

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number 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: March 18, 2003.

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 1F6278

EPA has received a pesticide petition (1F6278) from BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.380 by making permanent the tolerances for residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodities canola at 1.0 parts per million (ppm); eggs, milk, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. In addition, BASF had proposed extending the existing tolerance on succulent beans at 2.0 ppm for an additional 2 years. 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* BASF Corporation notes that metabolism in plants is understood, the residues of concern are vinclozolin, 3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione) and metabolites containing the 3,5-dichloroaniline moiety.

2. *Analytical method.* The proposed analytical method involves extraction, hydrolysis, distillation, partition, and derivatization followed by detection of residues by gas chromatograph/electron capture detector (gc/ecd). An enforcement method has been published in FDA's Pesticide Analytical Methods, Volume II pg. 876-887.

3. *Magnitude of residues.* Data previously submitted in support of the tolerances in canola, succulent beans and meat, milk, poultry, and eggs have been reviewed by the Agency and been found adequate to support the tolerances requested.

B. Toxicological Profile

1. *Acute toxicity.* On July 18, 2000, EPA published in the **Federal Register** (65 FR 44453) (FRL-6594-8), time

limited tolerances for vinclozolin in canola, succulent beans and meat, milk, poultry and eggs. The toxicological profile as reported in that **Federal Register** is repeated in this Notice. A battery of acute toxicity studies placed technical vinclozolin in toxicity category IV for acute oral toxicity lethal dose (LD)₅₀ of > 10,000 milligrams/kilograms (mg/kg), and acute inhalation toxicity (LC₅₀ of 29.1 mg/liter (L)); and toxicity category III for acute dermal toxicity (LD₅₀ of > 5,000 mg/kg). Technical vinclozolin caused minimal eye and dermal irritation and the technical material is positive for skin sensitization.

2. *Genotoxicity.* Genotoxicity testing showed no evidence of mutagenic activity. (For details see the July 18, 2000 **Federal Register** (65 FR 44453)).

3. *Reproductive and developmental toxicity—i.* In four developmental toxicity studies, vinclozolin was given orally from gestational day (gd) 6 through 19 as follows: Study 4—dose levels of 0, 15, 50, or 150 mg/kg/day; study 5—dose levels of 0, 50, 100, 200 mg/kg/day; study 6—dose levels of 0, 200, 400 mg/kg/day; and study 8—dose levels of 0, 600, and 1,000 mg/kg/day. At the gd 20, the fetuses were evaluated.

The developmental toxicity no observed adverse effect level (NOAEL) was set at 15 mg/kg/day and the developmental lowest observed adverse effect level (LOAEL) was 50 mg/kg/day. The maternal toxicity LOAEL was < 600 mg/kg/day.

ii. A developmental study in rats via dermal exposure for 6 hours/day on intact skin with dosages of 0, 60, 180, and 360 mg/kg/day highest dose tested (HDT) had a developmental NOAEL of 60 mg/kg/day and a maternal NOAEL of 60 mg/kg/day.

iii. A developmental study in rabbits via oral gavage resulted in dosages of 0, 20, 80, and 300 mg/kg/day HDT with a developmental NOAEL of 300 mg/kg/day and a maternal NOAEL of 300 mg/kg/day.

iv. A second developmental study in rabbits via oral gavage resulted in dosages of 0, 50, 200, and 800 mg/kg/day HDT with a development toxicity NOAEL of 200 mg/kg/day and a maternal toxicity NOAEL of 50 mg/kg/day.

A two-generation rat reproduction study (consisting of two studies: Study A—dose levels of 0, 2.0 and 4.1 mg/kg/day; study B—dose levels of 0, 4.9, 29, 100, and 307 mg/kg/day) with a reproductive NOAEL of 4.9 mg/kg/day and pup effects at 29 mg/kg/day; and with a parental NOAEL of 4.9 mg/kg/day. (For a detailed discussion of the