

assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 20, 2002.

**Debra Edwards,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

### BASF Corporation

*PP 1E6268*

EPA has received a pesticide petition (PP 1E6268) from BASF Corporation, P.O. Box 400, Princeton, NJ 08543-0400 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an import tolerance for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine-carboxylic acid) as its free acid or its ammonium salt (calculated as the acid), and its metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-

pyridinecarboxylic acid in or on the raw agricultural commodity canola seed at 0.1 part per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of imazethapyr in canola is adequately understood. Based on studies conducted on soybean, edible and forage legumes, corn and canola, parent imazethapyr and common metabolite CL 288511 are the only residues of concern for tolerance setting purposes.

2. *Analytical method.* Practical analytical methods for detecting and measuring imazethapyr residues of concern in canola are submitted to EPA with this petition. The analytical methods for canola seed are based on gas chromatography and capillary electrophoresis with limits of quantitation (LOQ) of 0.05 ppm. Measurement of imazethapyr residues in canola oil and meal are accomplished by gas chromatography with LOQ of 0.05 ppm. These validated methods are appropriate for the enforcement purposes of this petition.

3. *Magnitude of residues.* A total of 13 field trials were conducted with imazethapyr and its metabolite on canola in 1992, 1993, 1994, and 1999 at several different use rates and timing intervals to represent the use patterns, conditions and areas of use of this product in Canada. Apparent residues of imazethapyr (CL 263499) and metabolite CL 288511 in all canola seed samples were below the LOQ of 0.05 ppm regardless of rate or days after treatment sampled.

### B. Toxicological Profile

A complete, valid and reliable database of mammalian and genetic toxicology studies supports the proposed tolerance for imazethapyr on canola. This database was previously reviewed by EPA in support of the tolerance petitions and registration of imazethapyr on soybeans, legume vegetables, corn, alfalfa, and peanuts.

1. *Acute toxicity.* Imazethapyr technical is considered to be nontoxic (Toxicity Category IV) to the rat by the oral route of exposure. In an acute oral toxicity study in rats, the LD<sub>50</sub> value of imazethapyr technical was greater than 5,000 milligrams/kilogram body weight

(mg/kg bwt) for males and females. The results from an acute dermal toxicity study in rabbits indicate that imazethapyr is slightly toxic (Toxicity Category III) to rabbits by the dermal route of exposure. The dermal LD<sub>50</sub> value of imazethapyr technical was greater than 2,000 mg/kg bwt for both male and female rabbits. Imazethapyr technical is considered to be non-toxic (Toxicity Category IV) to the rat by the respiratory route of exposure. The 4-hour LC<sub>50</sub> value was greater than 3.27 milligram/liter (mg/L) (analytical) and greater than 4.21 mg/L (gravimetric) for both males and females.

Imazethapyr technical was shown to be non-irritating to rabbit skin (Toxicity Category IV) and mildly irritating to the rabbit eye (Toxicity Category III). Based on the results of a dermal sensitization study (Buehler), imazethapyr technical is not considered a sensitizer in guinea pigs.

2. *Genotoxicity.* Imazethapyr technical was tested in a battery of four *in vitro* and one *in vivo* genotoxicity assays measuring several different endpoints of potential genotoxicity. Collective results from these studies indicate that imazethapyr does not pose a mutagenic or genotoxic risk.

3. *Reproductive and developmental toxicity.* The developmental toxicity study in Sprague Dawley rats conducted with imazethapyr technical showed no evidence of developmental toxicity or teratogenic effects in fetuses. Thus, imazethapyr is neither a developmental toxicant nor a teratogen in the rat. The no observable adverse effect level (NOAEL) for maternal toxicity was 375 mg/kg bwt/day, based on clinical signs of toxicity in the dams (e.g., excessive salivation) at 1,125 mg/kg bwt/day. Imazethapyr technical did not exhibit developmental toxicity or teratogenic effects at maternal dosages up to and including 1,125 mg/kg bwt/day, the highest dose tested.

Results from a developmental toxicity study in New Zealand White rabbits with imazethapyr technical also indicated no evidence of developmental toxicity or teratogenicity. Thus, imazethapyr technical is neither a developmental toxicant nor a teratogen in the rabbit. The NOAEL for maternal toxicity was 300 mg/kg bwt/day, based on decreased food consumption and body weight gain, abortion, gastric ulceration and death at 1,000 mg/kg bwt/day, the next highest dose tested. The NOAEL for developmental toxicity and teratogenic effects was determined to be > 1,000 mg/kg bwt/day based on no developmental toxicity or fetal malformations associated with the administration of all doses.