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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 18 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F2980 Chlorothalonil on Dry Beans. Evaluation of Analytical Methodology and Residue Data. (No Accession Numbers).

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
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THRU: Charles L. Trichilo, Chief
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TO: Henry M. Jacoby
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Registration Division (TS-767)
and
Toxicology Branch
Hazard Evaluation Division (TS-769)

SDS Biotech Corporation (previously Diamond Shamrock Corp.) proposes to increase the established tolerance of 0.1 ppm for combined residues of the fungicide chlorothalonil (tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile (40 CFR 180.275) to 0.5 ppm. According to the petitioner the increased tolerance is necessary to cover residues of chlorothalonil and its 4-OH metabolite which may occur on dry beans as a result of the proposed amended use directions reducing the preharvest interval for the use of Bravo 500 on dry beans from 42 to 7 days. The proposed amended use pattern in turn will allow the grower more flexibility in timing applications of Bravo 500 to optimize disease control and thereby improve yields of dry beans. In addition, the proposed amended registration deletes reference to specific dry bean types, since the residue tolerance applies to all types of dry beans, including many specific varieties not listed in the current registration.

Effective September 9, 1983, the registration of BRAVO 500 was transferred from Diamond Shamrock Corp. to SDS Biotech Corp., the EPA Registration Number was changed from 677-313 to 50534-8.

Background

In PP#8E2065 Diamond Shamrock Corp. originally requested that a tolerance be established for residues of chlorothalonil and its 4-OH metabolite at 0.3 ppm on dry beans to reflect 3 to 4 applications of (2.25 or 1.50 lbs act/A/Application respectively) with a 14-day PHI. In the T. McLaughlin 11/30/78 review of that petition, RCB recommended against the proposed tolerance since residues of chlorothalonil were detected on dry beans (a livestock and poultry feed item) up to 41 days after application, therefore, the need for the establishment of a tolerance for residues of chlorothalonil and its 4-OH metabolite in meat, milk, poultry and eggs was indicated. In addition, the need for a poultry feeding study was also indicated at that time. In a subsequent 1/19/81 amendment to the aforecited petition, the petitioner in an attempt to eliminate the need for a poultry feeding study, revised Section B increasing the PHI from 14 to 42 days and revised Section F decreasing the requested tolerance from 0.3 to 0.1 ppm. In the P.V. Errico 5/15/81 review of the aforementioned amendment, RCB recommended (TOX considerations permitting) for the proposed 0.1 ppm tolerance in/on dry beans provided the petitioner agreed to limit usage to 3 applications of 1-5 lb act/A with a 6 week PHI. In a subsequent 11/22/81 amendment, the petitioner revised Section B to conform with our above recommendation in the previous amendment and with TOX Branch's concurrence a 0.1 ppm tolerance was established in 40 CFR 180.275 for combined residues of chlorothalonil and its 4-OH metobolite on the rac "dry beans" at 0.1 ppm.

A Diamond Shamrock amended regisration application (Reg. No. 677-313) for the chlorothalonil formulation BRAVO 500 to reduce the PHI from 42 to 7 days on dry beans was submitted on March 17, 1983 (EPA Accession No. 249882). The amended registration application was supported by dry bean residue data submitted from 6 states (CO, DE, NE, ND, MI and TN) reflecting 3 to 5 applications of BRAVO 500 using a maximum rate of 1.56 lbs ai/A/Appl. and PHI's ranging from 0 to 29 days. Residues of chlorothalonil ranged from non-detectable to 0.07 ppm. No residues of the 4-OH metabolite (<0.01 ppm), HCB (<0,03 ppm) and PCBN (<0.005 ppm) were found.

In the L. Propst 8/8/83 review of the 3/17/83 registration amendment, RCB concluded that although the residue data submitted in Acc. No. 249882 cited above would be covered by the existing 0.1 ppm tolerance for combined residues of chlorothalonil and its 4-OH metabolite, on the other hand, residue data

previously submitted in conjunction with PP#8E2065 reported total residues of chlorothalonil and its 4-OH metabolite at (0.33, 1.27) and (0.26, 0.27 ppm) at 0 and 7 days PHI respectively, following 3 applications of 1.5 lbs ai/A/Appl. These results clearly indicated that the 0.1 ppm tolerance would not be adequate to cover all residues of chlorothalonil that may occur as a result of the proposed amended registration.

The above conclusions were conveyed to the petitioner by EPA in a reject letter dated September 2, 1983, and the subject amended tolerance proposal is the petitioner's response to that reject letter.

Conclusions

1a. No detectable residues of HCB (<0.003 ppm) and PCBN (<0.005 ppm) were found on dry bean samples following the proposed use of BRAVO 500 formulation. Therefore, the impurity levels of HCB and PCBN found in the formulation should pose no concern in regard to the subject tolerance amendment on dry beans.

1b. All inerts in BRAVO 500 are cleared under 40 CFR §180.1001.

2a. For the purpose of establishing an amended chlorothalonil tolerance on the rac dry beans (foliage treatment) at 0.5 ppm we conclude that the nature of the residue in plants is not adequately understood. Our conclusion is based upon the need for information on plant metabolism studies that would be appropriate for foliar preharvest uses. (see Chlorothalonil Registration Standard, 11/4/83, Residue Chemistry Chapter, Nature of the Residue in Plants p. 2 under Conclusions, and Nature of the Residue section of this review). Accordingly, a ring-labeled ^{14}C chlorothalonil foliar applied bean metabolism study is needed.

2b. We (RCB) cannot conclude that the nature of the residue in animals is adequately understood until both plant and animal metabolism deficiencies have been resolved. We will need the lactating ruminant (goat) ^{14}C metabolism study that the petitioner agreed to submit at the 1/11/84 meeting held between the petitioner and representatives of RD and RCB.

3. A conclusion on the adequacy of the analytical methodology that is needed to enforce the proposed tolerance on dry beans depends upon the outcome of the plant and animal metabolism studies.

4a. No additional residue data were submitted in support of the proposed amended tolerance on dry beans. Residue data submitted in conjunction with PP#8E2065 and in support of an amended registration application for BRAVO

500 (Reg. No. 677-313) (Acc. No. 249882) were cited or referenced by the petitioner. We judged the data inadequate to support the proposed amended tolerance on dry beans for the following reasons: (1) residue data reflected ground applications only whereas currently registered (and proposed) Section B permits both ground and aerial applications; (2) clarification by the petitioner as to the total number of applications permitted per growing season (residue data reflected 1 to 5 applications); (3) questionable validity of residue data submitted in support of PP#8E2065 (i.e., no sample storage or handling information provided); and (4) submitted residue studies conducted in areas not totally representative of all the principal growing regions of the important classes or varieties of dry beans as indicated on pp. 289-290 of 1981 edition of Agricultural Statistics and illustrated in Figure 1 (p. 2 of the USDA Farmer's Bulletin #1996 Growing Dry Beans in the Western States; 1947).

4b. Prior to the initiation of these additional residue studies we have requested in 4d below, the petitioner's intent regarding mode of application to dry beans (i.e., ground vs aerial) should be clarified since both the registered and proposed labeling in Section B does not preclude aerial applications. All of the previously submitted residue studies on dry beans reflected ground applications only, therefore, if it is the intent of the petitioner to restrict use to ground application only then Section B must be so revised and the requested additional residue data from CA and ID must reflect this use pattern. Additionally, the petitioner should amend the proposed Section B to restrict the number of applications permitted since the currently registered label limits the number of applications permitted per growing season to three. The requested additional residue data should also reflect this label restriction.

4c. The petitioner should provide information, if available, on the conditions and length of sample storage prior to residue analyses for all of the studies submitted in support of PP#8E2065. In the absence of this information the subject residue data cannot be used as a basis (together with the additional residue data we have requested below) for the establishment of a revised tolerance on dry beans.

4d. For a favorable tolerance recommendation on dry beans, the petitioner should provide additional residue data (chlorothalonil, 4-OH chlorothalonil, HCB and PCBN) reflecting the maximum proposed application rate at the minimum proposed PHI. At a minimum, the requested residue studies should be conducted in CA on the bean classes or varieties (Pinto, Red Kidney, Lima, Pink, and Blackeye) and from ID on the variety (Great Northern). For these studies the sampling to analysis

intervals should be kept to a minimum, and at any rate, the submitted residue data must be accompanied by documented storage stability data for residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN on dry beans.

5. Pending submission by the petitioner of the requested additional residue studies cited above in conclusion 4d, resolution of the deficiencies also cited in conclusion 4c and in addition resolution of outstanding deficiencies related to the nature of the residue in both plants and animals (see conclusions 2a and 2b above), we reserve our final conclusion regarding the transfer of residues to meat, milk, poultry and eggs. If significant levels of PCBN and HCB are detected on the rac dry beans in the requested additional residue studies then the protocol of the forthcoming lactating goat ^{14}C metabolism study cited in the Nature of the Residue section of this review (see MF. Kovacs 1/20/84. memo of conference re chlorothalonil on almonds, rice, wheat, meat, milk, poultry and eggs) will need to be revised to include residues of PCBN and HCB in the lactating goat diet and the proposed tolerance expression for meat and milk amended to include these residues. Additionally a new poultry metabolism study will need to be initiated in order to determine the potential of PCBN and HCB residues to transfer to the meat and eggs of poultry and a tolerance proposed for poultry to include those residues in the tolerance expression.

   Finally, even if the requested additional dry bean residue samples contain no signficant residues of PCBN and HCB, provided the forthcoming lactating ruminant goat ^{14}C labeled metabolism study cited above should show a need for further investigation of livestock and poultry rac's for unreported secondary residues, then the petitioner would need to reanalyze some of his reserve samples from previous feeding studies or initiate new feeding studies where appropriate residue data may be needed.

6. The International Tolerance Sheet is attached. There are no Canadian or Mexican tolerances for the commodity dry beans per se. However, Canadian and Mexican tolerances for residues of chlorothalonil per se on snap beans at 5 ppm and beans (string) at 5 ppm have been established. Codex IRL limits of 5 ppm for beans (green in pod) and beans (lima) at 0.5 ppm both at Step 9 have been established for combined residues of chlorothalonil and its 4-OH metabolite. We consider the latter Codex IRL tolerance (0.05 ppm - lima beans) to be compatible with the proposed U.S. tolerance.

Recommendations

We recommend against establishment of the proposed tolerance and revision of the existing labeling for the reasons given in conclusions 2a, 2b, 3, 4a, 4b, 4c, 4d and 5. Requirements for resolution of these deficiencies are also discussed in the appropriate conclusions above.

Detailed Considerations

Manufacture

The manufacturing process for technical chlorothalonil was discussed in our review of PP#4E1502 (memo of 11/27/74, R. Schmitt).

Hexachlorobenzene (HCB) was reported to be a contaminant (at an average level of [redacted] in 8% of 308 batches of technical chlorothalonil that were analyzed (PP #8E2025, memo of 12/28/78 T. McLaughlin). A second impurity in the technical material is pentachlorobenzonitrile (PCBN) which may be present at levels of up to [redacted] (see PP#1E2473, memo of 3/4/82, K. Arne).

The BRAVO 500 formulations utilized in the submitted dry bean residue studies (see EPA Accession No. 249882) assayed out at [redacted] respectively of the impurities HCB and PCBN. Following application of these formulations to dry beans in 3 to 5 applications at a rate of 1.56 lbs ai/A/Appl with PHI's ranging from 0 to 29 days, no detectable residues of HCB (<0.003 ppm) and PCBN (<0.005 ppm) were found on any of the dry bean samples analyzed. These impurity levels should pose no concern in regard to the subject tolerance amendment on dry beans.

IMPURITY INFO IS NOT INCLUDED

Formulation

The formulation to be used is BRAVO 500 which contains 4.17 lb. active chlorothalonil per gallon or 500 g/liter. This formulation was described in our review of an amendment to PP#6F1799 (see memo of 8/13/80, P. V. Errico). All inerts in BRAVO 500 are cleared under 40 CFR §180.1001.

Proposed Use

The "currently registered use" for chlorothalonil on beans (dry, navy, pinto, kidney, lima, blackeye) to control Rust, Anthracnose, Downy mildew and Cercospora leafspot (blackeye only) allows for 2 to 3 pts of BRAVO® 500 (1.04 to 1.56 lbs ai/A) per application. Begin applications during early bloom stage and repeat at 7 to 10 day intervals. Under conditions favoring disease development the high rate specified and shortest application interval should be used. Use is restricted only to beans harvested dry with pods removed. Both ground and aircraft methods of application are recommended

unless specific directions for ground application only are given for a crop. Do not apply within 6 weeks of harvest. Do not allow livestock to graze in treated areas or feed treated plant parts to livestock and do not make more than 3 applications per year.

In the current submission the directions for use on dry beans have been amended as follows: (1) reduction in the PHI for use of BRAVO 500 on dry beans from 6 weeks to 7 days; (2) elimination of the current restriction on a maximum of 3 applications per year; and (3) deletion of the reference to specific dry bean types since the residue tolerance applies to all types of dry beans, including many specific varieties not listed in the current registration. In addition, no label restrictions are currently in effect or contemplated by the petitioner in the current submission to restrict applications to dry beans grown only in specific states or geographical areas and no label restriction has been imposed limiting application by ground equipment only.

Nature of the Residue

Plants

No new plant or animal metabolism studies were submitted with this petition. The metabolism of chlorothalonil in plants and animals has been reviewed in detail in conjunction with earlier petitions (PP#'s 7F0599, 1F1024, 2F1230, 4E1502, 6F1799 and 8G1871).

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 dry beans. 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 multiple foliar applications of chlorothalonil to dry beans 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 dry beans 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 amended tolerance on dry beans, we will require that the petitioner submit a ring-labeled ^{14}C foliar chlorothalonil bean metabolism study.

For the purpose of establishing an amended tolerance of 0.5 ppm chlorothalonil on the rac dry beans as proposed in this petition, we therefore conclude that the nature of the residue in plants is not adequately understood.

Animals

Although, as cited above, the metabolism of chlorothalonil in animals has been reviewed in earlier petitions and the conclusion arrived at that the parent compound and the 4-OH metabolite are the residues of concern, RCB has concluded (see Chlorothalonil Registration Standard 11/4/83 Residue Chemistry Chapter, Nature of the Residue in Animals, p. 12) that, since the metabolism of chlorothalonil in plants is not adequately understood, a final decision as to the animal metabolism data requirements cannot be made and accordingly the animal metabolism of chlorothalonil as well as the metabolic residues of concern in feed items are not presently understood.

Since the feed item dry beans, as a result of the proposed amended use pattern in this petition, could bear residues of chlorothalonil and its 4-OH metabolite at levels approaching 0.5 ppm (see Residue Data below), the potential exists for transfer of these residues to meat, milk, poultry and eggs and consequently our concerns expressed above regarding the metabolism and nature of chlorothalonil residues in animals is appropriate to the current petition.

In a subsequent conference with the petitioner (see M. F. Kovacs Jr. 1/20/84 memo re chlorothalonil on almonds, rice, wheat, meat, milk, poultry and eggs) the petitioner agreed to submit a lactating ruminant (goat) ^{14}C metabolism study for both chlorothalonil and its 4-OH metabolite. Pending the results of the ruminant metabolism study the petitioner will then submit a revised tolerance for meat and milk. No future tolerance request is currently contemplated by the petitioner for poultry and eggs since the tolerance proposals for rice and wheat (both poultry feed items) were withdrawn by the petitioner (see our M. F. Kovacs Jr. 1/20/84 conference memo).

Our final conclusion regarding the nature of the residue in animals will then be contingent upon resolution of the plant and animal metabolism deficiencies cited above including identification of metabolic residues of concern in plants and in animal feed items also cited above in the Chlorothalonil Registration Standard.

Analytical Methodology

Submitted in PP# 2E2065 (Acc. No. 096971)

Basically the method of enforcement for determination of residues of Chlorothalonil and its 4-OH metabolite as outlined in PAM II was used to obtain residue data. In essence, this method entails the simultaneous extraction of the parent and 4-OH metabolite from dry beans using acidified acetone, separation of the two on a Florisil column, conversion of the metabolite to its methyl ester, and determination of the derivative and parent compound via MC- or EC-GLC. This method was validated in PAM II for potatoes and with modifications for extraction of oily crops such as peanuts was further validated by EPA on peanuts (PP#1F1024, memos of May 18, 1971 and August 10, 1972).

With this method, recoveries of chlorothalonil from dry beans fortified at 0.05 to 0.5 ppm ranged from 67 to 100% and averaged 84%, recoveries of the 4-OH metabolite fortified at 0.04 to 0.5 ppm ranged from 60 to 105% and averaged 87%. Check values for both chlorothalonil and the 4-OH metabolite were both reported at either 0.01 ppm or <0.05 ppm. Based on the chromatograms submitted we consider the sensitivity of the method to be <0.05 ppm for both chlorothalonil and its 4-OH metabolite.

Submitted in Support of Amended Registration Application on Dry Beans, 3/17/83; EPA Reg. No. 677-313 (Acc. No. 249882)

For dry bean analysis the residue method employed was a modification of the PAM II method described above. In this method chlorothalonil, HCB and PCBN are extracted with acetonitrile, the extract diluted with water, acidified and the residues partitioned into petroleum ether. The petroleum ether extract is taken to dryness, the resultant residue dissolved in 20:80 mixture of methylene chloride, hexane which was transferred to a Florisil column. Residues of chlorothalonil, HCB and PCBN were each selectively eluted from the column by the selection of appropriate solvent mixture. Residues of chlorothalonil, HCB and PCBN in their respective fractions were concentrated and dissolved in an appropriate volume of toluene prior to subsequent quantitation by GLC with a ^{63}Ni ECD. Residues of the 4-OH metabolite of chlorothalonil were separately extracted from dry beans with acidified acetone. The acetone was evaporated and the resultant

aqueous phase acidified and partitioned against petroleum ether. The petroleum ether phase was discarded, the aqueous phase further acidified to <pH 2 and partitioned with a 1:1 petroleum ether: diethyl ether mixture. The combined ether extracts were concentrated and the resultant residue of 4-OH chlorothalonil was converted to the methyl ether derivative with the methylating reagent 3-methyl-1-p-tolyltriazene. The derivative of 4-OH chlorothalonil was then dissolved in dichloromethane and cleaned-up on an alumina column prior to analysis by GLC with a ^{63} Ni ECD.

With this method, recoveries of chlorothalonil from dried beans fortified at 0.03 to 0.50 ppm ranged from 69 to 112% and averaged 86%; recoveries of the 4-OH metabolite fortified at 0.02 to 0.10 pm ranged from 65 to 82% and averaged 72%. Recoveries of HCB from dried beans fortified at 0.01 to 0.04 ppm ranged from 70 to 90% and averaged 81%; recoveries of PCBN fortified at 0.02 to 0.05 ppm ranged from 80 to 100% and averaged 89%. Check values for chlorothalonil, 4-OH chlorothalonil, HCB and PCBN were reported at <0.01, <0.01, <0.003 and <0.005 ppm respectively. Based on the chromatograms submitted we consider the sensitivity of the method to be ca 0.01 ppm for both chlorothalonil and its 4-OH metabolite and 0.003 and 0.005 ppm respectively for HCB and PCBN.

We cannot conclude at this time that adequate analytical methods are available to enforce the proposed tolerance on dry beans until the nature of the residue in plants and animals has been adequately resolved.

Residue data

No additional residue data have been submitted by the petitioner to support the currently proposed tolerance increase on dry beans for combined residues of chlorothalonil and its 4-OH metabolite from 0.1 to 0.5 ppm.

The petitioner has, however, cited and included by reference residue studies previously submitted in conjunction with PP# 8E2065 in support of a tolerance request of 0.3 ppm on dry beans (see T. McLaughlin 11/30/78 memo) and residue data (EPA Acc No. 249882) submitted in support of the petitioner's request for an amended registration application for BRAVO 500 (Reg. No. 677-313) to reduce the PHI from 42 to 7 days. (see L. Propst 8/18/83 memo).

Dry bean samples submitted in EPA Acc. No. 249882 were stored in a frozen condition for periods of time ranging from 1 1/2 to 2 months. Although no storage stability studies were submitted with the aforecited residue data, storage stability studies for chlorothalonil and its 4-OH metabolite reviewed in conjunction with PP# 3F2875 (see M. F. Kovacs, Jr., 11/7/83 memo) indicated that these residues are stable in frozen storage

for periods of time up to 4 months. Accordingly, we are not raising any questions with respect to the accuracy of the residue data submitted in conjunction with EPA Acc. No. 249882.

On the other hand, dry bean samples submitted in conjunction with PP#8E2065 were stored (with the exception of one CO study) under unspecified conditions and for all studies (7) for unspecified periods of time, possibly ranging from 1 to 3 years prior to analysis. Essentially no sample analyses dates or sample-handling information was provided by the petitioner in conjunction with PP# 8E2065. In our M. F. Kovacs Jr., 11/7/83 review of PP# 3F2875, we cited a study by (Northover, J., and B. Ripley 1980. J. Agr. Food Chem; Vol. 28, No. 5 pp. 971-974) that indicated chlorothalonil residues are more labile at ambient temperature, since a 50% decrease in residue was calculated to occur within 10-15 days following spiking of grapes. Accordingly, in the absence of information on the conditions and length of sample storage prior to residue analysis, we seriously question the validity of the residue data previously submitted for dry beans in support of PP# 8E2065.

Residue data cited in Acc. No. 249882 for dry beans (navy, pinto and lima) were collected in 1982 from plots located in CO, DE, NE, ND, MI and TN. Bean plants were treated via ground equipment only (although the label permits both ground and aerial application) with 3 to 5 applications (number of applications permitted not specified on label) of BRAVO® 500 using the maximum permitted rate of 1.56 lb ai/A/Appl. at 7 to 16 day intervals. Preharvest intervals ranged from 0 to 29 days (7 days recommended). Samples were analyzed for residues of chlorothalonil, the 4-hydroxy metabolite, HCB and PCBN. Residues of chlorothalonil ranged from non-detectable (<0.01 ppm) to 0.07 ppm. The maximum residue reflected 5 applications of BRAVO® 500 to DE grown lima beans at a 0 day PHI. No residues of the 4-OH metabolite (<0.01 ppm), HCB (<0.003 ppm) and PCBN (<0.005 ppm) were found in any of the residue trials.

Residue data submitted in conjunction with PP# 8E2065 for dry beans (navy and pinto) were collected in 1972 through 1975 from plots located in MI(3), NE, MN and CO. Bean plants were treated via ground equipment only (although label permits both ground and aerial application) with 1 to 4 applications (number of applications permitted not specified on label) of BRAVO 6F at either 1.5 or 2.25 lb ai/A/Appl (0.67 and 1.0X the maximum recommended) at 5 to 10 day intervals. Preharvest intervals ranged from 7 to 69 days (14 days recommended). In one 1973 MI study, navy beans were treated with 3 applications of BRAVO W-75 at either 1.5 or 2.0 lb ai/A (0.67 and 0.89X the maximum recommended) at 6 to 8 day intervals and PHI's of either 0 or 7 days. For BRAVO 6F treated beans, combined residues of chlorothalonil and its 4-OH metabolite ranged from

<0.05 to 0.2 ppm at PHI's ranging from 7 to 69 days. The maximum combined residue occurred following a 1X application in the 1975 MI trial at a 14-day PHI (the recommended PHI at that time). For BRAVO W-75 treated beans, residues of chlorothalonil ranged from 0.08 to 0.23 ppm and of the 4-OH metabolite ranged from 0.18 to 1.04 ppm. The maximum total residue (0.23 + 1.04 = 1.27 ppm) reflected a 0-day PHI and 3 applications at a 0.89X rate. At a 7 day PHI (the PHI recommended in the current submission) maximum combined residues of chlorothalonil and its 4-OH metabolite were (0.09 + 0.18 = 0.27 ppm) also reflecting 3 applications at a 0.89X rate.

Although it was concluded in the T. McLaughlin 11/30/78 memo re PP#8E2085 that the aforecited residue data supported the then proposed 0.3 ppm tolerance on dry beans at a 14-day PHI, because of TOX concerns and additionally RCB's concerns about potential transfer of residues to livestock and poultry, Sec B was amended to increase the PHI from 14 to 42 days and limit use to a maximum of 3 applications per growing season. This amended use was the basis for the subsequent issuance of a 0.1 ppm tolerance on the commodity dry beans.

Based on our reevaluation of the aforecited residue data we conclude that the data are inadequate to support the proposed 0.5 ppm tolerance on dry beans resulting from the proposed amended use for the following reasons: (1) in the absence of information on the conditions and length of sample storage prior to residue analyses we question the validity of the residue data submitted in support of PP#8E2065, (2) residue data from all studies reflected ground applications only whereas Section B permits both ground and aerial applications, (3) although the submitted residue data reflecting 1 to 5 applications are consistent with the proposed labeling which does not specify the maximum number of applications, on the other hand, the currently registered use restricts applications to a maximum of 3 per growing season, and (4) the submitted residue studies were conducted in areas not totally representative of all of the principle growing regions of the crop dry beans as indicated in the USDA publication Agricultural Statistics.

Citing the above publication, we have derived from pp 289-290 of the 1981 edition the following table describing the areas and classes of dry edible bean production in the U.S. (1978-80):

States	Classes (1) - (7)	% of Total U.S. Acreage	U.S. Production by classes 1000 (cwt)	
MI*	(2)*	33	(1) Pinto	7207
CA	(1),(4),(5),(6),(7)	14	(2) Pea (navy)	5657
CO*	(1)*	11	(3) Great Northern	1979
ID	(3)	10	(4) Red kidney	1756
ND*	(1)*(3)	10	(5) Lima	1119
NE*	(1)*(3)*	9	(6) Pink	1102
MN*	(2)*	3	(7) Blackeye	811
NY	(2)(4)	3	Others	2206
WY	(3)	2		
UT, KS, MT	(1)(3)	2	Total U.S.	
Other States		3	(dry edible	21,837
		100	beans)	

* Represents location and class of dry bean residue data previously submitted by petitioner.

Following a careful examination of this table it is readily evident that two major dry bean producing states, CA and ID, representing 14, and 10% respectively of the total dry bean acreage in the U.S. were not represented in previously submitted residue studies. Further examination of this table together with our observation of the attached map (Figure 1) graphically depicting the major geographical production areas for each type or class of dry beans, reveals that CA is also the principle location of many of the major dry bean classes (Red Kidney, Lima, Pink and Blackeye). With the exception of a 1982 lima bean study from DE, none of the major dry bean classes or types were represented in the previously submitted residue studies. It should be further noted that the petitioner has proposed that Section B be amended to delete reference to specific dry bean types, since the residue tolerance applies to all types of dry beans including specific varieties not listed in the current registration. In the current registration the varieties (Navy, Pinto, Kidney, Lima and Blackeye) are listed. It is interesting to note, however, that residue data were never submitted for two of the varieties (Kidney and Blackeye) on the current label. Since it is the intent of the petitioner that the proposed tolerance applies to all types of dry beans, then it is even more imperative that the major classes or varieties of dry beans are represented in the residue studies submitted in support of the proposed tolerance amendment.

For a favorable tolerance recommendation on dry beans the petitioner should provide additional residue data (chlorothalonil, 4-OH chlorothalonil, HCB and PCBN) reflecting the maximum proposed application rate at the minimum proposed PHI. At a minimum, the requested residue studies should be conducted in CA on the bean classes or varieties (Pinto, Red Kidney, Lima, Pink and Blackeye) and from ID on the variety (Great Northern).

For these studies the sampling to analysis intervals should be kept to a minimum and, at any rate, the submitted residue data must be accompanied by documented storage stability data for residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN on dry beans.

Prior to the initiation of these additional residue studies the petitioner's intent regarding mode of application to dry beans (i.e., ground vs. aerial) should be clarified since both the registered and proposed labeling in Section B does not preclude aerial applications. All of the previously submitted residue studies on dry beans reflected ground applications only, therefore, if it is the intent of the petitioner to restrict use to ground application only, then Section B must be so revised and the requested additional residue data from CA and ID must reflect this use pattern. On the other hand, if the petitioner opts not to revise Section B to limit use to ground applications only, then we must judge all of the previously submitted residue studies to be invalid, and accordingly the requested additional residue studies should be expanded to include aerial applications from CA and ID and from additional states representative of the major dry bean growing areas of the U.S. (The petitioner should consult Figure 1 for guidance in this area.)

Additionally, the petitioner should amend the proposed Section B to restrict the number of applications permitted, since the currently registered label limits the number of applications permitted per growing season to three. The requested additional residue data should also reflect this label restriction. And lastly, the petitioner should provide information, if available, on the conditions and length of sample storage prior to residue analyses for all of the studies submitted in support of PP#8E2065. In the absence of this information, the subject residue data cannot be used as a basis (together with the additional residue data we have requested above) for the establishment of a revised tolerance on dry beans.

Meat, Milk, Poultry and Eggs

No additional large animal (beef cattle, dairy cattle, goat, swine) feeding studies were submitted in this petition.

A cold cattle feeding study with chlorothalonil and 4-OH chlorothalonil submitted in conjunction with PP#1F1024 (see W. Cox 1/6/71 memo) and ^{14}C poultry feeding studies with the same compounds were submitted in conjunction with PP#3F2875. The aforecited feeding studies are all discussed in detail in the M. F. Kovacs, Jr., 11/7/83 review of PP#3F2875. However, because of the numerous and still outstanding deficiencies cited in the review, we concluded that the nature of the residue in ruminants and in poultry were not adequately understood, and

accordingly could not arrive at a final conclusion regarding the adequacy of the petitioner's proposed tolerances of 0.05 ppm in meat and 0.1 ppm in milk, poultry and eggs.

Dried beans can comprise up to 20%, 20% 15% and 25% of the diet of beef cattle, dairy cattle, poultry and swine, respectively.

Although currently no other tolerances other than almond hulls at 0.2 ppm are pending for chlorothalonil and its 4-OH metabolite on rac's and their processed by-products that are feed items, permanent tolerances have been established for chlorothalonil on the following livestock feed items: cull carrots (0.3 ppm), potatoes (0.1 ppm), tomatoes (5.0 ppm), soybeans (0.2 ppm) and beans (dry) 0.1 ppm. For the reasons cited in our M. F. Kovacs, Jr., 11/7/83 review of PP#3F2875, only the feed items (carrots, peanuts, potatoes, soybeans and dry beans) for which tolerances have been established must be considered, in addition to the proposed tolerance on almond hulls when appropriate tolerances are established by the petitioner for residues of chlorothalonil and its 4-OH metabolite in the meat and MBP of cattle, goats, hogs, horses, sheep and poultry.

We therefore,reserve our final (180.6(a)) conclusions regarding the need for meat, milk, poultry and egg tolerances as a result of the currently proposed amended tolerance, until such time that the petitioner has submitted the additional residue data (including residues of PCBN on HCB) reflecting our recommended amended Section B, and furthermore has reproposed a revised tolerance level commensurate with the residue data obtained.

If significant levels of PCBN and HCB are detected on the rac dry beans in the requested additional residue studies, then the protocol of the forthcoming lactating goat ^{14}C metabolism study cited in the Nature of the Residue section of this review (see M. F. Kovacs 1/20/84 memo of conference re chlorothalonil in almonds, rice, wheat, meat, milk, poultry and eggs) will need to be revised to include residues of PCBN and HCB in the lactating goat diet, and the proposed tolerance expression for meat and milk amended to include these residues. Additionally, a new poultry metabolism study will need to be initiated in order to determine the potential of PCBN and HCB residues to transfer to the meat and eggs of poultry and tolerance proposed for poultry to include those residues in the tolerance expression.

Finally, even if the requested additional dry bean residue samples contain no significant residues of PCBN and HCB, provided the forthcoming lactating ruminant goat ^{14}C metabolism study cited above should show a need for further investigation of livestock and poultry rac's for unreported secondary residues, then the petitioner would need to

reanalyze some of his reserve samples from previous feeding studies or initiate new feeding studies where appropriate residue data may be needed.

Other Considerations

The International Residue Limit ((IRL) Status sheet is attached. According to it there are no Canadian or Mexican tolerances for the commodity dry beans per se. However Canadian and Mexican tolerances for residues of chlorothalonil per se on snap beans at 5 ppm and beans (string) at 5 ppm have been established. Codex IRL limits of 5 ppm for beans (green in pod) and 0.5 ppm for beans (lima) at Step 9 have been established for combined residues of chlorothalonil and its 4-OH metabolite. A review of the residue data in this petition indicates that the Codex IRL of 0.5 ppm for beans (lima) would be compatible with the 0.5 ppm on dry beans proposed in this petition.

FIGURE 1 Reproduced from the USDA Farmers Bulletin #1996
Growing Dry Beans in the Western States; 1947

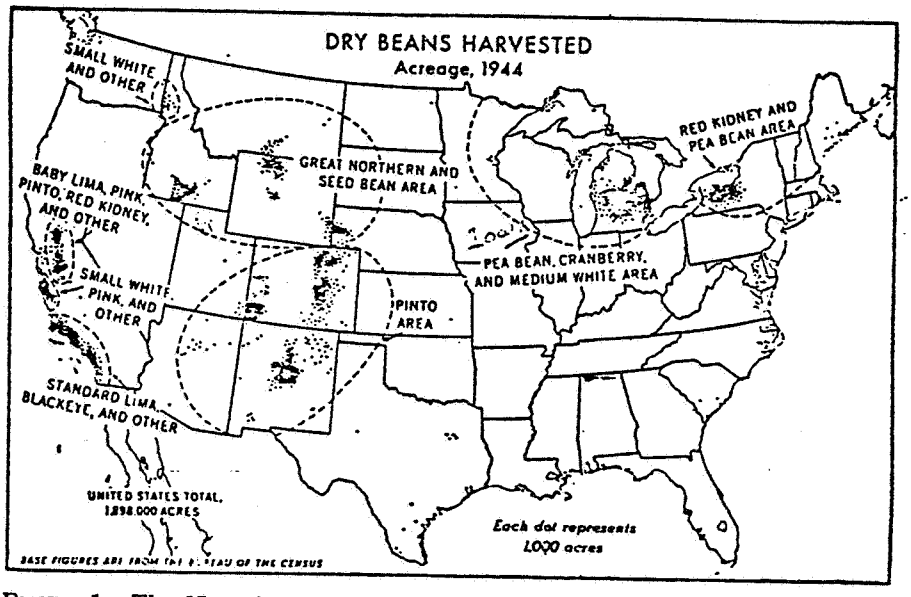

FIGURE 1.—The 15 major types of beans are mostly concentrated in 9 States. There is some overlapping of types among areas and States, but the major producing areas for each type are fairly distinct.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Chlorothalonil

PETITION No. 4F2980 (Amended Tolerance)

CCPR NO. _____

Codex Status

[ ] No Codex Proposal Step 6 or above

Residue (if Step 9): Sum of Chlorothalonil and 4-hydroxy-2,5,6-trichloro-1,3-benzene-dicarbonitrile 1/

Crop(s)	Limit (mg/kg)
beans (green) in pod)	5
beans (lima)	0.5 2/

Proposed U. S. Tolerances

For Sec 180.275

Residue: Chlorothalonil and Metabolite*

Crop(s)	Tol. (ppm)
Dry Beans	0.5

CANADIAN LIMIT

Residue: Chlorothalonil

Crop	Limit (ppm)
Snap beans	5 3/

MEXICAN TOLERANCIA

Residue: Chlorothalonil presumably

Crop	Tolerancia (ppm)
Beans (string)	5 3/

* 4-hydroxy-2,5,6-trichloroisophthalonitrile

Notes: 1/ A residue definition revision to chlorothalonil only has been proposed.

2/ No limit for dry beans per se, but the beans (lima) would presumably cover dry lima beans.

3/ Presumably covers succulent and dry.

HED:DCR-19588:M.F.Kovacs:bje:Raven:557-2226:CBI.27:4/3/84:Del.4/13/84
Revised:DCR-34298:M.F.Kovacs:KIM:CBI-27:4/13/84:Del.4/28/84