Responses to Major Comments on Technical Support Document

Public Health Goal For Bentazon In Drinking Water

Prepared by

Pesticide and Environmental Toxicology Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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INTRODUCTION

The following are responses to major comments received by the Office of Environmental Health Hazard Assessment (OEHHA) on the proposed public health goal (PHG) technical support document for bentazon as discussed at the PHG workshop held on October 6, 1998, or as revised following the workshop. Some commenters provided comments on both the first and second drafts. For the sake of brevity, we have selected the more important or representative comments for responses. Comments appear in quotation marks where they are directly quoted from the submission; paraphrased comments are in italics.

These comments and responses are provided in the spirit of the open dialogue among scientists that is part of the process under Health and Safety Code Section 57003. For further information about the PHG process or to obtain copies of PHG documents, visit the OEHHA web site at www.oehha.org. OEHHA may also be contacted at:

Office of Environmental Health Hazard Assessment
301 Capitol Mall, Room 205
Sacramento, California 95814
(916) 324-7572
RESPONSES TO MAJOR COMMENTS RECEIVED

University of California, Riverside

Comment 1:  More information is needed on adverse effects seen at a LOAEL identified in the 52-week oral toxicity study of bentazon in dogs (Allen et al., 1989), underlining the significance of the finding of feces with red areas in a dog at this level in the light of hematological changes seen in other studies.  (Paraphrased).

Response 1:  More details on the adverse effects seen at the LOAEL in the 52-week study in dogs were provided and a discussion on hematological changes caused by bentazon was broadened.

Comment 2:  The reviewer suggested broadening discussion of a cancer bioassay by Takehara and Tajima (1984) by providing incidence of tumors observed in female rats regardless of their not being useful in establishing PHG.  (Paraphrased)

Response 2:  The discussion was broadened, the incidence of the tumors was given and the reasons for not using them in establishing PHG were presented.

Comment 3:  The incidence of liver tumors in control B6C3F1 mice should be provided.  (Paraphrased)

Response 3:  The incidence of liver tumors in control B6C3F1 mice was presented.

Comment 4:  The reviewer recommended that the OEHHA consider adding a 2-3x modifying factor while establishing PHG based upon the following considerations:

  a) Water consumption rates for children up to 1 year of age [mean 44 ml/kg-day; 90th percentile 102 ml/kg-day] is considerably higher than that of adults [21 ml/kg-day; 90th percentile 34 ml/kg-day] (USEPA, 1996).  In addition, the effects were seen within a one-year period.  The addition of a modifying factor is consistent with current concern about sensitive subpopulations and the effects of pesticides on children.  [Based on the multigenerational animal studies, children do not appear more sensitive to bentazon than adults do.]

  b) Small number of dogs tested (6) per dose in the key study.

  c) The one-year dog study, although standard, is considerably shorter than the dog's lifetime.

  d) The identification of blood in the feces was determined by visual observation.  It is possible with using a more sensitive or thorough detection method, fecal blood may have been detected at a lower dose.”

Response 4:  We do not think that adding a 2-3x modifying factor to the equation we used for calculating PHG for bentazon would be defensible based on the best currently available scientific data.  The following is a reply to the reasons listed above by the reviewer.
a) We acknowledge that water consumption rates for children up to one year of age is higher than that of adults and consequently the exposure to any chemical present in water would be higher than that of adults. However, the currently available data do not justify concerns about children being more sensitive to bentazon exposure than adults. Results from reproductive and developmental toxicity studies do not seem to support the notion of children's higher sensitivity to bentazon exposure. In addition, in the light of the absence of data on bentazon's metabolism in humans, it would be inappropriate to speculate whether children are more or less sensitive to toxic effects of this compound.

b) The standard number of non-rodents (e.g. dogs) required in chronic toxicity studies according to U.S. EPA [(under the Federal Insecticide, Fungicide, and Rodenticide Act) FIFRA] is at least four animals/sex/dose. The subject chronic toxicity dog study used six dogs/sex/dose. Therefore it exceeded the necessary criterion for this parameter.

c) A chronic toxicity study in dogs is designed to study non-cancer effects and a one-year duration of exposure is generally considered in the scientific community to be adequate to induce the majority of such effects, including hematological alterations produced in the subject study (Allen et al., 1989).

d) At a LOAEL of 400 ppm blood in the feces was visually identified only in one dog. It is possible that with a more sensitive or thorough detection method, fecal blood would have been identified in more animals and also at lower level of treatment (100 ppm). However, this method of detection is currently acceptable, although the use of more sophisticated methods, especially methods focused on cellular changes, pharmacokinetics, behavior, and neurotoxicity, might mean that the presently accepted LOAELs maybe lower.

Comment 5: The reviewer suggested providing more substantiation for a NOAEL of 150 mg/kg-day identified in a developmental toxicity study in rabbits (Becker et al., 1987) by describing adverse effects found in a range-finding experiments at the 300 and 450 mg/kg-day doses.

Response 5: The adverse effects found in the range finding study were described.

University of California, Davis

Comment 1: The reviewer suggested keeping a PHG for bentazon at the previously established level of 18 ppb instead of a newly established value of 200 ppb. He supported his view by the following:

The recommended change hinges on one chronic study on dogs leading to an order of magnitude increase in MCL. Increasing concern for materials in ground water and the lifespan of Bentazon in water possibly makes this a high profile decision. Although the agency could stick to its guns and increase the allowable level, there seems little compelling evidence to do so beyond the single dog study. Alternative: Rather than increase the level, one could argue to keep it where it is. Reasons include its presence in wells, lack of knowledge of the mechanism of Bentazon's toxicity, uncertainty as to endocrine disruptor effects (although the two and three generation studies reported make them unlikely), pathology appearing at high dose levels for several species, and recent heightened concerns for lifetime exposures. The decrease in finding the compound in wells in California may reflect its withdrawal from use. (See CDFA News Release 89-50) Conclusion: The Agency should consider whether prudence suggests keeping the level where it is."

BENTAZON in Drinking Water
California Public Health Goal (PHG)
Responses to Major comments 3 February 1999
Response 1: OEHHA can not disregard a good quality chronic toxicity study in dogs. One study with well-substantiated results is sufficient, in our evaluation, to impact the overall health risk assessment. The uncertainties listed by the reviewer are common for the most of the chemicals being currently assessed, especially lack of knowledge of the mechanism of toxicity and the uncertainty as to endocrine disruptor effects. (Nevertheless they are listed in the revised version of the document). Current concerns for lifetime exposures seem to be alleviated by the results from the chronic toxicity study in dogs. In conclusion, it would be untenable and irresponsible to disregard the results of this study in our assessment. Therefore we uphold our current PHG level for bentazon (200 ppb).