SEP 4 1986

MEMORANDUM

SUBJECT: Post-Phase II Registration Standard Support Team Meeting for Folpet

FROM: Eugene M. Wilson, Assistant PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Addressees

The Office of Pesticide Programs (OPP) procedures for development of Registration Standards include two major meetings of the OPP Registration Standard Project Support Team. The first of these meetings (the Pre-Phase II Meeting) is an informational meeting intended to provide an overview (regulatory history) for the chemical and put it in regulatory and scientific perspective for the support team. This meeting occurs at the very beginning of the data review and evaluation phase (Phase II) of the Registration Standard process. The presence of external program offices at this meeting will provide those offices the opportunity for upfront involvement in Registration Standard decisionmaking. The second of these meetings (the Post-Phase II Meeting) occurs at the conclusion of Phase II of the Registration Standard process and is intended to establish agreement on the science conclusions, data requirements, and regulatory position/rationale which flow from the science findings.

The Pre-Phase II Meeting for folpet was held on September 26, 1985. In the time interval since that meeting, no new information has been communicated on this chemicals progress in Phase II of the Registration Standard review. The Phase II review for folpet was completed on August 21, 1986.

In keeping with OPP's procedures for development of Registration Standards, the Post-Phase II Meeting for folpet has been scheduled for September 10, 1986 at 10:00 a.m. in Room 1112A, Crystal Mall Building 2.

As stated above, the purpose of the Post-Phase II Meeting is to establish agreement on the science conclusions, data requirements, and regulatory position/rationale which flow from the science findings.

The attachments provide the information each participant will need for evaluating the pesticide and its uses in developing the Agency's regulatory position and rationale with regard to reregistration. These attachments are listed and described below:

A. Draft Registration Standard: This document included the proposed regulatory position and rationale, unique label language, science summary, data tables, tolerance reassessment, and bibliography.

B. Preliminary Quantitative Use Analysis: This document, prepared early in Phase I of the Registration Standard process by the Benefits and Use Division, provides a brief description of the use(s) for the pesticide under review.

C. Science Chapters: These chapters, prepared by the science reviewers in the Hazard Evaluation Division, document the science reviewers' evaluation of the data to support the reregistration of the pesticide and its uses. These chapters include:

1) Product and Residue Chemistry Chapter
2) Toxicology Chapter
3) Environmental Chapter
4) Exposure Assessment Chapter

D. Science Summary Memo: This memo, prepared by the Science Integration Staff of the Hazard Evaluation Division, provides the "bottom line" findings from the science chapters.

E. Summary of Registered Uses: This summary, prepared by the Benefits and Use Division, as a table of contents for the larger "Index of Currently Acceptable Uses," provides a listing of the major use categories and the crops under each use.

If after reviewing the enclosed material you find that you are not interested in taking part in the discussion on this Registration Standard, please notify the Registration Division Product Manager of your decision by completing the attached "Notice of Nonparticipation" form and return it and the material to the PM at Room 237 Crystal Mall Building 2.

If, however, you find that you are interested in taking part in the discussion on this Registration Standard you should:

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- Review the attachments referred to above and come to the meeting ready to discuss the items on the attached agenda.
- If you have specific questions, let me know them ahead of time so I or other members of the team can be prepared to respond to them at the meeting.
- If you would like to revise the language of the document, or add a section, bring copies of the proposed language to the meeting for the team's consideration.
- If you only have a general interest, come to the meeting and participate in the discussion.

Participants at this meeting, and decision meetings that will follow, should be authorized to state a position on behalf of their office, so that decisions made are the official position of the organizations represented.

The Registration Standard, as revised at the meeting, will be circulated to all offices after the meeting for formal concurrence.

ADDRESSEES:

External Program Offices

Barbara Britton	(OPPE)
Penny Fenner-Crisp	(ODW)
Phyllis Flaherty	(CMS)
Cara Jablon	(OGC)
Francine Jacoff	(OSW)
Hugh Spitzer	(ORD)

OPP Offices

Paul Mastradone	(HED/EAB)
Dennis McLane	(HED/EEB)
Randy Perfetti	(HED/RCB)
Tina Levine	(HED/SIS)
Steve Saunders	(HED/TOX)
Phyllis Johnson	(BUD/SSB) (Index)
Janet Anderson	(BUD/SSB) (QUA)
Jean Lupinacci	(BUD/EAB) (PQUA)
Bill Grosse	(PSD/PMSD)
Dick Longmire	(OPP/FWS)
Franklin Gee	(RD/PCS)
Eugene Wilson	(RD/PM-21)

Attachments: Meeting Agenda
Preliminary Quantitative Use Analysis
Science Chapters
Science Summary Memo
Data Tables
Summary of Uses
Notice of Nonparticipation Form

ADDRESSEES:

FOLPET (081601-7), EPA Case No. GS-0630

EXTERNAL PROGRAMS OFFICES

Jim Lamb	(AA/OPTS Staff)	E633	TS-788	382-2892
Cara Jablon	(OGC)	W513F	LE-132P	382-7505
Barbara Britton	(OPPE)	W401	PM-223	382-7568
Hugh Spitzer	(ORD)	W621	RD-689	382-2593
Penny Fenner-Crisp	(ODW)	E1101C	WH-550D	382-7589
Phyllis Flaherty	(OCM)	M2624A	EN-342	382-7826
Francine Jacoff	(OSW)	SE242K	WH-562B	382-4789

OPP PROJECT SUPPORT TEAM

Tina Levine	(HED/SIS)	1123?	TS-769	557-7892
Steve Saunders	(HED/TOX)	820-G	TS-769	557-2320
Paul Mastradone	(HED/EAB)	815	TS-769	557-1993
Randy Perfetti	(HED/RCB)	812-B	TS-769	557-4381
Dennis McLane	(HED/EEB)	1101	TS-769	557-1405
Janet L. Andersen, Ph.D.	(BUD/SSB)(QUA)	713	TS-768	557-3533
Jean Lupinacci	(BUD/EAB)(PQUA)	700	TS-768	557-1391
Franklin Gee	(RD/PCS)	1120B	TS-767	557-9098
Bill Grosse	(PMSD)	222	TS-757	557-3613
Dick Longmire	(OPP/PCS)	1101	TS-757	557-7666
Phyllis Johnson	(BUD/SSB)(INDEX)	701A	TS-768	557-3790
Eugene Wilson	(RD/PM-21)	229	TS-767	557-8540
Carol Monroe	(RD/SRB)	1006	TS-767	557-9710

FOLPET

Post-Phase II Meeting Agenda

1) INTRODUCTION

- Introduction of attendees
- Explanation of the purpose and scope of the meeting

2) AGREEMENT ON SCIENCE CONCLUSIONS INCLUDING THE DATA TABLES

- Are data requirements adequately covered?
- Are all data gaps identified?
- Are data requirements met through use of data on similar chemicals?
- Are special studies needed?
- Do footnotes adequately explain the reason for data requirements which are more or less stringent than guidelines requirement?
- Schedule for submitting data.
- Resolution of issues.

3) AGREEMENT ON REGULATORY POSITION AND RATIONALE

- Acute toxicology problems:
- Chronic toxicology problems:
- Exposure problems:

  - reentry
  - rotational crop

- Water problems:
- Residue problems:
- Tolerance-related problems:

  - Should additional tolerances be granted until specific data gaps are filled?

- Wildlife risks:
- Disposal problems:
- Unique labeling statements:
- Resolution of issues:

4) AGREEMENT ON SPECIFIC DECISIONS WHICH OPP POLICY GROUP MUST MAKE IN REGARD TO IDENTIFIED PROBLEMS/ISSUES (IF APPLICABLE)

5) SUMMARY OF DECISIONS

NOTICE OF NONPARTICIPATION IN THE REGISTRATION STANDARD DEVELOPMENT PROCESS FOR FOLPET

TO: Eugene M. Wilson, Assistant Product Manager 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)
Room No. 237
Crystal Mall Building No. 2

We will not be taking part in the discussions and development of the Registration Standard for this chemical for the following reason(s):

_____
(name)

_____
(title)

_____
(office)

_____
(date)