

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.

Interregional Research Project Number 4 (IR-4)

PP 8E5012

EPA has received a pesticide petition (8E5012) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR 180.532 by extending the time-limited tolerance to December 31, 2004, for residues of cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine in or on the raw agricultural commodities onion, dry bulb at 0.60 part per million (ppm); onion, green at 4.0 ppm; and strawberry at 5.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; 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. Syngenta Crop Protection, Inc., Greensboro, NC 27409 is the manufacturer of the chemical pesticide, cyprodinil. Syngenta Crop Protection, Inc., prepared and submitted the following summary of information, data, and arguments in support of the pesticide petitions. This summary does not necessarily reflect the findings of EPA.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of cyprodinil is adequately understood for the purpose of the proposed tolerances.

2. *Analytical method.* Syngenta has developed and validated analytical methodology for enforcement purposes. This method (Syngenta Crop Protection, Inc., Method AG-631B) has passed the Agency petition method validation for several commodities and is currently the enforcement method for cyprodinil. An extensive data base of method validation data using this method on various crop commodities is available.

3. *Magnitude of residues.* Complete residue data to support the requested tolerances for strawberry, onion, dry bulb, and onion, green have been submitted. The requested tolerances are adequately supported.

B. Toxicological Profile

An assessment of toxic effects caused by cyprodinil is discussed in Unit III.A. and Unit III.B. of the **Federal Register** dated June 22, 2001 (66 FR 33478) (FRL-6778-1).

1. *Animal metabolism.* The metabolism of cyprodinil in rats is adequately understood.

2. *Metabolite toxicology.* The residues of concern for tolerance setting purposes is the parent compound. Based on structural similarities to genotoxic nucleotide analogs, there was concern that the pyrimidine metabolites (CGA-249287, NOA-422054) may be more toxic than the parent compound. However, EPA's review indicates similar results in an acute oral and mutagenicity studies with both the parent compound and the CGA-249287 metabolite. EPA concluded that the toxicity of the CGA-249287 and NOA-422054 metabolites is no greater than that of the parent, conditional on submission and review of confirmatory data of an acute oral toxicity study and bacterial reverse mutation assay for the NOA-422054 metabolite. Although the metabolites CGA-232449 and CGA-263208 were determined to be of potential toxicological concern, they are not expected to be more toxic than cyprodinil *per se*.

3. *Endocrine disruption.* Cyprodinil does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that cyprodinil might have any effects on endocrine function related to development and reproduction. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* A Tier III acute and chronic dietary exposure evaluation was made using the Dietary Exposure Evaluation Model (DEEMTM), version 7.76 from Exponent. Empirically derived processing studies for apple juice (0.39X), apple pomace (5.22X), grape juice (0.29X), dried prunes (2.05X), and lychee fruit peeling factor (0.0092X) were used in these assessments. The apple juice processing factor was used as a surrogate for pear juice and all other processing factors used DEEMTM defaults. All consumption data for these assessments were taken from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) with the 1994-1996 consumption database and the

Supplemental CSFII children's survey (1998) consumption database. These exposure assessments included all registered uses and pending uses on watercress, bushberries, caneberries, juneberries, ligonberries, pistachios, salal. A notice of filing for the pending uses was published in the **Federal Register** of May 1, 2002 (67 FR 21671) (FRL-6833-4). In addition to the registered and pending uses, this notice of filing includes exposure assessments for: Brassica, head and stem (Subgroup 5A), Brassica, leafy greens (Subgroup 5B), turnip, greens, carrot, herbs (Subgroup 19A), lychee, longan, and Spanish lime. Secondary residues in animal commodities were estimated based on theoretical worst-case, yet nutritionally adequate animal diets and transfer information from feeding studies.

i. *Food.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection, Inc., has estimated aggregate exposure from all crops for which tolerances are established or proposed. These assessments utilized residue data from field trials where cyprodinil was applied at the maximum intended use rate and samples were harvested at the minimum pre-harvest interval (PHI) to obtain maximum residues. Percent of crop treated values were estimated based upon economic, pest, and competitive pressures. The values used in these assessments were: Almonds, pome fruits, stone fruits, and grapes 100%; onions 9%; strawberries 42%; watercress 95%; berries 13%; pistachios, herbs 80%; crop group 5A and 5B, carrots, turnip, greens, lychee, longan, and Spanish lime 10%.

ii. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. EPA has not conducted an acute dietary risk assessment since no toxicological endpoint of concern was identified during the review of the available data.

iii. *Chronic exposure.* The cyprodinil Tier III chronic dietary exposure assessment was based upon residue field trial results. For the purpose of aggregate risk assessment, the exposure values were expressed in terms of margin of exposure (MOE) which was calculated by dividing the no observable adverse effect level (NOAEL) by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the reference dose (RfD). Chronic exposure to the most exposed subpopulation (children 1 and 2 years old) resulted in a MOE of 1,203 (7.48%