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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP 4 1986

MEMORANDUM

SUBJECT: EPA Registration No. 239-1246. Captan,
June 9, 1986 Response to the Registration
Standard Guidance Document.
No Accession Number. RCB No. 1132.

FROM: Lynn M. Bradley, Chemist
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TO: Eugene M. Wilson, PM Team 21
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and

Office of Compliance Monitoring
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and

Spencer L. Duffy, Captan Review Manager
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THRU: Andrew R. Rathman, Section Head
Residue Chemistry Branch
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Stauffer Chemical Company, by letter from R. Riggs to H. Jacoby (PM 21) dated June 9, 1986, has responded to the Captan Registration Standard Guidance Document (March 10, 1986). This letter requests several time extensions and questions several requirements in relation to the April 29, 1985 Data Call-In (DCI) by Special Review. The letter also states that a Captan Task Force will conduct the studies

required by the Standard as the Captan Residue Task Force is responding to the DCI. Both task forces are composed of Stauffer, Chevron, and Makhteshem-Agan (America), Inc. The former specifically includes Calhia, a wholly owned subsidiary of Stauffer.

First, Stauffer requests a time extension for all requirements generated by the Standard, due to time needed to organize a task force. Stauffer mentions that PR Notice 85-5 allows for this. The letter requests 3 months; the tables indicate a 6-month extension. RCB does not object to a general 3- or 6-month extension.

Stauffer's letter and footnote 3, table A, mention the crop residue data required by the April 1985 DCI, and state that requirements under the Standard are greater in scope. After speaking with Jack Wise of Stauffer (Telecon, August 11, 1986), apparently this is due to requirements of other branches of Hazard Evaluation Division. Mr. Wise also delivered, at my request, two copies of the residue program being conducted for the DCI.

Stauffer requests a 1-year extension for submission of the residue data required by the Standard. The reasons are 1) guidance document arrived too late to plan field trials for the 1986 growing season, 2) end-use product registrants have been somehow left out, and 3) IR-4 and other minor use interests need extra time to schedule residue trials in support of their interests. Reason #1 is sufficient justification for a 1-year extension. Residue Chemistry Branch (RCB) recommends that a 1-year extension be granted for all field residue data required by the Captan Registration Standard. We note that this extension does not apply to the requirements of the DCI of April 1985. We do recommend that the residue data developed for the DCI be referenced or resubmitted with the Standard response.

Regarding the seed treatment residue studies, we accept that a wide discrepancy exists between the DCI and the Standard. The DCI requires residue data on six representative crops grown from treated seed, whereas the Standard requires residue data for each and all raw agricultural commodities (RAC's) grown from treated seed. Provided that (as expected) detectable residues of Captan and Tetrahydrophthalimide (THPI) do not occur in any of the six representative commodities for which the DCI requires data, we will not require additional studies on RAC's grown from treated seed. Seed treatments are only considered nonfood uses if a radiolabeled study shows no residues. Commodities having seed treatment uses

must have tolerances, and for any RAC's where no tolerance exists, a method sensitivity tolerance would still be needed in order to retain the seed treatment use.

The questions concerning additional plant and animal metabolism studies (Nature of the Residue) are being addressed by the Registration Standards section of RCB in a separate memorandum (D. Edwards, August 13, 1986). We agree that the requirement for additional residue analytical method should be held in abeyance until completion and evaluation of the metabolism studies. Prior to development of new methods, the additional compounds to be quantitated (if any) must be identified--thus the time period for method development, if needed, should properly begin after evaluation of the metabolism studies.

Conclusions and Recommendations

1. RCB does not object to either a 3- or 6-month time extension for all deadlines as justified by formation of a task force.
2. RCB does not object to the requested 1-year extension for the residue field trial data requirement. Since the Standard was issued too late for 1986 trials to be conducted, it seems needed. This extension should not cover studies required by the April 1985 DCI letter.
3. Provided that detectable residues of Captan and THPI are not found in the seed treatment studies required by the April 1985 DCI, it will not be necessary to conduct any additional studies of RAC's grown from treated seed. We note that all registered seed treatments will require a tolerance--if none exists for other use patterns, a method sensitivity tolerance should be established.
4. The justification for additional metabolism studies, as required under Nature of the Residue, is discussed separately (see memorandum of D. Edwards, August 13, 1986).

cc: S.F., R.F., Circ, Reg. Std. file (Captan), LMB(2), PMSD/ISB

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