

DEC 3 1985

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MEMORANDUM

SUBJECT: Captan Special Review--Review and Analysis  
of Rebuttal Comments  
No Accession Number RCB #1420

FROM: Lynn M. Bradley, Chemist  
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TO: Bruce Kapner, PM 70  
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and

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THRU: Charles L. Trichilo, Chief  
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Comments on the Captan PD 2/3 from three sources have been distributed to RCB and other HED branches for rebuttal. The comments are summarized and our responses given below.

Food and Drug Administration, DHHS

Two letters from FDA were received. The first, from Don Reed to Bruce Kapner dated July 8, 1985, transmits results of a yet unpublished survey of grapes and strawberries for captan and folpet, along with descriptions of the analytical methods used.

The second, a letter from John Wessel to Steve Schatzow dated July 23, 1985, is a summary of FDA captan monitoring data for 1978-84; 25 crops having captan tolerances are

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included, although many are represented by only one or a few analyses. A copy of Don Reed's letter to Kapner is also attached.

EPA Comments:

The grape and strawberry data are new, and will be incorporated into future dietary exposure analysis. The monitoring data are already available to us in computer printout form, and most of them were considered in Janice Jensen's original dietary exposure analysis. Questions about methodology have been resolved since that analysis was done, but those data are still insufficient for a complete dietary exposure analysis. The compilations forwarded to us by John Wessel will be far easier to work with than the printout format.

Stauffer Chemical Company

Stauffer's arguments are based on the following outline:

- I. EPA Overestimated Dietary Exposure
  - Real data are available
  - A. FDA monitoring (summary presented)
  - B. Market basket survey (summary presented)
- II. Risk Assessment should be based on actual exposure rather than tolerance levels
  - A. Tolerances exaggerate exposure
  - B. Other risk assessments use real data, why not captan
- III. EPA has sufficient THPI data from which to extrapolate estimates
  - A. Data are available (detailed listing of available THPI data is presented)
  - B. Captan and THPI are nonsystemic and levels will be greatly reduced during routine preparation
- IV. TMRC recalculation presented
  - A. Average residue from data in tolerance reduction petition used after correction for percent of crops treated (78% of consumption)
  - B. Proposes using average residue corrected as above where available and tolerance corrected by ratio for crops where data are not available (22% of consumption)

EPA Comments:

- I. We agree that dietary exposure is likely overestimated. Monitoring data and market basket survey represent only a portion of crops having captan tolerances, and do not include any THPI data. If we used them we would not know how much of the residue we were missing.
- II. We agree that actual exposure data should be used when available. We have requested data so that we can use actual exposure estimates for all crops, all uses. Data on residue reduction during washing, peeling, and cooking have also been requested and will be factored into exposure analysis when received.
- III. THPI data do not show consistent ratio to captan residues. THPI may be systemic. EPA does not consider that sufficient data are available.
- IV. We could have calculated an incomplete exposure analysis from data not representing maximum doses. Petition data are valid, but not sufficient for lowering tolerances. Using these data for exposure would leave many unanswered questions. RCB advised obtaining required data before redoing exposure estimates; PD 2/3 thus went forward on schedule without awaiting revised exposure estimates.

Chevron Chemical Company

Chevron's comments are substantially similar to Stauffer's; they object to use of tolerance levels for dietary risk assessment. They argue that available data are sufficient to support calculation of a realistic dietary exposure assessment, and that EPA's reasons for not doing so are "unsupportable."

EPA Comments:

We continue to believe that additional data are needed to support a comprehensive dietary exposure analysis; the piecemeal extrapolations and estimations suggested by Chevron (and Stauffer) are not satisfactory.

There are long-standing unmet data requirements for captan and we are unwilling to pretend that data in hand are sufficient. RCB has been seeking additional data since at least 1980 (memo of A. Rathman, RCB, to Joe Boyd, SPRD, November 12, 1980, regarding a captan 3(c)(2)(B) letter).

Conclusions and Recommendations

Until the data requested are available, RCB cannot perform a comprehensive and accurate dietary exposure assessment for captan. The hit-and-miss extrapolations and guesstimates suggested by Stauffer and Chevron do not adequately replace the missing and needed data.

Note to PM. These comments may require reanalysis if any major changes occur during preparation of the PD 4.

~~Attachment~~

cc: IMB, Captan SF., PMSD/ISB, Circu, r.f.