Shaughnessy Number: 081901

Date out of EFGWB: MAY 2 1991

To: S. Lewis
Product Manager 23
Registration Division (H7505C)

From: Akiva Abramovitch, Section Head
Environmental Fate Review Section #3
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Thru: Hank Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File #: 050534-00008

Chemical Name: Chlorothalonil

Type Product: fungicide

Product Name: Bravo 500

Company Name: Fermenta ASC Corporation

Purpose: 24(c) special local need in Maine/to support shorter rotational crop intervals on potatoes

Date Received: 04/15/91

EFGWB#(s): 91-0524

Total Reviewing Time (decimal days): _____

Deferrals to: ___Ecological Effects Branch, EFED

___Science Integration and Policy Staff, EFED

___Non-Dietary Exposure Branch, HED

___Dietary Exposure Branch, HED

___Toxicology Branch

1

1. CHEMICAL:

chemical name: 2,4,5,6-tetrachloro-1,3-benzenedicarbonitrile
common name: Chlorothalonil
trade name: Bravo, Clortosip, Daconil 3787, Exotherm Termil.
structure:
CAS #:
Shaughnessy #: 081901

2. TEST MATERIAL: see DER

3. STUDY/ACTION TYPE: request for 24(c) use on potatoes in the state of Maine/to support shorter rotational crop intervals.

4. STUDY IDENTIFICATION:

Kenyon, R.G. and Ballee, D.L. **Residues of Tetrachloroisophthalonitrile (Chlorothalonil, SDS-2787), SDS-370-1, SDS-46851, HCB and PCBN on Rotated Crops from Maine -1990.** dated 12/21/90. preformed by Ricerca, Inc., Painesville, OH. sponsored and submitted by Fermenta ASC Corporation, Mentor, OH. received EPA 4/9/91 no MRID#.

5. REVIEWED BY:
Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

6. APPROVED BY:
Typed Name: Akiva Abramovitch
Title: Section Head, Review Section 3
Organization: EFGWB/EFED/OPP

Akiva Abramovitch
MAY 2 1991

7. CONCLUSIONS:

EFGWB cannot support granting the requested 24(c) exemption for use of chlorothalonil on potatoes in the state of Maine. Several environmental fate data requirements listed below remain unsatisfied. Accumulation in rotational crops and ground water concerns issues remain unsettled.

1) The field rotational crop accumulation study reviewed in this submission is not acceptable to fulfill the data requirement because the soil was not analyzed at planting time. Therefore, it is not certain that residues were available for uptake, or at what level. For these reasons, the study can only be considered supplemental indicating that under the experimental conditions, no uptake was observed.

2) *From previous reviews*: Several other data requirements are unfulfilled, including photolysis in water, photolysis on soil, and aerobic soil metabolism. Some of this information is necessary to the proper execution and evaluation of the field studies, and should therefore be addressed before field studies are repeated. The soil photodegradation and aerobic soil metabolism data will be of particular interest.

3) *From previous reviews*: Due to findings of chlorothalonil degradates in ground water both monitoring and small scale prospective studies have been required (JHJ 10/31/90). To data no protocols or data have been received.

9. BACKGROUND:

The data requirements are summarized below.

Hydrolysis -- fulfilled -- MRID # 00405-39 -- stable at pH 5 and 7; 10% degrades in 30 days at pH 9; 2,4,5,6-tetra-Cl-isophthalimide the only degradate

Aqueous Photolysis -- **not fulfilled** -- MRID#s 000872-81, 401834-18, 000405-40, 1899 Reg. Std. -- additional data are required -- MRID# 401834-18 could be made acceptable, and indicates stability to photolysis

Soil Photolysis -- **not fulfilled** -- (MRID# 001437-51, 1988 Reg. Std.)

Aerobic Soil Metabolism -- **not fulfilled** -- the study (per Guidelines subpart N) must establish patterns of disappearance of parent; appearance and disappearance of degradates; identity of degradates

Anaerobic Soil Metabolism -- fulfilled by acceptable anaeroabic aqueous metabolism study (10/23/85, also HLB 4/22/86, MRID# 0014790-75)

Anaerobic Aquatic Metabolism -- fulfilled -- (10/23/85, HLB 4/22/86, MRID# 001479-75) -- $t_{\frac{1}{2}}$ 5-15 days

Leaching/Adsorption/Desorption -- fulfilled (8/1/86, MRID#s 001151-05, -- 1537- 10) -- low leachability in lab, but findings in ground water triggered monitoring requirements. k_{ads} 3 (sand) to 29 (silt) in batch studies.]

Terrestrial Field Dissipation -- partially fulfilled (MRID # 000872-96, 1988 Reg. Std.). Other studies which have recently been reviewed are as follows:

Fresno, CA — MRID# 415648-29. This study is unacceptable for several reasons listed below. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of chlorothalonil and its degradates. These data do not serve to define a pattern or time course for the dissipation of chlorothalonil under field conditions. The data appear to scatter, rather than vary in a regular fashion. Soil sampling may not have gone deep enough to define the extent of leaching of chlorothalonil and its degradates. Chlorothalonil was detected at 0.01 ppm (average) in the lowest sampled depth (12 to 15" at 120 days following the last application made in 1986 at Plot 1, and at 318 days following the last application at Plot 2). In addition, soil was not sampled at 12-to 15-inch depth until 30 days posttreatment; it is possible that chlorothalonil may have been present in both plots at this depth prior to 30 days posttreatment. The soil should have been sampled at all sampling intervals to depths (preferably two sampling depths) at which residues were nondetectable. Analyses were done on composited samples (and sampling variation thereby minimized). Without individual values for analyses, EFGWB cannot assess the "inherent" precision and accuracy of the procedures. For this reason, EFGWB strongly recommends at least three independent samples for each sampling event. The study author reported a half-life of 58 days for chlorothalonil in the upper 12 inches of soil using selected data from both treated plots. Because the residue levels were unusually high at certain sampling intervals (plot 1 at 0-30 days; plot 2 at 177 days and beyond), these data were not used in calculating the half-life. Since these values were arbitrarily discarded, the calculated half-life is considered to be of questionable validity.

Donalsonville, GA — MRID# 451648-28. The study is unacceptable. The data from Plot A do not serve to define a pattern or time course for the dissipation of chlorothalonil under field conditions. The analytical results for soil samples taken from Plot A are too randomly variable to allow an accurate assessment of the

dissipation of chlorothalonil and its degradates under field conditions. In addition, sampling was insufficient since soil was only sampled through day 29 following the tenth application, except for samples taken at 222 days posttreatment. The depth of soil sampling was insufficient to define the extent of leaching of chlorothalonil and its degradates. At both treated plots, chlorothalonil was detected at up to 0.02 ppm in the 9- to 12-inch depth. The soil was not sampled at the 12- to 15-inch depth until 29 or 222 days posttreatment; it is possible that chlorothalonil may have been present in both plots at this depth prior to 29 days posttreatment. At Plot B, the soil was sampled to a depth of 36 inches at 540 days following the last application, at which time SDS-3701 was detected at an average of 0.01 ppm in the 15- to 18-inch depth. The soil should have been sampled at all sampling intervals to depths (preferably two sampling depths) at which residues were nondetectable. Supplemental information which the study does provide includes the following:

1) Chlorothalonil was detected to a depth of 12-inches.

2) Chlorothalonil dissipated with an observed half-life of 14-29 days from the upper 12 inches of a plot of sandy loam soil that was treated at 10-day intervals with chlorothalonil (Bravo 720, 6 lb/gal F1C) at 1.12 lb ai/A/application ten times (total 11.2 lb ai/A).

3) The degradates occurred as follows:
   4-hydroxy-2,5,6-trichloroisophthalo nitrile (SDS-3701) was isolated as deep as the 9- to 12-inch depth
   2-hydroxy-5-cyano-3,4,6-trichlorobenzamide (SDS-47525) was isolated as deep as the 3- to 6-inch depth
   3-carboxy-2,5,6-trichlorobenzamide (SDS-46851), 3-cyano-2,4,5-trichlorobenzamide (SDS-47523/SDS-47524), and 3-cyano-2,4,5,6-tetrachlorobenzamide (SDS-19221) were isolated only in the 0-to 3-inch depth

4) The manufacturing impurities HCB and PCNB were isolated as deep as the 9- to 12-inch depth. The study authors stated that the levels of PCBN detected in soil from Plots A and B were related to the level of chlorothalonil residues present. The authors also concluded that the levels of HCB in the treated plots did not appear to be related to the Bravo 720 applications, since the concentrations of HCB were not significantly different than those detected in the control plot. In addition, pretreatment samples taken from the two treated plots contained detectable residues of HCB (0.003-0.006 ppm).

Greenfield, CA — MRID# 415648-30. This study is unacceptable. Plot B was replanted to broccoli on April 28, 1987, and re-treated as part of a rotational crop study reported separately. The cultural practices employed during the course of the study compromised study results. It is highly probable that these practices (cultivation, disking, and chiseling) resulted in movement of chlorothalonil residues to lower soil depths. Because the surface soil layers were mixed during the course of the study, the concentration of pesticide may have been diluted by bringing pesticide-free soil from lower horizons, and may have increased the rate of dissipation by aerating the soil and presenting new nutrient sources to the microbial population. Study results may also have been compromised by soil sampling procedures used -- samples may have been contaminated by the sampling process itself. Soil was not sampled deeply enough to define the extent of leaching of chlorothalonil and its degradates. At both treated plots, chlorothalonil residues were detected in the 12- to 15-inch depth, the lowest soil depth sampled. The soil should have been sampled to depths (preferably two sampling depths) at which residues were nondetectable. From selected data, the study author calculated a half-life of 40 days for chlorothalonil. The arbitrary exclusion of data used to calculate the half-life causes the resulting half-life to be of questionable value.

Accumulation in Confined Rotational Crop -- **MRID # 410302-11** -- lettuce, carrots, and wheat grown as confined rotational crops. Some uptake and concentration were detected at an exaggerated rate of application (4 x the maximum single application). Closely related metabolites accounted for around 1/3 of the total radioactivity observed in the

4

DATA EVALUATION REVIEW

I. Study Type: field rotational crop accumulation; guideline 165-2

II. Citation:

Kenyon, R.G. and Ballee, D.L. **Residues of Tetrachloroisophthalonitrile (Chlorothalonil, SDS-2787), SDS-370-1, SDS-46851, HCB and PCBN on Rotated Crops from Maine -1990**. dated 12/21/90. preformed by Ricerca, Inc., Painesville, OH. sponsored and submitted by Fermenta ASC Corporation, Mentor, OH. received EPA 4/9/91 no MRID#.

III. Reviewer

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

E.B. Conerly 4/30/91

IV. Conclusions:

This field crop accumulation study is not acceptable to completely fulfill the data requirement because the soil was not analyzed at planting time. Therefore, it is not certain that residues were available for uptake, or at what level. For these reasons, the study can only be considered supplemental. Under these experimental conditions, no uptake was observed.

V. Materials and Methods

general protocol -- the objective of the study was to determine the residues of chlorothalonil, 2,5,6-trichloro-4-hydroxyisophthalonitrile (SDS-3701), 3-carboxy-2,5,6-trichlorobenzamide (SDS-46851), hexachlorobenzene (HCB), and pentachlorobenzonitrile (PCBN) on rotated crops of corn, oats, and fresh peas grown on soil where crops had been treated the previous growing season. The follow crops were planted in the spring and harvested at normal maturity.

sampling -- crop samples were collected from August through October, 1990 at 13 sites in the state of Maine:

1) crops grown on soil where treated crops of potatoes had been grown

2) control crops grown where previous potato crops had not been treated

analyses -- chlorothalonil and other residues were selectively or directly partitioned into organic solvent by one of two extraction procedures depending upon crop group. Chlorothalonil, HCB, and PCBN were separated by column chromatography prior to quantitation by electron capture gas chromatography. Residues of SDS-3701 and SDS-46851 were derivatized to their methyl ether and methy ester, respectively, prior to quantitation. These residue derivatives were then subjected to column chromatography prior to quantitation. The assay methods were validated by determining recoveries from fortified samples -- these recoveries ranged from a low of 70 to a high of 117 percent across the spectrum of matrices and analytes (table attached).

plants. The remaining labelled material may derive from the soil "carbon pool". EGWB understands at this time that the residues which could be expected from use at legal label rates would not be of concern to TOX or Dietary Exposure Branches.

Accumulation in Field Rotational Crops -- one study discussed in the attached DER.

Previously reviewed MRID#s 415648-32 through -46 cannot be used to fulfill data requirements at this time. Levels of chlorothalonil and its degradates in the soil immediately posttreatment and at planting and harvest of the rotational crops could not be adequately assessed because the data were not presented in a reviewable format. In order for this study to be reevaluated, the registrant must provide summarized soil residue data, complete site characteristics, and meteorological data. In addition, the lengths of time the samples were stored frozen and acceptable freezer storage stability data must be provided. An ancillary Study - Freezer Storage Stability -- MRID#s 415648-20 through -27 cannot be used to fulfill data requirements because the experimental design used was not appropriate for determining the freezer storage stability of chlorothalonil and its degradates in the various plant matrices.

Laboratory Accumulation - Fish -- MRID #s 409745-31 and 409745-24 taken together -- Maximum bioconcentration factors reported for total[^{14}C]-in bluegill sunfish exposed to 0.06 ppm [^{14}C]Chlorothalonil for 28 days at 21^{0}C were 0.7-2.1X for edible tissues, 3.0-4.0X for non-edible tissues, and 2.3-3.6X for whole fish.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: See individual DER

11. COMPLETION OF ONE-LINER: new information added

12. CBI APPENDIX: attached to individual DER

VI. Study Author's Results and/or Conclusions:

Rotated crops of corn, oats and fresh peas were planted back into plots at several sites in Maine during 1990 at various pre-plant intervals following the harvest of the potatoes which had received 7 to 10 applications at rates ranging from 1.125 to 1.5 pints per acre during the 1989 growing season. These pre-plant intervals (time from last BRAVO application to planting of the rotated crop) ranged from 243 to 266 days. The rotated samples were harvested from 334 to 408 days after the last application.

No residues of chlorothalonil, SDS-3701, SDS-46851, HCB or PCBN were detected at method sensitivities of 0.01 ppm, 0.01 ppm, 0.03 ppm, 0.003 ppm, or 0.005 ppm, respectively, in any of the rotated corn, oats or fresh pea samples. Thus, no chlorothalonil related residues from the previous growing season were carried over into crops rotated into those treated areas in Maine.

VII. Reviewer's Comments:

These data are consistent with no residues being taken up in follow crops planted after potatoes, but are not definitive, for the following reasons:

1) No soil analyses were reported. It is impossible to assess the potential uptake without knowing that there were actually some residues present in the soil to which the plants were exposed. Some uptake has been demonstrated in confined rotational crops where application rates were exaggerated. It is EFGWB's understanding that, when the levels which were detected under these conditions are extrapolated to legal use levels, they are not of great concern at this time.

2) Some samples were not analyzed for all residue species, but some samples of each of the different crops were fully analyzed, with no reported residues.

VIII. CBI Information Addendum: attached

Page_____ is not included in this copy.

Pages 8 through 15 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Maine Department of Agriculture, Food and Rural Resources

Deering Building, State House Station 28, Augusta, Maine 04333

April 8, 1991

Susan Lewis
Product Manager, PM Team 21
Registration Division (H-7508W)
U.S. E.P.A.
401 M Street, SW
Washington, D.C. 20460

Dear Ms. Lewis:

I am writing to request that EPA perform an expedited review of the enclosed Maine residue study which ISK Biotech submitted to us on January 22, 1991. This data was collected to support a 24c label for Bravo 500 (EPA Reg. No. 50534-8) with reduced plant back restrictions for corn, oats and peas (application and label included in packet). Our Board has been hesitant to approve it, however, because they don't want to get involved in tolerance setting issues.

You indicated in our April 4th telephone conversation that this would be the preferable approach before the Board granted outright approval. At their meeting on April 5th, our Board members agreed and voted to approve the request contingent upon your Agency's finding that the residue study is adequate and appropriate.

ISK Biotech is proposing to reduce the plant back restrictions to 246 days for corn, 241 days for oats and 271 days for fresh peas. After reviewing a staff summary (enclosed) of ISK Biotech's national study, our Board voted to attach additional conditions as follows:

1. The 24c label would only be granted for an 18 month period (would allow potato use this year followed by one of the three crops in 1992).

2. The maximum allowable rate would be 1 1/2 pints per acre.

FAX 207 289-7548

16

University of Maine
Cooperative Extension

FEB 6 1991

February 4, 1991

Orono, Maine 04469

Mr. Robert Battesse, Director
Maine Board of Pesticide Control
State House Station #28
Augusta, Maine 04333

Dear Bob,

In the past few days the Maine Board of Pesticide Control has received a request for a Special Local Need State Registration under section 24(c) of FIFRA as amended from ISK Bioteck Corporation. The application is to alter the rotational crop planting restrictions for peas, oats and corn where BRAVO 500 fungicide was applied to potatoes the previous year. I am writing to encourage the board's favorable consideration of this application.

The production of disease and insect cycle interferring rotational crops are essential to the continued profitability and success of the Maine Potato Industry. The production of corn, oats and peas are especially essential in helping potato growers combat Colorado Potato Beetle populations as well as avert innoculum buildup of such pathogens as Rhizoctonia, White Mold, Verticillium and Fusarium fungi.

I understand considerable crop residue sampling was conducted during the late summer of 1990 to determine residue levels of chlorothalonil on fields of corn, oats and peas. I further understand no residues were found in testing the samples submitted. With the potential withdrawal of labeling for EBDC fungicides on the potato crop, chlorothalonil remains as the only broad spectrum, effective, limited phytotoxicity fungicide available for general use by the Maine Potato producer. The continued one full year plant back restriction for peas, oats, and corn places a severe crop management restriction on these growers.

I believe reducing the plant back restrictions by approximately 100 days on the three crops requested in Maine causes no environmental exposure, no applicator or field employee exposure concerns and no food safety problems for users of the crops. I shall be happy to discuss the special needs registration request with the board.

Sincerely,

Edwin S. Plissey
Extension Potato Specialist

cc Dave Lavway
Vaughn Holyoke
Bernard Shaw

3. The maximum allowable amount per season would be 15 pints.

You initially indicated such a review could take a month or so to complete. I am also enclosing a letter from Ed Plissey, Maine Cooperative Extension Service that further defines the urgent nature of this request. Thus I trust you will handle this as expeditiously as possible and contact me immediately if you need additional information and when you reach a final decision. If the eventual decision is favorable, we will complete processing of the application so growers may start planting oats this season on land that was planted to potatoes in 1990.

Thank you.

Sincerely,

Robert I. Batteese Jr.

Robert I. Batteese, Jr.
Director
Board of Pesticides Control

jlp
Enc. (3)
cc: B. Shaw
P. Curra
P. Ringhoff
E. Plissey
Board Members

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 17 1991

APR 17 1991

MEMORANDUM

SUBJECT: Request for an Expedited Review - Chlorothalonil - Shorter Rotational Crop Restrictions

FROM: Anne E. Lindsay, Director
Registration Division (H7505C)

TO: Ann L. Barton, Director
Environmental Fate and Effects Division (H7507C)

The Maine Department of Agriculture, Food and Rural Resources has requested an expedited review of rotational crop data that ISK Biotech (formerly Fermenta) submitted with their 24(c) application to shorten the 12 month rotational crop statement on their "Bravo", chlorothalonil, products. Maine has approved the request contingent upon the Agency finding that the study is adequate and appropriate.

Chlorothalonil is the main alternative to the EBDC's. Due to the EBDC controversy, growers last year switched from EBDC to chlorothalonil without recognizing the 12 month plant back restriction. If the 12 month restriction is not removed by this Spring, growers in Maine would be limited in the crops that can be planted.

Since the growing season has nearly started, the Registration Division is requesting that Environmental Fate and Groundwater Branch's review be completed no later than May 12, 1991. If it is not possible for you to complete these reviews by May 12, 1991, please indicate the earliest date that these reviews can be completed. Also let me know what pending actions will be effected by these expedited reviews.

CONCURRENCES								
SYMBOL	H7505C	H7505C	H7505C					
SURNAME		Lewis	Landry/ta					
DATE	4/12/91	4/15/91	4/15/91					

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

*U.S. GPO : 1986-159-319

9

DP BARCODE: D163512

CASE: 030292 DATA PACKAGE RECORD DATE: 04/30/91
SUBMISSION: S394387 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 350 GENRL CORRES REGISTRATION
CHEMICALS: 081901 Chlorothalonil (tetrachloroisophthalonitrile) 40.4000%

ID#: 050534-00008 BRAVO 500
COMPANY: 050534 FERMENTA ASC CORPORATION
PRODUCT MANAGER: 21 SUSAN LEWIS 703-557-1900 ROOM: CM-2 227
PM TEAM REVIEWER: JAMES STONE 703-557-7391 ROOM: CM-2 247
RECEIVED DATE: 04/09/91 DUE OUT DATE: 07/28/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 163512 EXPEDITE: Y DATE SENT: 04/11/91 DATE RET.: 04/30/91
CHEMICAL: 081901 Chlorothalonil (tetrachloroisophthalonitrile)
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 06/20/91 CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	04/15/91	04/30/91
BRAN: EFGB	04/16/91	04/30/91
SECT: CRS3	04/17/91	04/30/91
REVR : BCONERLY	04/17/91	04/30/91
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Maine has requested EPA review the attached data to see if it supports shorter rotational crop statments. Will be requesting an expedited review since need to know this Spring if can plant back the rotational crops. Refer to Brinson Conerly's review dated 3/5/91 of amendment to delete the statements completely.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Jen

APR 17 1991

MEMORANDUM

SUBJECT: Request for an Expedited Review - Chlorothalonil - Shorter Rotational Crop Restrictions

FROM: Anne E. Lindsay, Director
Registration Division (H7505C)

TO: Ann L. Barton, Director
Environmental Fate and Effects Division (H7507C)

The Maine Department of Agriculture, Food and Rural Resources has requested an expedited review of rotational crop data that ISK Biotech (formerly Fermenta) submitted with their 24(c) application to shorten the 12 month rotational crop statement on their "Bravo", chlorothalonil, products. Maine has approved the request contingent upon the Agency finding that the study is adequate and appropriate.

Chlorothalonil is the main alternative to the EBDC's. Due to the EBDC controversy, growers last year switched from EBDC to chlorothalonil without recognizing the 12 month plant back restriction. If the 12 month restriction is not removed by this Spring, growers in Maine would be limited in the crops that can be planted.

Since the growing season has nearly started, the Registration Division is requesting that Environmental Fate and Groundwater Branch's review be completed no later than May 12, 1991. If it is not possible for you to complete these reviews by May 12, 1991, please indicate the earliest date these reviews can be completed. Also let me know what pending actions will be effected by these expedited reviews.