

US EPA ARCHIVE DOCUMENT

FILE COPY

3-26-86



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 26 1986

PESTICIDE OFFICE OF
AND TOXICS

MEMORANDUM

SUBJECT: SDS Biotech Corporation's Responses of 2/5/85 and 12/23/85 to the Chlorothalonil Registration Standard Data Gaps (EPA Reg. No. 50534-7, RCB #385).

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Henry Jacoby, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Amy Rispin, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769C)

SDS Biotech Corporation submits requests for extensions of deadlines for submission of residue chemistry data on chlorothalonil [tetrachloroisophthalonitrile]. These requests are made in submissions dated February 5 and December 23, 1985. RCB's files do not show that the February 5, 1985 submission has been reviewed previously by RCB. Since the Registration Standard was issued on September 28, 1984, the following RCB/Registrant communications have taken place:

Dates of Registrant's Submissions

RCB Actions

02/05/85

- Received on 01/16/86 and under present review

03/28/85

- Completed review on 09/10/85

07/22/85

- Completed review on 09/23/85

12/23/85

- Received on 01/16/86 and under present review

The original deadline for residue studies identified as data gaps by the Chlorothalonil Registration Standard dated September 28, 1984 was December 28, 1985 (i.e., 15 months after the date of the Standard).

The petitioner contends that extensions of deadlines are needed because most crops could not be planted until approximately May 1, 1985. SDS Biotech requests extensions of 18 months (from May 1, 1985 through October 1986) for completion of crop field residue trials on raw agricultural commodities (RAC's) and 24 months (from May 1, 1985 to May 1, 1987) for processed food/feed residue studies. The petitioner indicates that PR Notice 85-5 suggests that up to 18 months will normally be allowed for generating crop field residue data and up to 24 months for processed food/feed residue studies. PR Notice 85-5 also states the following concerning residue chemistry data: "If data request is made at a time when planting is not normally done, additional time will be allowed."

The petitioner indicates that additional studies not cited in the Chlorothalonil Registration Standard support registered use patterns; the petitioner lists these studies in his Attachment 2 to the December 23, 1985 letter as a "Data Requirement Listing for the Owner Submission Method of Support for Part 158.125, Residue Chemistry Data Requirements." The petitioner indicates that the studies in Attachment 2 (which include references cited in the Standard and other studies) should all be considered by the Agency.

In the letter dated February 5, 1985, SDS Biotech listed its plans for satisfying the data requirements under Section 158.120 - Product Chemistry and Section 158.125 - Residue Chemistry, which were identified as data gaps in the Registration Standard. These plans (with revisions as of the December 23, 1985 letter) are summarized below, followed by SDS Biotech's Response and RCB's comments/conclusions:

Section 158.120 - Product Chemistry

SDS Biotech has indicated that it submitted updated Confidential Statements of Formula for two technical and eight formulated chlorothalonil products on December 28, 1984.

In the letter dated February 5, 1985, SDS Biotech indicated that it will submit generic data for chlorothalonil product chemistry by March 28, 1985.

RCB's Comments/Conclusions re: Product Chemistry

Product chemistry is not discussed in the letter dated December 23, 1985.

Note to PM: Has the generic data for chlorothalonil product chemistry been submitted?

Section 158.125 - Residue ChemistryData Gap - Plant Metabolism

The metabolism of chlorothalonil residues in plants is not adequately understood due to the lack of sufficient data on this topic. The following additional data are required:

- a. Studies in which unidentified water-soluble compounds, which constitute the major portion of the [^{14}C]chlorothalonil residues taken up from treated soil by plants, are characterized along with other possible metabolites of chlorothalonil.
- b. Translocation studies involving the application of ring-labeled [^{14}C]chlorothalonil to foliar plant surfaces. (One such study was submitted but involved immature plants.)

SDS Biotech's Response

The registrant has responded in part to this data gap in its March 28, 1985 submission (see Accession No. 25717) in which it has included the results of a lettuce metabolism study and has stated its intention of performing additional root crop and fruiting crop metabolism studies.

In the submission dated February 5, 1985, the petitioner referred to a study by Mason Gilbert, "Fate of Chlorothalonil in Apple Foliage and Fruit," J. Agric. Food Chem., 24, 1004-1007 (1976). This article was discussed in RCB's review of PP#4F3025 (memorandum of M. Kovacs, Jr., May 30, 1984):

"In this paper the possible translocation of ^{14}C -chlorothalonil was studied using 4-month-old McIntosh apple seedlings raised under greenhouse conditions in which the top and bottom surfaces of selected leaves were painted with a radioactive mixture of ^{14}C -chlorothalonil and ethephon. Seedlings were harvested after 3 days and covered with medical x-ray film for 2 weeks at 4°C in a dark room. In addition, leaves and fruit of mature McIntosh trees were harvested over a 12-day sampling period and analyzed for radioactive residues of chlorothalonil by LSC and by GLC following treatment with 500 ppm ^{14}C -chlorothalonil in an aqueous solution by brush application. Leaf samples and chopped apple samples were either rinsed with an acetone: 50% H_2SO_4 mixture (100:1 v/v) or extracted with acidic acetone (95:5 v/v) in a blender. All sample extracts were treated with NaHCO_3 , partitioned with hexane and the aqueous fractions acidified with 50% H_2SO_4 and partitioned with diisopropyl ether. The hexane and ether extracts were analyzed by GLC with a ^{63}Ni EC detector; these organic fractions were also analyzed by LSC.

Autoradiographs prepared from apple seedlings harvested 3 days after treatment demonstrated the absence of chlorothalonil translocation. Gilbert's paper reports that from 90-99% of the harvest residues of chlorothalonil were present in the outer waxy

layers of apple leaves and was not chemically degraded as evidenced by GLC analysis. Similarly, Gilbert said that 84-99% of the total ^{14}C residue on apples was surface in nature and presumably attributable to undegraded chlorothalonil.

However, after observing Figures 2, 3, and 4 of Gilbert's paper which are reproduced and attached to this review, it is difficult to agree with Gilbert that all of the extracted radioactive residues were only chlorothalonil. For example, at 0-day PHI, apple peeling (see Figure 3) contained about 11 ppm GLC equivalence of chlorothalonil. At 12-day PHI, the peeling contained about 3 ppm GLC equivalence of chlorothalonil. Therefore these GLC analyses do not indicate that 84-99% of the radioactive residue in each sample was recovered. On the other hand, if liquid scintillation detection did indicate that 84-99% of the radioactive residues were recovered, then 8 ppm (11 ppm - 3 ppm), about 73% of the total residue was not identified at 12-day PHI; that is, if the GLC procedure detected all of the chlorothalonil residues at 0-day PHI.

In our opinion the aforementioned study does not meet the Subpart O Residue Chemistry Guidelines requirements for a plant metabolism study since an adequate account of the applied chlorothalonil was not achieved. Gilbert should have indicated where the radioactive material was labeled and should have used TLC, mass spec., etc., in his work.

Although it was concluded in the earlier petitions cited above that the residue in plants (corn and tomatoes, PP#7F0599, and potatoes, PP#9F0743) is mainly surface in nature, and not translocatable with no uptake from roots to aerial plant parts with the parent compound and the 4-hydroxy metabolite the residues of concern, we now conclude that the metabolism studies cited in the earlier petitions are not translatable to the currently proposed use on apples. The earlier plant metabolism studies reflected primarily soil applications of chlorothalonil with the resultant translocated residues characterized in immature plant tissue. On the other hand, the currently proposed use involves foliar applications of chlorothalonil to apples approaching maturation, a physiological condition which would lend itself to a different rate and pattern of metabolite formation than that previously observed in earlier metabolism studies.

Our conclusions arrived at above concerning the nontranslatability of previously submitted chlorothalonil metabolism studies to the currently proposed use on apples are based upon the identified inadequacies of these studies (see Chlorothalonil Registration Standard, 11/4/83, Residue Chemistry Chapter, Nature of the Residue in Plants, p. 2 under Conclusions) and the EPA guidelines §171-4(a)(2), Subdivision O, Residue Chemistry with regard to plant metabolism requirements.

Accordingly, for the purposes of the proposed tolerance on apples, we will require that the petitioner submit a ring-labeled ^{14}C foliar chlorothalonil apple metabolism study.

For the purpose of establishing a permanent tolerance of 0.1 ppm on the rac apples as proposed in this petition, we therefore conclude that the nature of the residue in plants is not adequately understood."

No new response to this data gap is included in the subject (December 23, 1985) submission.

RCB's Comments/Conclusions re: Plant Metabolism

The following comments/conclusions are restated below from RCB's September 10, 1985 review by M. Firestone, Ph.D., of SDS Biotech's March 28, 1985 submission:

"The major terminal residue in lettuce was found to be the parent compound chlorothalonil. The relative amount of the metabolite 4-hydroxy-chlorothalonil (SDS-3701) was found to slowly increase with time.

While the lettuce metabolism study reflecting foliar application shows that the parent compound comprises a majority (> 87%) of the terminal residues up to 21-days post-application, the following questions remain with respect to the metabolism of chlorothalonil in lettuce:

1. To what extent can lettuce plants take up the five identified soil metabolites (i.e., should these metabolites be included in the chlorothalonil tolerance expression)?
2. To what extent is chlorothalonil translocated across foliar surfaces in mature lettuce plants?
3. What is the nature of the residue at very long PHI's?

The registrant must consider the above questions with respect to the pending root crop and fruit crop metabolism studies."

At this time, data gaps remain with respect to the metabolism of chlorothalonil in plants.

Data Gap - Animal Metabolism

The following comments/conclusions re: Animal Metabolism are restated below from RCB's September 23, 1985 review by M. Firestone, Ph.D., of SDS Biotech's July 22, 1985 submission:

"Presently, tolerances for residues of chlorothalonil in feed items are expressed in terms of the parent (DAC 2787) and its 4-hydroxy metabolite (DAC 3701); however, the propriety of

the currently established tolerance definition is currently in question due to the inadequacy of the available plant metabolism data (see Nature of the Residue in Plants section of the standard). Further, the metabolism of chlorothalonil and DAC-3701 in food animals is not adequately understood. The available ruminant studies did not utilize labeled material (except in one of the rumen fluid studies) and did not identify or quantify residues in tissues (muscle, liver, kidney, and fat). The available rat and dog metabolism studies are useful for comparative purposes but cannot substitute for studies involving poultry and ruminants. The following additional data are required:

- a. Studies which elucidate the metabolism, distribution, and accumulation of [^{14}C]chlorothalonil and of [^{14}C] DAC-3701 in poultry and ruminants, including eggs and milk, respectively. A non-ruminant (swine) metabolism study may be required if the ruminant metabolism study is found to differ significantly from that of the rat. Also, if the required plant metabolism data indicate that additional metabolites are residues of concern, additional animal metabolism studies utilizing these metabolites may be necessary.
- b. Data are also required for the determination of whether or not the impurities in technical chlorothalonil need to be included in the meat, milk, poultry and egg tolerances (note: the presence of hexachlorobenzene [HCB] and pentachlorobenzonitrile [PCBN] is of greatest significance)."

SDS Biotech's Response

SDS Biotech, in the latest letter dated December 23, 1985, indicates that a large number of laboratory animal metabolism studies have been conducted since the Standard was issued.

SDS Biotech (December 23, 1985 letter) intends to initiate lactating goat studies with ^{14}C -chlorothalonil in early 1986 and a later ^{14}C -SDS-3701 study.

RCB's Comments/Conclusions re: Animal Metabolism

RCB still requires poultry and ruminant feeding studies as specified in "a" and "b" below (as stated in RCB's review by M. Firestone dated September 23, 1985):

- a. "Studies which elucidate the metabolism, distribution, and accumulation of [^{14}C]chlorothalonil and of [^{14}C] DAC-3701 in poultry and ruminants, including eggs and milk, respectively. A non-ruminant (swine) metabolism study may be required if the ruminant metabolism study is found to differ significantly from that of the rat. Also, if the required plant metabolism data indicate that additional metabolites are residues of concern, additional animal metabolism studies utilizing these metabolites may be necessary."

- b. "Data are also required for the determination of whether or not the impurities in technical chlorothalonil need to be included in the meat, milk, poultry and egg tolerances (note: the presence of hexachlorobenzene [HCB] and pentachlorobenzonitrile [PCBN] is of greatest significance)."

The animal metabolism data gap has not been resolved.

Data Gap - Analytical Methodology

In the event that residues of HCB and PCBN are included in the tolerance definition for residues resulting from the use of chlorothalonil, an adequate validated analytical method should be submitted for regulatory enforcement purposes.

SDS Biotech's Response

None

RCB's Comments/Conclusions re: Analytical Methodology

At this time, RCB is unable to reach any final conclusion as to the need to include HCB and PCBN in the chlorothalonil tolerance expression. Thus, this issue remains outstanding as a possible data gap.

Data Gap - Magnitude of the Residue in Plants

According to the Chlorothalonil Registration Standard, additional residue data are required to support established tolerances and label directions for use on the following crops: carrots, parsnips (root), potatoes (RAC plus processed foods/feeds), onions (dry bulb and green), celery, broccoli, brussels sprouts, cabbage, cauliflower, beans (dried), snap beans, soybeans (processed foods/feeds only), tomatoes (RAC only), cucumbers, melons, pumpkins, squash (summer and winter), sweet corn (fresh market), bananas, mint hay (RAC plus processed foods/feeds), papaya (RAC), passion fruit (RAC), peanuts (RAC plus processed foods/feeds), and cottonseed (RAC plus processed foods/feeds).

SDS Biotech's Response

SDS Biotech has submitted comments concerning analyses of hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN). The registrant has also submitted comments concerning all of the above crops. These comments given below are followed by RCB's comments/conclusions.

Hexachlorobenzene (HCB) and Pentachlorobenzonitrile (PCBN)

Contaminants in Technical Chlorothalonil

The registrant argues the following in his February 5, 1985 submission:

". . . SDS Biotech has provided the Agency with various studies which have effectively demonstrated that residues of HCB do not occur from the presently registered uses of chlorothalonil. PCBN should not be present in chlorothalonil-treated crops at levels of toxicological concern. SDS Biotech agrees to provide additional data and conduct some additional studies; however, it has already been demonstrated that residues occurring on the harvested crop are in the same relative proportions to chlorothalonil as exist in the formulation; therefore, the EPA should not expect the registrant to routinely conduct costly analyses on each and every crop for HCB and PCBN. Analyses for chlorothalonil and SDS-3701, the primary metabolite, should satisfy residue requirements for most crops, especially if these residues are low. To require continued analyses for HCB and PCBN will essentially only continue to demonstrate what is already known.

SDS therefore requests the EPA require HCB and PCBN studies only for cases of special concern. Routine analyses should not be a continuing requirement. Reliable extrapolations could be made for expected HCB and PCBN residues on/in most crops, based on known information. A strong data base supports this position."

RCB's Comments/Conclusions re: Analyses of HCB and PCBN

RCB continues to require residue data on HCB and PCBN since these are residues of toxicological concern.

Carrots

SDS Biotech will provide additional data (February 5, 1985 letter).

RCB's Comments/Conclusions re: Carrots

This data gap has not been resolved. RCB awaits submission of residue data on carrots.

Parsnips

SDS Biotech wants to use residue data for carrots and potatoes to cover parsnips, rather than generate residue data for the minor crop parsnips.

Representative crops for the crop group root and tuber vegetables are carrots, potatoes, radishes, and sugarbeets.

RCB's Comments/Conclusions re: Parsnips

Since no residue data are available on radishes and sugarbeets, the petitioner cannot use the group tolerance approach. As far as climatic conditions are concerned, parsnip is adapted to much of the country, but commercial production is done mostly in the

northern portion of the country extending from the New England States to the Pacific Coast. At this time, additional residue data are required to support the established tolerance and label directions.

This data gap is not resolved. RCB awaits submission of residue data on parsnips.

Potatoes (RAC)

SDS Biotech indicated in the February 5, 1985 letter that additional crop residue data including assays for HCB and PCBN would be provided. Additional residue data on chlorothalonil, HCB, and PCBN were submitted on July 22, 1985 and reviewed. (Refer to review of September 23, 1985 by M. Firestone).

RCB's Comments/Conclusions re: Potatoes (RAC)

RCB repeats the conclusions contained in the September 23, 1985 review:

"The data contained in the subject submission are inadequate to satisfy the data gap outlined in the Standard.

Additional field trials must be conducted in California, Colorado, Idaho, and Oregon or Washington involving the maximum number of likely applications at intervals of 1 week and reflecting a 0-day PHI.

Residues of chlorothalonil, per se, its 4-hydroxy metabolite (and any other metabolites if found to be of toxicological concern), and the contaminants PCBN and HCB must be quantitated in all samples."

This data gap remains unresolved.

Potatoes (Processed Food/Feed)

SDS Biotech is conducting a potato processing study (December 23, 1985 letter). (A waiver of the potato processing study was previously requested in the February 5, 1985 letter.)

RCB's Comments/Conclusions re: Potatoes (Processed Food/Feed)

This data gap has not been resolved. RCB awaits submission of the potato processing study.

Onions (Dry Bulb)

SDS Biotech will provide the residue studies requested. As of the February 5, 1985 letter, the report (on 1985 studies) will be available in 1986.

Onions (Green)

Residue data will be obtained in 1985 (as of the February 5, 1985 letter).

Note: SDS Biotech plans to obtain data on one of the three crops garlic, leeks, and shallot in order to obtain a crop group tolerance. Since representative crops for the bulb vegetables crop group are onions (green and bulb) and one other bulb vegetable commodity, RCB has no objection to this plan.

RCB's Comments/Conclusions re: Onions (Dry Bulb and Green)

These data gaps have not been resolved. RCB awaits submission of the residue data.

Celery

SDS Biotech indicated in the February 5, 1985 letter that it would provide the additional crop residue data requested by the Standard, including analyses for HCB and PCBN. In addition, SDS Biotech planned to conduct a field-to-grocery store study to investigate the effects of commercial washing and trimming practices on the reduction of chlorothalonil levels prior to human consumption.

SDS Biotech submitted residue data on chlorothalonil, HCB, and PCBN in the July 22, 1985 submission. (Refer to the review of September 23, 1985 by M. Firestone.)

RCB's Comments/Conclusions re: Celery

RCB repeats the conclusions contained in the September 23, 1985 review:

"The data submitted in Report No. 334-3CR-80-0137-001 are not sufficient to satisfy the data gap outlined in the Chlorothalonil Registration Standard.

Field trials must be conducted in Florida, California, and Michigan reflecting at least 16 to 24 weekly foliar treatments, PHI's of 7 to 14 days, and analysis for residues of parent compound, all metabolites of toxicological concern, and the contaminants HCB and PCBN."

This data gap has not been resolved.

Broccoli

SDS Biotech will provide additional residue data, including assays for HCB and PCBN.

RCB's Comments/Conclusions re: Broccoli

This data gap has not been resolved. RCB awaits submission of residue data on broccoli.

Brussels Sprouts

SDS Biotech has submitted the following statement:

"Crop Field Trials: Additional crop residue data will be generated and provided to the EPA. It is believed that Brussels sprouts plantings are normally small acreages which are treated using ground equipment. SDS Biotech has developed a substantial data base comparing residues of chlorothalonil on various crops treated by aerial equipment vs. ground equipment. It has been determined that in all cases, chlorothalonil residues resulting from aerial applications are lower than corresponding residues from ground-applied applications. Because of the data base already available for comparison and the limited use, if any, of aerial applications on Brussels sprouts, SDS Biotech requests the EPA waive the need for studies involving aerial vs. ground comparisons."

RCB's Comments/Conclusions re: Brussels Sprouts

The Agency will not waive the requirement for data reflecting aerial applications. The company can either supply the aerial data, or revise the label to specify application by ground equipment and to delete directions for aerial application.

This data gap has not been resolved. RCB awaits submission of additional residue data.

Note: Tests should be conducted in California employing 13 weekly applications of the 4.17 lb/gal FlC at 1.43 lb ai/A and the 75 percent WP at 1.5 lb ai/A.

Cabbage

SDS Biotech will submit additional residue data, including assays for chlorothalonil, SDS-3701, HCB, and PCBN.

SDS Biotech requests a waiver of the requirement for aerial application data, for reasons given under "Brussels Sprouts."

RCB's Comments/Conclusions re: Cabbage

The Agency will not waive the requirement for data reflecting aerial applications. The company can either supply the aerial data, or revise the label to specify application by ground equipment and to delete directions for aerial application.

This data gap has not been resolved. RCB awaits submission of additional residue data.

Cauliflower

SDS Biotech will submit additional residue data, including assays for chlorothalonil, SDS-3701, HCB, and PCBN.

SDS Biotech requests a waiver of the requirement for aerial application data, for reasons given under "Brussels Sprouts."

RCB's Comments/Conclusions re: Cauliflower

The Agency will not waive the requirement for data reflecting aerial applications. The company can either supply the aerial

data, or revise the label to specify application by ground equipment and to delete directions for aerial application.

This data gap has not been resolved. RCB awaits submission of additional residue data.

Beans (Dried)

SDS Biotech will submit additional residue data, including assays for chlorothalonil, DAC-3701, HCB, and PCBN.

RCB's Comments/Conclusions re: Beans (Dried)

This data gap has not been resolved. RCB awaits submission of additional residue data.

Snap Beans

The letter dated February 5, 1985 indicated that additional residue data would be submitted. Additional residue data were submitted with the July 22, 1985 submission. (Refer to the review of September 23, 1985 by M. Firestone.)

RCB's Comments/Conclusions re: Snap Beans

RCB repeats the conclusions contained in the September 23, 1985 review:

"The petitioner will need to conduct additional field trials in the northeast, mid-Atlantic, and Great Lakes states which reflect the maximum number of likely applications possible.

Residue data must be generated for chlorothalonil, its 4-hydroxy metabolite, any other metabolites which are found to be of toxicological concern, HCB, and PCBN.

At this time, a Data Gap still exists regarding the adequacy of the snap bean residue data to support the established tolerance."

Soybeans (Processed Food/Feed)

As indicated in the December 23, 1985 letter, SDS Biotech has begun a soybean processing study in which chlorothalonil, SDS-3701, HCB, and PCBN are determined. The study will be conducted as follows:

"SDS Biotech plans to obtain field-weathered samples from soybeans treated approximately 7 days before harvest for comparison with samples treated at the normal pre-harvest interval (PHI) of 42 days. The 7-day PHI should maximize the possibility of residues occurring at sufficiently high levels to conduct a valid processing study. SDS Biotech does not believe that post-harvest spiking of samples is an appropriate or representative procedure for this study. The company also feels 3% field trash (by weight) is an inappropriate request. The American Soybean Association told SDS that the vast majority of soybeans are

sold as No. 1 and No. 2 beans, containing no more than 1% or 2% foreign material, respectively. Farmers have the ability to remove most foreign material during harvesting, and it is to their economic advantage to do so. We do not, therefore, believe that 3% field trash should be a necessary criterion of the study. The 7-day PHI is believed to be a preferred method for allowing for the possibility of significant residues to be present. It is expected that some trash will be present in the samples, however."

The report is not expected to be available until late 1986. SDS requests an extension for the soybean processing study.

RCB's Comments/Conclusions re: Soybeans (Processed Food/Feed)

In the Registration Standard, RCB stated that soybean samples to be processed should consist of approximately 3 percent field trash (by weight). RCB realizes that soybeans to be processed may actually contain 1 to 3 percent field trash. Since the majority of soybeans are sold with 1 or 2 percent field trash, RCB has no objection to use of soybeans with 2 percent field trash in the processing study.

This data gap has not been resolved. RCB awaits submission of the soybean processing study.

Tomatoes

SDS Biotech will submit additional residue data, including assays for HCB and PCBN.

"SDS Biotech has presented data to the Agency previously on the effects of washing and processing on residues on/in tomatoes and tomato products. Plans are also in progress to conduct a farmer-to-grocery store study to evaluate the effects of commercial packaging/handling procedures on reduction of chlorothalonil residues prior to human consumption of fresh tomatoes. This study, and previously reported washing/processing data, should enable fairly realistic estimates to be made of the actual dietary exposure to chlorothalonil relative to consumption of tomatoes and tomato products."

RCB's Comments/Conclusions re: Tomatoes

This data gap has not been resolved. RCB awaits submission of additional residue data.

Cucumbers

In the letter dated February 5, 1985, SDS Biotech made the following comments:

1. "Data have previously been presented to the Agency in support of the presently registered use pattern for BRAVO 500 on cucumbers, including the early vining application for control of belly rot. It is SDS Biotech's belief that the likelihood of significant residues occurring on the RAC is greatest when weekly applications are made while the fruit is developing. At the time when vines begin to form and a single 6.26 lb ai/A application is made for control of fruit belly rot, there are no fruit formed. Data have been previously submitted to the Agency which demonstrate there is no reasonable expectation that this application would contribute significantly to high residues occurring later on the harvested crop. Foliar applications made during the time when fruit are developing are expected to make, by far, the greatest contribution towards any residue in/on the harvested crop. Therefore, weekly foliar studies should be of greatest value in determining whether or not chlorothalonil residues may exceed the established tolerances."
2. "Plans are underway to conduct a processing study on cucumbers to determine the effects of washing and processing (into cucumbers) on reduction of residues, since residues are considered to be primarily surface residues which are greatly reduced during washing and processing operations (demonstrated through studies on other crops also)."
3. SDS Biotech requests a waiver of the requirement for aerial application data, for reasons given under "Brussels Sprouts."

Additional residue data on cucumbers were submitted in the July 22, 1985 submission (review dated September 23, 1985 by M. Firestone).

RCB's Comments/Conclusions re: Cucumbers

The Agency will not waive the requirement for data reflecting aerial applications. The company can either supply the aerial data, or revise the label to specify application by ground equipment and to delete directions for aerial application.

Since the vine application rate is almost 3X that of the foliar application rate, RCB continues to request the vine application along with at least nine multiple foliar applications as described below and in the Registration Standard.

RCB repeats the conclusions contained in the September 23, 1985 review:

"The geographical representation of the residue data submitted with the subject (July 22, 1985) response is considered inadequate since field trials were not conducted in the states of Texas, California, and South Carolina as specified in the Chlorothalonil Registration Standard. Additional field trials should be conducted

reflecting at least nine foliar applications (0-day PHI) and a single application at 6.26 lb ai/A during vine formation as previously requested. Residue data should also be generated for the metabolite DAC-3701 as well as HCB and PCBN.

Until the above additional data have been generated, RCB will be unable to reach any final conclusion regarding the adequacy of the established chlorothalonil tolerance for cucumbers.

Pending resolution of the data gap re: Nature of the Residue in Plants, additional residue data may also be required for chlorothalonil metabolites other than DAC-3701 found to be of toxicological concern in/on cucumbers."

Melons

In the submission dated February 5, 1985, SDS Biotech made the following comments:

"Although a tolerance of 5 ppm has been established for chlorothalonil on melons, residues are known to be surface residues which are primarily removed along with the peel. In the June 15, 1981 Federal Register, p. 31280, the EPA said, '. . . the rinds of fresh melons are not consumed by humans. Even if the rind is converted to preserves, the outside, impervious portion of the rind is also removed prior to cooking.' Although SDS Biotech plans to submit additional crop residue data on melons, residues present on the whole fruit would have little bearing on the actual human dietary exposure to residues present in the edible portion."

In the submission of July 22, 1985, SDS Biotech submitted additional residue data, including assays for HCB and PCBN. (Refer to the September 23, 1985 review by M. Firestone).

RCB's Comments/Conclusions re: Melons

RCB repeats the conclusions contained in the September 23, 1985 review:

"The data contained in the subject submission are not considered adequate to resolve the issues involving the adequacy of the melon tolerance.

As previously requested, field trials should be conducted in both California and Texas reflecting multiple (at least 11) weekly applications at the maximum (2.25 lb ai/A) label rate, and harvested on the last day of treatment. The following residues should be determined:

- a) chlorothalonil
- b) DAC-3701 (4-hydroxy metabolite)
- c) HCB
- d) PCBN
- e) any metabolite other than DAC-3701 found to be of toxicological concern

This data gap remains unresolved at this time."

Pumpkins

SDS Biotech intends to use residue data on squash to cover pumpkins.

RCB's Comments/Conclusions re: Pumpkins

Representative commodities of the crop group fruiting vegetables are cucumbers, melons (cantaloupe or muskmelon), and summer squash. Residue data will be available for cucumbers, melons, and summer squash. Therefore, a crop group tolerance may be possible.

This data gap has not been resolved. RCB awaits submission of residue data on the representative crops.

Squash (Summer and Winter)

SDS Biotech will submit residue data.

RCB's Comments/Conclusions re: Squash (Summer and Winter)

This data gap has not been resolved. RCB awaits submission of additional residue data on squash.

Corn (Fresh Market, Sweet)

As of the February 5, 1985 letter, SDS Biotech planned to conduct field studies in 1985 to obtain residue data on chlorothalonil, SDS-3701, HCB, and PCBN.

The petitioner made the following comment in the February 5, 1985 letter:

"The requirement for 8 weekly applications beginning just prior to silking is not a realistic requirement for sweet corn, as the crop would be too hard for use as 'sweet corn.' Tests will be conducted to represent the maximum number of applications normally expected according to label instructions."

RCB's Comments/Conclusions re: Corn

If fewer than eight applications will be made in the residue data which will be submitted, then SDS Biotech should revise the labels for corn to state that no more than X number of applications should be made per season, X being the number of applications which the residue data support.

Bananas

In the February 5, 1985 letter, SDS Biotech indicated that residue studies, including analyses for HCB and PCBN, would be

conducted in "countries where reliable studies can be carried out."

SDS Biotech also made the following comment in the February 5, 1985 letter:

"Based on a fairly large number of residue studies on other crops, no residues of HCB or PCBN are anticipated. SDS Biotech does not, therefore, believe that a great number of studies will be needed to demonstrate that HCB and PCBN residues are not expected to occur in bananas. A few representative studies should suffice."

In the submission dated July 22, 1985, SDS Biotech submitted residue data on bananas from Panama. (Refer to the review dated September 23, 1985 by M. Firestone.)

RCB's Comments/Conclusions re: Bananas

RCB repeats the conclusions contained in the September 23, 1985 review:

"RCB considers the Panama banana study inadequate because of the limited number of applications, the low application rate, and the length of time between treatments (approximately 3X those requested).

Also, no residue data have been submitted for residues of HCB and PCBN in bananas.

Until the registrant satisfies the data gaps cited in the Registration Standard, sufficient data remain unavailable to reassess the adequacy of the established tolerance of 0.5 ppm and label directions for bananas. Since the nature of the residue in plants is not considered adequately understood, the registrant should be informed that residue data may also be required for chlorothalonil metabolites other than DAC-3701 if they are found to be of toxicological concern.

This data gap has not been resolved."

Mint Hay (RAC)

SDS will submit additional residue data, including analyses for HCB and PCBN.

SDS may seek to expand the label to allow use in the Northwest.

In the Registration Standard, the Agency stated that mint hay is not under the control of the grower. SDS Biotech wishes to retain the label restriction against feeding of extracted mint hay to livestock as explained below:

"Commercial practices consist of primarily tractor-drawn stills which are set in the field and utilize steam distillation for removal of the mint oil. In the majority of cases, the spent hay remains on the farm under the control of the grower. SDS Biotech acknowledges that mint hay may potentially be used as a livestock feed; however, previous investigations by the company found that feeding of mint hay to livestock is essentially not done. Following are references who can be contacted for additional

information:

Dr. Calvin B. Scotland
 Washington State University
 Prosser, WA 99350
 509/984-5500

Dr. Ralph Green
 Dept. of Botany & Plant Pathology
 Purdue University
 W. Lafayette, IN 47907
 317/494-4642

Based on SDS Biotech's present knowledge, we do not agree with the EPA that the label restriction against the feeding of extracted mint hay to livestock is inappropriate; It is understood that the majority of mint hay 'is under the control of the grower'. It is apparent that EPA's concern about the potential for residue resulting in meat and milk from the feeding of mint hay does not correlate with established practices, and therefore is not justified. We feel the benefits from the use of chlorothalonil on mint vastly outweigh the potential hazards on any small amount, if any, that may be fed. We therefore request the EPA allow the present label feeding restriction to remain in effect, since this is a minor crop."

RCB's Comments/Conclusions re: Mint Hay (RAC)

The registrant contends that in the majority of cases, the spent hay remains on the farm under control of the grower. We must, however, consider also that portion of the mint hay production that does leave the farm for removal of mint oil. Thus, the Agency maintains the position that mint hay is not completely under grower control.

This data gap is not resolved. RCB awaits submission of additional data.

Mint (Processed Food/Feed)

SDS will submit residue data for mint oil, including analyses for HCB and PCBN.

RCB's Comments/Conclusions re: Mint (Processed Food/Feed)

This data gap is not resolved. RCB awaits submission of additional data.

Papaya

SDS Biotech has indicated that it cannot justify the expense of generating the requested residue data on this minor crop. Papaya is a minor crop of approximately 3000 acres, located primarily in Hawaii.

SDS Biotech would like the Interregional Research Project No. 4 (IR-4) to conduct these studies.

Otherwise, SDS Biotech wants EPA to extrapolate from available residue data on papaya and other crops to conclude that residues on papaya are "primarily surface residues which would be removed along with the peel" leaving extremely low residues in the edible portion.

Papaya (Processed Food/Feed)

As stated above, SDS Biotech cannot justify the expense of conducting a processing study on papaya.

RCB's Comments/Conclusions re: Papaya and Processed Food/Feed

Residue data on papaya fruit may be submitted either by the petitioner or IR-4. RCB concludes that no residue data will be required on those fractions resulting from a papaya processing study. The data gap for residues on papaya fruit is not resolved.

Passion Fruit

SDS Biotech cannot justify the expense of generating residue data on this minor crop.

SDS Biotech would like the IR-4 to conduct these studies.

Otherwise, SDS Biotech wants EPA to extrapolate from residue data on other crops to conclude that residues on passion fruit are surface residues.

Passion Fruit (Processed Food/Feed)

As stated above, SDS Biotech cannot justify the expense of conducting a processing study on passion fruit. The company wants to use washing and processing studies on other crops to estimate residues in passion fruit after washing and processing.

RCB's Comments/Conclusions re: Passion Fruit and Processed Food/Feed

Residue data on passion fruit may be submitted either by the petitioner or IR-4. Because of today's agricultural practices, RCB will not require residue data on those fractions resulting from a passion fruit processing study. The data gap for additional residue data on passion fruit, the raw agricultural commodity, is not resolved.

Peanuts

SDS Biotech will provide additional residue data on peanuts.

Peanuts (Processed Food/Feed)

A processing study on peanuts is underway.

SDS Biotech requests an extension of the deadline for this study for the following reason:

"An attempt will be made shortly before harvest to produce a field incurred spike on peanuts previously treated with chlorothalonil throughout the growing season. By the time samples can be obtained from 1985 field studies, are processed, analyzed, and a report is written, it is expected results will not be available until 1986."

RCB's Comments/Conclusions re: Peanuts and Processed Food/Feed

These data gaps are not resolved. RCB awaits submission of additional residue data and a processing study.

(The extension request is discussed at the end of this review.)

Cottonseed

SDS Biotech indicates it has no registration for this use, so no work is planned.

RCB Comments/Conclusion re: Cottonseed

None

Recommendations

The Chlorothalonil Registration Standard guidance package was mailed on October 26, 1984; so on April 26, 1986, the Registrant will have had 18 months in which to generate residue data on RAC's and will have had 24 months in which to generate residue data on processed food/feed commodities on October 26, 1986. Thus, to extend the deadlines to November 1, 1986 for completion of crop field residue trials on raw agricultural commodities and to May 1, 1987 for processed food/feed residue studies would be time frames of about 24 and 30 months, respectively. The petitioner contends that extensions of deadlines are needed because most crops could not be planted until approximately May 1, 1985.

In summary, the following data gaps are still outstanding:

1. Generic data for chlorothalonil product chemistry, if not confirmed by PM #21.
2. Plant metabolism
3. Animal metabolism
4. Possibly an adequate validated analytical method for HCB and PCBN if these compounds are regulated.
5. Residue data on the following raw agricultural commodities: carrots, parsnips (root), potatoes (RAC plus processed foods/feeds), onions (dry bulb and green), celery, broccoli, brussels sprouts, cabbage, cauliflower,

beans (dried), snap beans, soybeans (processed foods/feeds only), tomatoes (RAC only), cucumbers, melons, pumpkins, squash (summer and winter), sweet corn (fresh market), bananas, mint hay (RAC plus processed foods/feeds), papaya (RAC), passion fruit (RAC), peanuts (RAC plus processed foods/feeds), and cottonseed (RAC plus processed foods/feeds).

Considering the magnitude of residue and metabolism data needed, the registrant should have initiated a vigorous program during the growing seasons of 1985. If extensions are granted, RCB recommends that periodic progress reports be submitted to the Agency.

cc: Circu., RF, Chlorothalonil SF, Bill Boodee-Chlorothalonil
Reg. Std. File, Reviewer-N.Dodd, PMSD/ISB-Eldredge
RDI:J.H.Onley:3/7/86:R.D.Schmitt:3/10/86
TS-769:RCB:CM#2:RM 810:X1681:N.Dodd:Kendrick & Co.:3/17/86