C. Aggregate Exposure

1. *Dietary exposure— Food*. For purposes of assessing the potential dietary exposure under the proposed tolerances, Novartis has estimated aggregate exposure based on the theoretical maximum residue contribution (TMRC) from the benoxacor tolerance of 0.01 ppm in or on raw agricultural commodities for which tolerances have been established for metolachlor. In conducting this exposure assessment, Novartis has made very conservative assumptions--100% of all raw agricultural products for which tolerances have been established for metolachlor will contain benoxacor residues and those residues would be at the level of the tolerance (0.01 ppm) which result in an overestimate of human exposure.

2. *Drinking water*. Although benoxacor is mobile and hydrolyzes slowly at low pHs, it rapidly degrades in the soil (half-life of 49 days under aerobic conditions and 70 days anaerobically). Based on this data, Novartis does not anticipate exposure to residues of benoxacor in drinking water. This is supported by extensive experience with metolachlor, where in large scale ground water monitoring studies, metolachlor has been detected in less than 4% of the samples with the typical value being 1 ppb or less. Since benoxacor is formulated as a 1 to 30 ratio with metolachlor, (maximum of 0.2 pounds benoxacor per acre) the presence of benoxacor in groundwater is highly unlikely. The EPA has not established a Maximum Concentration Level for residues of benoxacor in drinking water.

3. *Non-dietary exposure*. Novartis has evaluated the estimated non-occupational exposure to benoxacor and based on its low use rate concludes that the potential for non-occupational exposure to the general population is unlikely except for the potential residues in food crops discussed above. Benoxacor is used only on agricultural crops and is not used in or around the home.

D. Cumulative Effects

Novartis also considered the potential for cumulative effects of benoxacor and other substances that have a common mechanism of toxicity. Novartis concluded that consideration of a common mechanism of toxicity is not appropriate at this time. Novartis does not have any reliable information to indicate that toxic effects seen at high doses of benoxacor (generalized liver toxicity, nephrotoxicity and the occurrence of forestomach tumors in an organ not present in humans) would be cumulative with those of any other chemical compounds; thus Novartis is considering only the potential risks of benoxacor in its aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base for benoxacor, Novartis has calculated that aggregate exposure to benoxacor will utilize 4.7% of the RfD for the U.S. population based on chronic toxicity endpoints and only 0.4% based on a margin of exposure assessment and a carcinogenic NOEL of 4.2 mg/kg/day. EPA generally has no concern for exposures below 100 percent 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. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to benoxacor residues.

2. *Infants and children*. Using the same conservative exposure assumptions used for the determination in the general population, Novartis has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of benoxacor is 5.3% for nursing infants less than 1 year old, 20.2% for non-nursing infants, 11.9% for children 1-6 years old and 7.7% for children 7-12 years old. These worst case estimates are likely at least 4 times greater than actual values when considering that benoxacor residues have not been detected at the limit of quantitation of 0.005 ppm (tolerance is 0.01 ppm) and using a more realistic market share of 50% rather than the conservative 100%. Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Novartis concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to benoxacor residues.

F. International Tolerances

A maximum residue level has not been established for benoxacor by the Codex Alimentarius Commission.

[FR Doc. 97–30659 Filed 11–20–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5925–9]

Availability of Draft Document on Information for States on Developing Affordability Criteria for Drinking Water

AGENCY: Environmental Protection Agency.

ACTION: Notice of document availability.

SUMMARY: The Environmental Protection Agency is making available for public comment a draft document entitled Information for States on Developing Affordability Criteria for Drinking Water. The Safe Drinking Water Act Amendments of 1996 require the Agency to publish information to assist states in developing affordability criteria. To meet the statutory schedule, this information must be published by February 6, 1998. The draft document being made available today was developed by a diverse working group of stakeholders under the auspices of the National Drinking Water Advisory Council (NDWAC). The full NDWAC reviewed this draft and recommended it to EPA as a draft to be made available for public comment. EPA invites interested members of the public to submit comments on the draft document. EPA will consider public comments and publish a final document by the February 6, 1998, statutory deadline.

DATES: Submit comments on or before December 31, 1997.

ADDRESSES: Address all comments concerning this draft document to Peter E. Shanaghan, Small Systems Coordinator, Office of Ground Water and Drinking Water, Mail Code 4606, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:

Peter E. Shanaghan, 202–260–5813 or shanaghan.peter@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: A copy of the draft document may be obtained by calling the Safe Drinking Water Hotline at 1–800–426–4791. The hotline operates Monday through Friday, 9:00 a.m.–5:30 p.m. (EST). The document may also be downloaded from EPA's homepage, http://www.epa.gov/OGWDW.

Elizabeth Fellows,

Acting Director, Office of Ground Water and Drinking Water.

[FR Doc. 97–30660 Filed 11–20–97; 8:45 am]

BILLING CODE 6560–50–M