

under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 these petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: August 4, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by Syngenta Crop Protection, 410 Swing Road, Greensboro, NC 276419, and represents the view of the Syngenta Crop Protection. 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.

Syngenta Crop Protection

PP 7E4916, 8E5029, 8E5030, 9E6055, and 2E6374

EPA has received pesticide petitions (7E4916, 8E5029, 8E5030, 9E6055, and 2E6374) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for combined residues of s-metolachlor and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholine, each expressed as the parent compound s-metolachlor in or on the following raw agricultural commodities:

1. PP 4E4420 proposes the establishment of tolerances for pepper, bell and pepper, nonbell at 0.50 part per million (ppm).

2. PP 7E4916 proposes the establishment of a tolerance for carrot, root and horseradish at 0.1 ppm.

3. PP 8E5029 proposes the establishment of a tolerance for rhubarb at 0.1 ppm.

4. PP 8E5030 proposes the establishment of a tolerance for swiss chard at 0.1 ppm.

5. PP 9E6055 proposes the establishment of a tolerance for asparagus at 0.1 ppm.

6. PP 2E6374 proposes the establishment of a tolerance for onion, green at 0.2 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism.* [The qualitative nature of S-metolachlor residues in plants is adequately understood based upon available EPA approved corn, potato, and soybean metabolism studies. The metabolism of S-metolachlor involves conjugation with glutathione, breakage of this bond to form the mercaptan, conjugation of the mercaptan with glucuronic acid, hydrolysis of the methyl ether, and conjugation of the resultant alcohol with a neutral sugar. EPA has determined that residues of concern in plants include parent and metabolites, determined as the derivatives CGA-37913 and CGA-49751.

2. *Analytical method.* The Pesticide Analytical Manual (PAM) Vol. II, Pesticide Regulation Section 180.368 lists a gas chromatography/nitrogen phosphorous detector (GC/NPD) method (Method 1) for determining residues in or on plants and a gas chromatography/mass spectrometry method (GC/MSD) method for determining residues in livestock commodities. These methods determine residues of S-metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis. The limit of quantitation (LOQ) for the method is 0.03 ppm for CGA-37913 and 0.05 ppm for CGA-49751.

3. *Magnitude of residues.*—i. *Asparagus.* Magnitude of residue trials were conducted under the direction of IR-4 in EPA regions 2, 5, and 11 in New Jersey, Michigan, and Washington. Applications were made pre-emergence to dormant asparagus in the spring and samples were collected for analysis 16 days after application. There were no

detectable residues found in asparagus at harvest.

ii. *Carrot.* Field trials were conducted in Florida, Michigan, and New York to support the proposed tolerance for S-metolachlor in or on carrots grow on high organic matter (muck) soils.

iii. *Green onion.* Magnitude of residue trials were completed by IR-4 in New York, California, and Michigan (EPA region 1, 10, and 5, respectively). One post-emergence broadcast application was made when the onions had 2 true leaves. Marketable green onion plants were collected 43 to 45 days following the application. Maximum residues found were 0.168 ppm.

iv. *Rhubarb and Swiss chard.* As the EPA review announced in the October 2002 TRED has confirmed that a 0.1 ppm tolerance is appropriate for S-metolachlor in celery and as celery is the representative crop for the Leafy Petiole Subgroup, IR-4 has proposed tolerances be established for rhubarb and Swiss chard.

B. Toxicological Profile

1. *Acute toxicity.* [The data base for acute toxicity for S-metolachlor is complete. S-metolachlor is moderately acutely toxic (Toxicity Category III) by the oral and dermal route and relatively non-toxic (Toxicity category IV) by the inhalation route. It causes slight eye irritation (Toxicity Category III) and is non-irritating dermally (Toxicity Category IV); the active ingredient was found to be positive in a dermal sensitization test but this effect is mitigated in end-use product formulations.]

2. *Genotoxicity.* The data base for S-metolachlor has been deemed to be adequate by EPA. Gene mutation studies (Guideline 870.5100), micronucleus (Guideline 870.5395), and unscheduled DNA synthesis (Guideline 870.5550) studies have recently been reviewed and approved by EPA. There is no evidence of a mutagenic or cytogenetic effect *in vivo* or *in vitro* with S-metolachlor.

3. *Reproductive and developmental toxicity.* The data base for developmental and reproductive toxicity for S-metolachlor are considered complete according to EPA reviews. The prenatal developmental studies in the rat and rabbit with S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. No significant developmental toxicity was observed in most studies even at the highest doses tested. In a two-generation reproduction study, there was no evidence of parental or reproductive toxicity at the highest dose tested (80 mg/kg/day). The results indicate that S-metolachlor is not