

SUPPLEMENTARY INFORMATION: EPA issued notices, published in the **Federal Register** of March 18, 1987 (52 FR 8527), November 25, 1987 (52 FR 45238), November 1, 1989 (54 FR 46119), December 13, 1991 (56 FR 65080), and June 10, 1992 (57 FR 24644), which announced that Zeneca, Inc. (formerly ICI Americas, Inc.), 1800 Concord Pike, Wilmington, DE 19897, had submitted pesticide petitions 7F3488, 7F3560, 1F3992, 2F4109, 2F4114, 7H3560, and 7H5543 and that Coopers Animal Health, Inc., P.O. Box 419167, Kansas City, MO 64141-0167, had submitted PP 9F3770 to EPA requesting that the Administrator, pursuant to sections 408(d) and 409(b) of the FFDCFA, 21 U.S.C. 346a(d) and 348(e), establish tolerances and food/feed additive regulations for residues of the pyrethroid lambda-cyhalothrin in or on the raw agricultural commodities (RACs) soybeans at 0.01 part per million (ppm); poultry meat, fat, and meat byproducts (mbyp) (PP 7F3488); wheat grain at 0.01 ppm, sunflower seeds at 0.03 ppm; sweet corn at 0.01 ppm; poultry meat and mbyp at 0.01 ppm (PP 7F3560); sorghum grain at 0.2 ppm; milk at 0.1 ppm; meat of cattle, goats, horses, and sheep at 0.04 ppm, fat at 2.0 ppm, liver at 0.1 ppm and kidney at 0.1 ppm (PP 1F3992); corn grain (field, pop, and seed) at 0.05 ppm, corn fodder at 3.0 ppm, corn silage at 1.0 ppm and corn grain dust at 0.1 ppm (PP 2F4109); peanut hulls and peanut nutmeats at 0.05 ppm; peanut hulls and peanut nutmeats at 0.05 (PP 2F4114); cattle meat and mbyp at 0.1 ppm; cattle fat at 1.0 ppm from direct dermal treatment of cattle (PP 9F3770); sunflower hulls at 0.7 ppm; and sunflower oil at 0.05 ppm (PP 7H5543).

The tolerance expression for lambda-cyhalothrin has been revised and now includes combined residues of parent compound and its epimer. (See the **Federal Register** of March 27, 1995 (60 FR 15683).) The correct commodity expression for peanut nut meat is peanuts. Corn silage is covered under the commodities for corn fodder and forage. Based upon submitted residue data and because residues in corn grain were nondetected, EPA concluded that a tolerance in/on corn grain dust is not required. Since residues concentrate when corn grain is processed into flour, EPA concluded that a food additive tolerance of 0.15 ppm for corn grain flour is required.

At the request of Zeneca Ag products, EPA issued in the **Federal Register** of March 5, 1992 (57 FR 10353), an amendment to PP 7F3560 to increase the proposed tolerance level for the insecticide in or on wheat grain to 0.03

and proposed establishing tolerances for residues of the insecticide lambda cyhalothrin in or on the RACs wheat forage at 2.0 ppm and wheat straw at 2.0 ppm, and the document amended FAP 7H5543 by adding the processed commodity wheat bran at 0.2 ppm and wheat shorts, germ at 0.05 ppm.

After evaluation of the wheat processing study, EPA concluded that the residues in midlings, shorts, germs resulting from the product use rate are no greater than the proposed tolerance on whole wheat grain, and thus no food/feed additive tolerances are required for the processed commodities wheat, shorts and germs.

In June 29, 1994, Zeneca, Inc., requested that certain petitions be amended by increasing the proposed tolerances for the RACs corn, forage (PP 2F4109) to 6.0 ppm; corn, sweet (kernel + kernel with husk removed (k + kwhr)) (PP 7F3560) to 0.05 ppm; sorghum, grain (PP 1F3992) to 0.2 ppm; establish tolerance for sorghum, grain dust (PP 1F3992) at 1.5 ppm; corn grain flour (FAP 7H5543) at 0.15 ppm; increase tolerance for sunflower, seeds (PP 7F3560) to 0.2 ppm; establish proposed tolerance in or on wheat hay and grain dust (PP 7F3560) at 2.0 ppm; increase the tolerance for milk, fat (reflecting 0.2 ppm in whole milk) to 5.0 ppm; meat mbyp of cattle, goats, hogs, horses, and sheep to 0.2 ppm; fat of cattle, goats, hogs, horses, and sheep to 3.0 ppm; meat, fat, mbyp and eggs of poultry to 0.01 ppm, and processed food/feed items sunflower, hulls (FAP 7H5543) to 0.5 ppm and sunflower, oil (7H5543) to 0.3 ppm.

In a letter dated February 10, 1995, Zeneca Ag Products requested that a tolerance be established in or on sunflower, forage (PP 7F3560) at 0.2 ppm.

The scientific data submitted in the petitions and other relevant material have been evaluated. The toxicological data considered in support of the tolerances have been discussed in the **Federal Register** published March 29, 1995 (58 FR 15683).

The acceptable Reference Dose (RfD) based on a NOEL of 0.1 mg/kg/body weight/day from the chronic dog study and a safety factor of 100 is 0.001 mg/kg/body weight/day. A chronic dietary exposure/risk assessment has been performed for lambda-cyhalothrin using the above RfD. Available information on anticipated residues and percent crop treated was incorporated into the analysis to estimate the Anticipated Residue Contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues. The ARC from

established tolerances and pending action are estimated to be 0.000192 mg/kg/bwt/day and utilize 19.24 per cent of the RfD for the U.S. population. The ARC for children, aged 1 to 6 years old, and nonnursing infants (subgroups most highly exposed) utilizes 32 and 58 percent of the RfD, respectively.

Generally speaking, the Agency has no cause for concern if anticipated residues contribution for all published and proposed tolerances is less than the RfD.

The metabolism of the chemical in plants and livestock is adequately understood for this use. Any secondary residues occurring in meat and meat by-products will be covered by the existing tolerances. There is no reasonable expectation of finite residues in poultry commodities; therefore, no tolerances are necessary at this time. An adequate analytical method (gas liquid chromatography with an electron capture detector) is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Divisions (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington VA 22202, (703) 305-5232.

The Agency issued a conditional registration for lambda-cyhalothrin for use on cotton with an expiration date of August 30, 1990 (see the **Federal Register** of May 24, 1988 (53 FR 18558)). The conditional registration was subsequently amended and extended to November 15, 1996 (see the **Federal Register** of February 22, 1995 (60 FR 9783)). The registrations were amended and extended to allow time for submission and evaluation of additional environmental effects data. To evaluate the effects of the synthetic pyrethroids on fish and aquatic organisms and its fate in the environment, additional data were required to be collected and submitted during the period of conditional registration. Such requirements included a sediment bioavailability and toxicity study and a small-plot runoff study that must be submitted to the Agency by July 1, 1996. Because of the conditional status of the registration, tolerances have been established for lambda-cyhalothrin on a