

(RfD) approach is appropriate for quantitation of human risks.

6. *Animal metabolism.*

Trifloxystrobin is moderately absorbed from the gastrointestinal tract of rats and is rapidly distributed. Subsequent to a single oral dose, the half life of elimination is about 2 days and excretion is primarily via bile. Trifloxystrobin is extensively metabolized by the rat into about 35 metabolites, but the primary actions are on the methyl ester (hydrolysis into an acid), the methoxyimino group (O-demethylation), and the methyl side chain (oxidation to a primary alcohol). Metabolism is dose dependent as it was almost complete at low doses but only about 60% complete at high doses.

In the goat, elimination of orally administered trifloxystrobin is primarily via the feces. The major residues were the parent compound and the acid metabolite (CGA-321113) plus its conjugates. In the hen, trifloxystrobin is found as the major compound in tissues and in the excreta, but hydroxylation of the trifluormethyl-phenyl moiety and other transformations, including methyl ester hydrolysis and demethylation of the methoxyimino group, are also seen. In conclusion, the major pathways of metabolism in the rat, goat, and hen are the same.

7. *Metabolite toxicology.* Metabolism of trifloxystrobin has been well characterized in plants, soil, and animals. In plants and soil, photolytically induced isomerization results in a few minor metabolites not seen in the rat; however, most of the applied materials remained as parent compound as shown in the apple and cucumber studies. All quantitatively major plant and/or soil metabolites were also seen in the rat. The toxicity of the major acid metabolite, CGA-321113 (formed by hydrolysis of the methyl ester), has been evaluated in cultured rat hepatocytes and found to be 20 times less cytotoxic than the parent compound. Additional toxicity studies were conducted for several minor metabolites seen uniquely in plants and/or soil. The studies indicate that these metabolites, including CGA-357261, CGA-373466, and NOA-414412, are not mutagenic to bacteria and are of low acute toxicity ($LD_{50} > 2,000$ mg/kg).

In conclusion, the metabolism and toxicity profiles support the use of an analytical enforcement method that accounts for parent trifloxystrobin.

8. *Endocrine disruption.* CGA-279202 does not belong to a class of chemicals known for having adverse effects on the endocrine system. Developmental toxicity studies in rats, rabbits, and

reproduction study in rats, gave no indication that CGA-279202 might have any effects on endocrine function related to development and reproduction. The subchronic and chronic studies also showed no evidence of a long-term effect related to the endocrine system.

C. *Aggregate Exposure*

1. *Dietary exposure.* Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U.S. population and selected population subgroups to residues of trifloxystrobin. These analyses cover all registered crops plus the crops of vegetable, root, except sugar beet, subgroup 1B, except radish; and the leafy petiole subgroup 4B.

The dietary exposure evaluation model ((DEEMTM) v.7.76 software) was used to estimate the chronic and acute dietary exposure. This software uses the food consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals CSFII 1994–1998.

EPA established an acute population adjusted dose (aPAD) of 2.5 milligrams/kilogram/day (mg/kg/day) for acute dietary risk assessments based on a NOAEL of 250 milligrams/kilogram of body weight/day from a rabbit developmental toxicity study and an uncertainty factor (UF) of 100. For chronic dietary analyses, EPA established a chronic population adjusted dose (cPAD) of 0.038 based on a NOAEL of 3.8 from a rat reproductive toxicity study and UF of 100.

Bayer CropScience believes that results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of trifloxystrobin on currently registered uses plus the pending uses on vegetable root crops, except sugar beets, subgroup 1B, except radish; and the leafy petiole subgroup 4B.

i. *Food.* Acute and chronic dietary exposure assessments were performed using tolerance values for all crops and assuming 100% crop treated. Acute exposure, expressed at the 95th percentile of exposure, was 0.59% of the aPAD for females 13 to 50 years old (only population subgroup of concern). The chronic exposure was 17.3% cPAD for the total U.S. population and 51.5% cPAD for the most sensitive population, children 1 to 6 years old.

ii. *Drinking water.* Using DEEM software, acute and chronic drinking water levels of concern (DWLOC) were calculated. The acute DWLOC was

74,560 and the chronic DWLOC was 1,100 for the total U.S. population and 184 for the most sensitive population subgroup, children 1 to 6 years old. These values are above the estimated concentrations of trifloxystrobin and its metabolites in drinking water as published in the **Federal Register** of May 22, 2002, (67 FR 35915–35924) (FRL-7178-6). Therefore, Bayer CropScience believe that there is reasonable certainty that exposure from trifloxystrobin will not result in harm to the adult U.S. population or infants and children.

2. *Non-dietary exposure.* As published in the **Federal Register** of May 22, 2002, (67 FR 35915–35924) (FRL-7178-6), EPA calculated post application exposure estimates and risk estimates for adults and children resulting from the use of trifloxystrobin on turf and recreational use sites.

The margin of exposure (MOE) that resulted were above 100 and all risks were considered below EPA's level of concern (LOC).

D. *Cumulative Effects*

EPA has determined that unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, trifloxystrobin does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed, as published in the **Federal Register** of May 22, 2002, (67 FR 35915–35924) (FRL-7178-6), that trifloxystrobin has a common mechanism of toxicity with other substances.

E. *Safety Determination*

1. *U.S. population.* Based on the information supplied under aggregate exposure described above, Bayer CropScience believe that there is reasonable certainty that exposure from trifloxystrobin will not result in harm to the adult U.S. population.

2. *Infants and children.* Based on the information supplied under aggregate exposure described above, Bayer CropScience believes that there is reasonable certainty that exposure from trifloxystrobin will not result in harm to infants and children.

F. *International Tolerances*

There are no codex, Canadian, or Mexican maximum residue limits (MRLs) established for trifloxystrobin. [FR Doc. 03-5193 Filed 3-4-03; 8:45 am]