

determined that the request 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.

The Notice of Filing was published in the **Federal Register** on November 21, 1997 (62 FR 62304) (FRL-5755-2). The petitioner at that time was Novartis Crop Protection, Inc. In the **Federal Register** of February 13, 1998 (63 FR 7299) (FRL-5771-1), EPA published a final rule establishing tolerances for residues of benoxacor at 0.01 ppm for all commodities for which tolerances have been established for metolachlor. No benoxacor risk assessments have been performed by the Agency since that time.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of benoxacor in plants and animals is adequately understood for purposes of these tolerances. Identified metabolic pathways are similar in plants and animals (goat, hen, and rat).

2. *Analytical method.* Adequate enforcement methodology, gas chromatography/nitrogen phosphorous detection (GC/NPD), is available to enforce the tolerance expression. An analytical methodology for the determination of benoxacor and its metabolites in plant and animal commodities (Syngenta Analytical Method AG536(C)) is available upon request from EPA. Analytical Method AG536c involves extraction, filtering, dilution, partitioning, and cleanup. Samples are then analyzed by capillary gas chromatography using N/P detection. The limit of quantitation (LOQ) is 0.01 ppm.

3. *Magnitude of residues.* The magnitude of the residue in plants is adequately understood for the purposes of these tolerances. More than 30 residue trials were conducted in 19 States on a variety of agricultural crops, corn (field and sweet); soybeans, potatoes, green beans, radishes, sorghum, peanuts, head lettuce, and peas. There were no detectable residues of benoxacor at the LOQ of 0.01 ppm (many samples were analyzed at an LOQ of 0.005 ppm and no residues were detected) in any RAC or processed commodity. No transfer of residue to animals is expected through their diet.

B. Toxicological Profile

The toxicological profile of benoxacor and the end points for use in risk

assessments are discussed in the final rule published in the **Federal Register** of February 13, 1998 (63 FR 7299) (FRL-5771-1).

C. Aggregate Exposure

1. *Dietary exposure.*—i. *Food.* Tolerances have been established (40 CFR 180.460) for the residues of benoxacor in or on a variety of RACs. Risk assessments were conducted by EPA to assess dietary exposures and risks from benoxacor. In this action, Syngenta Crop Protection is requesting to amend only the tolerance expression and therefore believes that the most recent Food Quality Protection Act (FQPA) dietary assessment completed by EPA is valid in the consideration of this amendment request.

ii. *Acute exposure and risk.* Since there are no acute toxicological concerns for benoxacor, EPA has previously determined that an acute dietary risk assessment was not required.

iii. *Chronic exposure and risk.* For the purpose of assessing chronic dietary exposure from benoxacor, EPA has previously considered the established benoxacor tolerance of 0.01 ppm and the RACs for which tolerances have been established for metolachlor. There are no other established U.S. tolerances for benoxacor, and there are no other registered uses for benoxacor on food or feed crops in the United States. Benoxacor is used currently only as a herbicide safener in end-use product formulations that contain S-metolachlor. There are no longer any registrations of other active ingredients that contain benoxacor.

In conducting this exposure assessment, EPA previously assumed tolerance level residues and 100% crop treated, resulting in a large overestimation of dietary exposure and protective of any chronic dietary exposure scenario. The chronic reference dose (cRfD) is 0.004 milligram/kilogram/day (mg/kg/day). Based on the chronic dietary exposure of 0.000205 mg/kg/day for the U.S. population and 0.000828 mg/kg/day for the most highly exposed population subgroup (non-nursing infants less than 1-year old), this chronic dietary risk assessment resulted in the use of 5.13% of the RfD for the U.S. population and 20.7% of the RfD for the most highly exposed population subgroup. A cancer dietary margin of exposure (MOE) was calculated to be 1,950 using 0.4 mg/kg/day as the point of departure.

iv. *Drinking water.* For the purposes of assessing chronic exposure in drinking water, EPA has previously considered the registered uses and the

available data on persistence and mobility for benoxacor. The Agency has determined through a qualitative risk assessment that the physical and chemical characteristics of benoxacor are such that it is not expected to impact water resources. While benoxacor has the potential to be mobile, it is not persistent (half-life in soil of 49 days under aerobic conditions and 70 days anaerobically). In light of these findings, EPA has previously determined that benoxacor's use as a safener in S-metolachlor formulations will not impact ground water or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water.

2. *Non-dietary exposure.* All registered S-metolachlor products to which benoxacor is added as a safener are commercial agricultural products not registered for residential use. The potential for nonoccupational exposure to benoxacor by the general population is therefore unlikely except for the potential residues in food crops discussed above.

D. Cumulative Effects

EPA has previously determined that a cumulative assessment is not required for benoxacor. Benoxacor does not share a common mode of toxicity with any other moiety regulated by EPA further supporting the lack of a need for conducting a cumulative assessment in relation to this requested tolerance amendment.

E. Safety Determination

1. *U.S. population.*—i. *Acute risk.* Since there are no acute toxicological concerns for benoxacor, EPA has no cause for concern for acute aggregate exposure.

ii. *Chronic risk.* EPA has previously concluded that aggregate chronic exposure to benoxacor from food and water will utilize 5.13% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1-year old (utilizing 20.7% of the RfD). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA has previously concluded that there is a reasonable certainty that no harm will result from aggregate exposure to benoxacor residues.

The carcinogenic risk from food uses of benoxacor for the general U.S. population was calculated previously by