the tolerances are sought. The nature of the residues is adequately understood for the purposes of establishing these tolerances. Adequate analytical methodology, capillary electrophoresis, is available for enforcement purposes. Because of the long lead time from establishing this tolerance to publication, enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, 22202.

There are currently no actions pending against the registration of this chemical. There is no expectation of residue occurring in meat, milk, poultry,