

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Steven A. Book, Interim Director



MEMORANDUM

TO: Larry L. Nelson, Ph.D., Chief  
Medical Toxicology Branch  
Department of Pesticide Regulation  
1220 N Street  
Sacramento, CA 95814

FROM: Richard J. Jackson, M.D., M.P.H.  
Hazard Identification and  
Risk Assessment Branch  
2151 Berkeley Way, Annex 11  
Berkeley, CA 94704

A handwritten signature in cursive script, appearing to read "Richard J. Jackson", with a long horizontal line extending to the right.

DATE: December 30, 1991

RE: Dietary Exposure Assessment for Abamectin on Pears

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Under the Section 18 Emergency Exemption abamectin may now be used on pears. The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the California Department of Pesticide Regulation's (CDPR) dietary exposure assessment (July 9, 1991) of abamectin in pears and submits the following comments.

As you know, several staff of OEHHA and CDPR met on September 23, 1991 to discuss the current status of abamectin's registration. This discussion was very useful in sorting out what data are available for risk assessment and identifying the limitations of those data. Consequently, as was noted during this meeting, and in previous memoranda, OEHHA still has several health-related concerns regarding the continued registration of abamectin for use on food crops in California. OEHHA requests that CDPR provide regular updates on the status of abamectin registration. The update should address the issues raised by OEHHA in its reviews of the risk characterization document, the exposure assessment and those issues raised in the September 23 meeting. OEHHA also understands that CDPR will present an evaluation of human data which were recently obtained from the registrant.

By way of background, CDPR's dietary exposure assessment considers: 1) acute dietary exposure to abamectin's residues in pears, and 2) chronic dietary exposure to abamectin's residues in all currently registered food uses



(i.e. cottonseed, strawberries, celery, head lettuce and pears). Acute and chronic dietary exposure assessments were conducted using the software programs, Exposure-4 and Exposure-1, respectively. The acute dietary exposure assessment program estimates the distribution of user-day consumptions (in this case pear-eaters) and the chronic dietary assessment program determines annualized averages of the consumptions of foods (in this case pears) for the overall U. S. population and also for specific population sub-groups. Food consumption data were based on the U. S. Department of Agriculture (USDA) Nationwide Food Consumption Survey of 1987-88.

Residues of 20 ppb for unprocessed pear commodities and 2 ppb for all processed (canned/cooked) pear commodities were assumed for the risk calculations. Twenty ppb is the proposed residue action level in pears. This value was recommended based on the residue analysis at 21 days (with the highest value of 18.9 ppb), which is the current preharvest interval required under Section 18, changed from a seven-day period in 1990. The change was triggered by interim dietary assessment for pears which indicated that certain population sub-groups (e.g., non-nursing infants, children one to six years of age) did not have adequate margins of safety (MOS) for acute exposure using anticipated residues on pears at the proposed seven day pre-harvest interval.

Based on the currently established No-Observed-Effect-Levels (NOELs) used in the dietary exposure assessments, both the acute and chronic dietary exposure analyses indicate that there is an adequate MOS for abamectin's adverse effects.

The results of the exposure assessment and concurrent high MOS values do not alleviate OEHHA's previous concerns regarding the registration of abamectin in California food crops. OEHHA agrees that protective MOS values do exist for very severe adverse effects (death, tremors, pup survival, etc.) and other obvious clinical symptoms. However, more subtle adverse changes which often precede these effects apparently cannot be determined from the available data. Thus, the possible health risks for other different categories of adverse effects has not been adequately assessed. These concerns should be acknowledged in the revised document.

OEHHA has several other concerns about the methodology used in the exposure assessment. These are discussed below.

1. CDPR exposure analyses for nursing infants do not include maternal milk as a source of abamectin. Therefore, dietary exposure for nursing infants may actually be higher than the exposure determined by CDPR. This can and should be corrected in the revised document.

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2. CDPR's policy regarding the use of the minimum detection level (MDL) for acute dietary exposure assessments and 50% of MDL for chronic dietary assessments for residues below MDL should be substantiated in the revised document.

Thank you for the opportunity to review your document. If you have any questions regarding these comments, please contact me or Dr. Michael J. DiBartolomeis at ATSS 571-3063.

cc: Jolanta Bankowska, Ph.D.  
Steven A. Book, Ph.D.  
Michael J. DiBartolomeis, Ph.D.  
Anna M. Fan, Ph.D.