12-13-84

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

DEC 13 1984

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP# 3F2875 Chlorothalonil on Almonds, Rice, Wheat, Meat, Milk, Poultry, and Eggs. Amendment of 7/20/84. Accession No. 072736

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THRU: Charles L. Trichilo, Chief
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TO: Henry Jacoby, Product Manager No. 21
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and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Background:

Diamond Shamrock originally proposed permanent tolerances for the combined residues of chlorothalonil and its 4-OH metabolite in/on the following raw agricultural commodities (See M.F. Kovacs Jr. 11/7/83 review of PP# 3F2875):

Almonds	0.05 ppm
Almond hulls	0.1 ppm
Rice	4.0 ppm
Wheat	0.1 ppm
Meat	0.05 ppm
Milk	0.1 ppm
Poultry	0.1 ppm
Eggs	0.1 ppm

Present Consideration

As a result of a meeting on 1/11/84 with RCB, the petitioner is requesting a conditional registration for the use of chlorothalonil on almonds.

The present consideration of 7/20/84 (submitted by SDS Biotech Corporation, formerly Diamond Shamrock) consists of amended Sections B, C, D, E, and F.

Most of the deficiencies discussed in RCB's 11/7/83 review involved the commodities rice, wheat, and poultry. In the currently submitted amended Section F, the petitioner has withdrawn the proposed tolerances for rice, wheat, eggs and poultry and has thereby rendered moot deficiencies 1a, 1b, 1c, 2d, 3a, 4c, 4d, 4e, 5a, 5b, 6c, and 6d. However, in the currently submitted Section F, the petitioner has reproposed tolerances for chlorothalonil and its 4-OH metabolite of 0.05 ppm on almonds and 0.2 ppm on almond hulls.

For clarity, each deficiency addressed in the 11/7/83 review of PP# 3F2875 (memo of M. Kovacs, Jr.) will be restated followed by the petitioner's response and RCB's comments/conclusions. The numbering of the deficiencies follows that used in the 11/7/83 review.

Deficiency 2a

For the purpose of establishing a tolerance for wheat, rice and almonds we conclude that the nature of the residue is not adequately understood. A ^{14}C chlorothalonil wheat metabolism study the results of which can be translated to the additional proposed uses on rice and almonds should be submitted by the petitioner. The labeled ^{14}C chlorothalonil utilized in this study should approximate the proposed foliar use on wheat at the proposed label rates of application and should be conducted to plant maturity to enable RCB to assess the total terminal residue at harvest.

Petitioner's Response - 2a

In a subsequent conference with the petitioner on 1/11/84, RCB agreed that the petitioner did not have to submit additional residue studies on almonds but should submit a plant metabolism study. The petitioner stated that a green leafy vegetable metabolism study would be easier to conduct than the wheat metabolism study originally requested by RCB (PP# 3F2875, memo of M. Kovacs, Jr., 11/7/83). The petitioner wanted to know if a green leafy vegetable metabolism study could support the reproposed almond tolerance. RCB and RD replied that the proposed metabolism study could be submitted in order to support the reproposed chlorothalonil tolerance on almonds, but added that if the wheat and rice tolerance were reproposed, a wheat metabolism would then be required.

The petitioner has submitted a protocol for a lettuce metabolism study with the present amendment. From the proposed starting date of the lettuce metabolism study, apparently work related to the submitted protocol has already begun.

RCB's Comments/Conclusions

Since the petitioner has now provided the protocol for the lettuce metabolism study, RCB will review this protocol.

The protocol shows that the petitioner intends to use an application rate which will approximate 3 pints Bravo® 500 (1.6 lb. a.i.)/A and intends to apply topically radioactive chorothalonil (ring-labeled) every 5-7 days to lettuce plants until crop maturity. A minimum number of 4 applications will be made.

"Subsamples of processed lettuce will be subjected to an organic/aqueous extraction procedure. The organic extracts will be analyzed for identification of the 14_C residues by a variety of techniques which may include but are not limited to thin layer chromatography, high performance liquid chromatography, gas chromatography, gas chromatography/mass spectrometry and chemical derivatization."

RCB suggests that the petitioner investigate the effect of acid and/or base hydrolysis as well as enzymatic hydrolysis on the extraction of the 4-OH metabolite and other possible residues from lettuce. The effect of hydrolysis on the release of 4-OH chlorothalonil residues from ensiled corn has previously been studied (see PP# 2F1230, PP# 6F1749); however, the nature and quantities of conjugates of 4-OH chlorothalonil (if conjugates do form) in ensiled corn may be different from those in the raw agricultural commodity lettuce.

The petitioner should also compare the magnitude of chlorothalonil and 4-OH chlorothalonil residues obtained by the enforcement method to those residues obtained by the 14_C method that he will use in his metabolism studies.

If residues of toxicological concern are identified in the lettuce metabolism study other than chlorothalonil and its 4-OH metabolite, then the petitioner will be required to provide analytical methodology suitable for enforcement of the total residue so identified.

The petitioner also submitted an article, "Fate of Chlorothalonil in Apple Foliage and Fruit," by M. Gilbert in J. Agric. Food Chem., 24, 1004(1976) with the present submission. This article was discussed in RCB's review of PP# 4F3025 (memo of M. Kovacs, Jr., 5/30/84) and was found to be deficient as a metabolism study because an adequate account of the applied chlorothalonil was not achieved.

The petitioner has submitted an earlier translocation and metabolism study on lettuce (Accession No. 092248) in which soil was treated with ring-labeled chlorothalonil and aged 90 days before the lettuce was planted. Extensive uptake of radioactive residues occurred. Virtually all of the radioactive residue was water soluble and none of the residue was identified. For this reason, this study was found to be deficient in the chlorothalonil Registration Standard.

Since the petitioner did not submit the requested plant metabolism studies with this amendment, the nature of the residue resulting from this proposed use (multiple foliar applications on crops approaching maturation) is still not adequately understood. Deficiency 2a is not resolved.

Deficiency 2c

For the purpose of establishing a tolerance for meat and milk as proposed in this petition, we conclude that the nature of the residue in ruminants is not adequately understood. Notwithstanding, EPA's validation of previously submitted unlabeled dairy cattle feeding studies conducted by IBT, we will also need a lactating ruminant (dairy cattle or goat) 14_C metabolism study with chlorothalonil and its 4-OH metabolite to elucidate the distribution and accumulation of these residues in ruminant tissues and in milk. In addition, until the requested additional residue studies on wheat (grain and straw) have been submitted by the petitioner, we cannot ascertain the magnitude of PCBN and HCB residues on these cattle feed items. If significant levels of these residues are found in the requested residue studies then the requested 14_C metabolism studies must contain these impurities in the ruminant diet in order to determine the potential of these residues to transfer to meat and milk (see Residue Data and Residues in Meat, Milk, Poultry and Eggs.)

Petitioner's Response - 2c

In a conference with the petitioner on 1/11/84, RCB agreed that the petitioner should submit a lactating ruminant (goat) 14_C metabolism study for chlorothalonil and 4-OH chlorothalonil after the completion of the lettuce metabolism study. The petitioner has indicated that results from a goat 14_C metabolism study will be submitted.

RCB Comments/Conclusions

If significant levels of residues of toxicological concern other than chlorothalonil and 4-OH chlorothalonil are found in the lettuce study then these compounds may have to be included in a new cattle feeding study.

Until RCB has received and evaluated the results of the forthcoming goat metabolism study, the nature of the residue in a lactating ruminant is still not adequately understood. Deficiency 2c is still outstanding.

Deficiency 2d.

For the purpose of establishing a tolerance for poultry and eggs, we tentatively conclude that the nature of the residue in poultry is adequately understood. However, our tentative conclusions regarding the adequacy of both the submitted poultry metabolism study and the nature of the residue in poultry is contingent upon our finding of toxicologically insignificant residues of both HCB and PCBN in the requested additional residue studies on wheat (grain and processed fractions) and in rice hulls as a result of the requested additional rice processing study. If significant levels of these residues are found as a result of requested additional residue studies, then a poultry metabolism study containing these impurities in the diet, must be conducted in order to determine the potential of these residues to transfer to the meat and eggs of poultry. (See Residue Data and Residues in Meat, Milk, Poultry and Eggs).

Petitioner's Response - 2d

In a revised Section F, the petitioner has withdrawn the proposed tolerances for rice, wheat, poultry, and eggs.

RCB's Comments/Conclusions

Since almond hulls are not a poultry feed item, RCB considers it appropriate to withdraw the proposed tolerances for chlorothalonil and the 4-hydroxy metabolite on poultry, as secondary residues in poultry are not expected to occur from the amended proposed use on almonds alone. Deficiency 2d is moot.

Deficiency 3b

Adequate analytical methodology is available to detect residues of 4-OH chlorothalonil per se in meat and milk. (See MTO submitted in conjunction with PP# 2F1230, B. Puma memo of 6/27/72). However, the current tolerance proposal for meat, milk, poultry and eggs is expressed as combined residues of chlorothalonil and its 4-OH metabolite. We cannot arrive at a final conclusion regarding the adequacy of analytical methodology to enforce the proposed tolerances in meat, milk, poultry and eggs until a MTO is conducted on these substrates for both chlorothalonil and its 4-OH metabolite. The initiation and conduct of this additional MTO must await the results of the requested IBT validation data, 14_C ruminant metabolism study and additional studies for residues of PCBN and HCB on wheat (grain and processed fractions), wheat straw and in rice hulls as a result of the requested additional rice processing study. If toxicologically significant residues of HCB and PCBN are found in these livestock feed items, then these residues may need to be included in the tolerance and also undergo a MTO.

Petitioner's Response - 3b

The petitioner did not directly address this deficiency as he contends that tolerance levels for residues of chlorothalonil and 4-OH chlorothalonil in meat, milk, poultry, and eggs are unnecessary.

RCB's Comments/Conclusions

Since almond hulls are not considered a poultry feed item, RCB agrees that for the purposes of this amendment only tolerances for chlorothalonil and 4-OH chlorothalonil in poultry and eggs are not needed. However, for the purposes of the proposed use on almonds RCB considers it necessary to establish tolerances for these residues in milk and meat. See our detailed discussion below under deficiencies 6a and 6b. Deficiency 3b is therefore not resolved.

Deficiency 4b

The proposed tolerance of 0.1 ppm for combined residues of chlorothalonil and its 4-OH metabolite on almond hulls is not adequate to cover residues resulting from the proposed use. A more appropriate tolerance proposal would be 0.2 ppm.

Petitioner's Response - 4b

In a revised Section F, the petitioner has proposed that a tolerance for the combined residues of chlorothalonil and 4-OH chlorothalonil on almond hulls be established at 0.2 ppm.

RCB's Comments/Conclusions

Deficiency 4b is resolved provided that chlorothalonil and 4-OH chlorothalonil are the only residues of toxicological concern.

Deficiencies 6a and 6b

These deficiencies involve the adequacies of the proposed tolerances for residues of milk (deficiency 6a) and meat (deficiency 6b) and are discussed here concurrently.

6a. We tentatively conclude that the proposed 0.1 ppm tolerance for combined residues of chlorothalonil and its 4-OH metabolite in milk is adequate to cover secondary residues transferring to milk as a result of the proposed uses on almonds, rice and wheat. However, we cannot arrive at a final conclusion regarding the adequacy of the proposed tolerance until the requested residue studies on wheat grain and straw including processed fractions (validated with storage stability studies to include residues of PCBN and HCB), the IBT validation, the 14_C lactating ruminant (to include residues of PCBN and HCB if warranted) studies have been submitted and a successful MTO has been conducted by EPA in milk for the significant residues of toxicological concern detected in the aforementioned studies.

6b. We tentatively conclude that the proposed 0.05 ppm tolerance for combined residues of chlorothalonil and its 4-OH metabolite in meat is inadequate to cover secondary residues transferring to meat as a result of the proposed uses on almonds, rice and wheat. However, we cannot reach any final conclusion in the present review regarding appropriate meat (including muscle, liver, kidney and fat) tolerances until the requested residue (wheat grain, straw and processed fractions), storage stability, IBT validation, the 14_C lactating ruminant metabolism studies and a successful MTO on meat and meat byproducts for significant residues of toxicological concern have been conducted. Contingent upon the results of the above residue, validation and metabolism studies and pending the completion of a successful MTO of the proposed meat and meat byproduct methodologies, we do recommend at this time that the tolerance for meat (including muscle, liver and fat) should be set at a level of at least 0.2 ppm and for kidney at a level of at least 0.5 ppm. We also recommend that when the meat tolerance is established that it be stated in terms of meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep.

Petitioner's Response

The petitioner argues that the residue levels of chlorothalonil and 4-OH chlorothanlonil are so low ("de minimus") that the establishment of tolerances for finite residues in meat and milk at analytical limits of detection would greatly overestimate levels of any residues expected to occur in meat and milk. According to the petitioner," The de minimus principle is a well-established common law principle under which the law does not concern itself with trifling matters". The petitioner presents the following arguments to bolster his contention that tolerances for residues of chlorothalonil and its 4-OH metabolite in meat and milk are not needed. The petitioner's arguments are presented below followed by RCB's comments/conclusions.

Deficiencies 6a, 6b, Petitioner's Response #1

1. The proposed use of chlorothalonil calls for applications of BRAVO 500 to be made during the dormant stage up to petal fall. No applications are to be made to the developing fruit.

   Long preharvest intervals and the fact that chlorothalonil is not systemic (residues occur only on the surface) contribute to excellent dissipation of residues prior to harvest to the crop.

RCB's Comments/Conclusions

Levels of chlorothalonil and 4-OH chlorothalonil are not as negligible as the petitioner implies. Some residue data submitted by the petitioner with PP# 1G 2471 ranged from 0.05 to 0.66 ppm. It was on the basis of the preceding residue data on almond hulls that RCB concluded that the originally requested tolerance level, 0.1 ppm for the combined residues of chlorothalonil and its 4-OH metabolite, was inadequate. See deficiency 4b.

Deficiencies 6a, 6b; Petitoner's Response #2

2. Previously submitted data involving assays from 84 samples of almond hulls demonstrate no detectable residues of chlorothalonil are present at harvest time in the majority of the samples. Only 6 of the 84 samples had chlorothalonil residues above the limit of detection. It is also concluded from presently available data that residues of the primary metabolite (DS-3701), pentachlorobenzonitrile (PCBN) and hexachlorobenzene (HCB) are not expected to be present in almond hulls at levels high enough to be detected, which are <0.03 ppm, <0.004 ppm and <0.008 ppm for DS-3701, HCB and PCBN, respectively.

RCB's Comments/Conclusions

Generally, RCB assumes a worst case scenario in order to err on the safe side. Because of the residue data cited above, it would be an unwarranted assumption that residue levels of chlorothalonil and 4-OH chlorothalonil are so low that secondary residues in animal commodities will not be of concern.

Deficiencies 6a, 6b; Petitioner's Response #3

3. The EPA reviewed PP-3F2875 and declared appropriate tolerances for chlorothalonil on almond hulls to be 0.2 ppm. Since almond hulls comprise a maximum of 25% of the diet of a dairy cow, there would be a maximum of only 0.05 ppm in the total feed, assuming as a worst case that the diet contained the maximum level of chlorothalonil allowed by a 0.2 ppm tolerance on almond hulls.

RCB's Comments/Conclusions

Tolerances for chlorothalonil and its 4-OH metabolite have been established on the following feed items: cull carrots (1 ppm), parsnips (1 ppm), peanuts (0.3 ppm), potatoes (0.1 ppm), tomatoes (5 ppm), soybeans (0.2 ppm), and mint hay (2 ppm). The restriction against feeding spent mint hay to livestock is impractical because the spent hay is not under control of the grower. Currently tolerances for secondary residues of chlorothalonil and its 4-OH metabolite in meat and milk have not yet been established. RCB does not therefore consider it appropriate to calculate the dietary intake of residues of chlorothalonil and its 4-OH metabolite by a dairy cow on the basis of the contribution from almond hulls "alone". A diet consisting of 50% corn, 25% tomato pomace (5 ppm) and 25% almond hulls (0.2 ppm) would impose a maximum dietary exposure to residues of chlorothalonil and its OH-metabolite of 1.30 ppm upon a dairy cow.

Deficiencies 6a, 6b; Petitoner's Response #4

4. If a rather small 500 kg (1100 lb) dairy cow consumed a rather large diet of 20 kg (44 lb) of feed per day containing 0.05 ppm chlorothalonil residues, the cow would consume a maximum of 1 mg of chlorothalonil per day. This translates to 0.002 mg/kg of body weight per day, which is approximately 63,000 to 276,000 times less than levels fed in oncogenicity studies with rats and mice (See Table 1).

Note: $\frac{1 mg}{1 kg} = 1$ ppm

$0.05 \text{ ppm} = \frac{0.05 \text{ mg}}{\text{kg}}$

$20 \text{ kg feed} \times \frac{0.05 \text{ mg}}{\text{kg}} = 1 \text{ mg chlorothalonil/day}$

$\frac{1 \text{ mg chlorothalonil}}{500 \text{ kg cow}} = 1 \text{ mg chlorothalonil/day}$

$\frac{1 \text{ mg chlorothalonil}}{500 \text{ kg cow}} = \frac{0.002 \text{ mg}}{1 \text{ kg}}$

RCB's Comments/Conclusions

The above calculation submitted by the petitioner is based on the assumption that almond hulls are the only source of chlorothalonil in the cow's diet. Other potential sources of chlorothalonil in the cow's diet are discussed above (see RCB's comments/conclusions to deficiencies 6a, 6b; Petitioner's response #3). A diet containing a maximum potential dietary exposure of 1.30 ppm chlorothalonil translates to 0.05 ppm mg/kg of bodyweight. Comparing this value to dosages fed to rats and mice in oncogencity studies is an irrelevant exercise. Grossly exaggerated doses are used in those studies.

Deficiencies 6a, 6b, Petitioner's Response #5, #6

5. In previously submitted studies, no detectable residues of chlorothalonil occurred in meat and milk when chlorothalonil was fed at 250 ppm in the diet, which is 5000 items greater than the theoretical worst-case associated with the feeding of almond hulls containing 0.2 ppm that comprise 25% of the diet.

6. When proposing tolerances associated with the feeding of rice and wheat, the EPA tentatively concluded that a tolerance for combined residues of chlorothalonil and DS3701 at 0.1 ppm in milk would be acceptable. DS-3701 is not expected, however, to be present at levels of detection in almond hulls or in milk from the feeding of almond hulls. DS-3701 does not bioaccumulate and has not been shown to be tumorigenic. Based on previously submitted milk and meat studies, only 0.2% of the chlorothalonil residues in the feed of a dairy cow are expected to transfer to milk as DS-3701. If maximum residues in feed are 0.05 ppm, no detectable residues of chlorothalonil or DS3701 would be expected in meat or milk. As noted in item 4, above, a 500 kg cow consuming 20 kg of feed containing 0.05% chlorothalonil would consume a total of 1 mg chlorothalonil per day. If 0.2 % of that transfers into a total of 10 kg of milk/day, the theoretical maximuum concentration of DS3701 in milk would be about 0.2 ppb. Most cows produce much more than 10 kg milk per day, further diluting any residues. Consequently, there should be no toxicological concern with residues in meat and milk.

RCB's Comments/Conclusions

The nature of the residue in a lactating ruminant is not adequately understood. RCB therefore can make no decision on the appropriateness of meat and milk tolerances for chlorothalonil and 4-OH chlorothalonil until it has had a chance to review the data from the requested metabolism study of radiolabeled chlorothalonil in a lactating ruminant (goat as discussed by RCB in the 1/11/84 meeting with the petitioner). RCB will then conclude whether residues of concern would be expected to occur in meat and milk and, if so, submit the outcome to TOX for toxicological consideration. If the lettuce metabolism study indicates the presence of residues of toxicological concern (besides those discussed above), feeding and metabolism studies using these metabolites may then be required. Although feeding studies have previously been conducted, the analytical methodology used in these studies may not have detected other residues of concern besides chlorothalonil and 4-OH chlorothalonil in meat and milk. This problem may be resolved once the results of the requested lactating goat ^{14}C metabolism study have been evaluated by RCB. Therefore at this time RCB is unwilling, even on a conditional basis, to assume that residues of concern in meat and milk are so low that regulation is not necessary.

Deficiencies 6a, 6b; Petitioner's Response #7

7. Residues of chlorothalonil at levels as high as 0.2 ppm on almond hulls are expected to be the exception, rather than the rule. Analytical data indicate residues expected on almond hulls will generally be below the limit of detection.

RCB's Comments/Conclusions

As previously stated above, RCB assumes a worst case scenario in order to err on the safe side. See our discussion under Deficiencies 6a, 6b; petitioner's response #2.

Deficiencies 6a, 6b; Petitioner's Response #8

8. Almond hulls are not a poultry feed item; therefore, there is no need to establish poultry and egg tolerances to support the use of chlorothalonil on almonds.

RCB's Comments/Conclusions

RCB agrees that there will be no residues of concern in poultry and eggs from the proposed use on almonds.

Deficiencies 6a, 6b; Petitioner's Response #9

9. Almonds are grown commercially in the U.S. only in California. Thus, almond hulls would be a potential feed item primarily in California. It is expected BRAVO 500 would be applied only to a portion (probably <25%) of the crop and that the extent of use would vary from year to year as conditions which favor disease development vary. Some years it may be needed and used extensively, while other years may require only limited use of BRAVO 500. It is also expected that only a small portion of dairy cows and other livestock would be fed any almond hulls in their diet, and it would certainly be seldom that almond hulls would comprise as much as 25% of the diet in lactating dairy animals, due to the low nutritional value of almond hulls. High protein diets are necessary to maintain milk production in dairy animals, thus much lower levels of hulls would be fed to these animals. Milk is composited from many farms into large tanks; thus, any residues possibly occurring in milk as a result of the use of chlorothalonil on almonds would be further diluted.

RCB's Comments/Conclusions

As previously mentioned in RCB's comments/conclusions under Deficiencies 6a and 6b, Response #3, almond hulls are not the only source of chlorothalonil and 4-OH chlorothalonil in the diet of cattle. It is not appropriate to consider the dietary burden of chlorothalonil and its 4-OH metabolite imposed upon cattle by almond hulls alone, when chlorothalonil is currently registered for use on several crops which are livestock feed items. See our discussion under Deficiencies 6a, 6b; Petitioner's Response #3. Some of these items, such as soybeans, have a high protein content and could comprise a substantial portion of a cow's diet. After the C^{14} plant (lettuce) and C^{14} animal metabolism studies have been submitted and RCB has a clearer picture of the nature of the residue in animals, a conclusion may then be drawn on the appropriate tolerance levels for chlorothalonil, 4-OH chlorothalonil, and any other residues of toxicological concern in the meat and milk of livestock.

For the reasons cited above under RCB's comments/conclusions under Responses 1-7,9 we conclude that for the purposes of the proposed use on almonds that deficiencies 6a and 6b are still outstanding.

Deficiency 6c & 6d

6c. We tentatively conclude that the proposed 0.1 ppm tolerance for combined residues of chlorothalonil and its 4-OH metabolite in eggs is adequate to cover secondary residues transferring to eggs as a result of the proposed uses on almonds, rice and wheat. However, we cannot arrive at a final conclusion regarding the adequacy of the proposed tolerance until the results of the requested residue studies on wheat grain and processed fractions (validated with storage stability studies to include residues of PCBN and HCB) and the rice processing study (to ascertain the concentration of PCBN and HCB residues in rice hulls) have been submitted, the determination by RCB/TOX as to the need for a poultry metabolism study based on the results of the additional residue studies submitted, and a successful MTO has been conducted by EPA on eggs for the significant residues of toxicological concern detected in the aforementioned studies.

6d. We conclude that the proposed 0.1 ppm tolerance for combined residues of chlorothalonil and its 4-OH metabolite in poultry is inadequate to cover secondary residues transferring to poultry as a result of the proposed uses on almonds, rice and wheat. However, we cannot reach any final conclusion in the present review regarding an appropriate tolerance for poultry until the requested residue (wheat grain and processed fractions, rice processed fractions), storage stability and possibly poultry metabolism studies and a successful method tryout on poultry tissue for significant residues of toxicological concern, have been obtained. Contingent upon the results of the above residue and metabolism studies and pending the completion of a successful MTO of the proposed methodology for poultry tissue, we do recommend at this time that the tolerance for poultry should be set at a level of at least 0.3 ppm. We also recommend that when the poultry tolerance is established that it be stated in terms of meat, fat and meat byproducts of poultry.

Petitioner Response - 6c and 6d

The petitioner has withdrawn the proposed chlorothalonil tolerances for rice, wheat, poultry, and eggs in a revised Section F.

RCB Comments/Conclusions

By withdrawing the proposed tolerances for rice, wheat, poultry, and eggs in a revised Section F, deficiencies 6c, and 6d which were cited in RCB's most recent review of PP# 3F2875 (memo of M. Kovacs, Jr., 11/7/83) become moot.

Other Considerations

1. The petitioner also requests that RCB apply the provisions of 40 CFR 180.6(b) and not require the establishment of tolerances for chlorothalonil and 4-OH chlorothalonil on meat and milk.

Section 40 CFR 180.6(b) states:

> "When it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is no reasonable expectation of finite residues in light of data such as those reflecting exaggerated pesticide levels in feeding studies and those elucidating the biochemistry of the pesticide chemical in the animal, a tolerance may be established on the raw agricultural commodity without the necessity of a tolerance on food products derived from the animal".
>
> Since the requested studies aimed at elucidating the nature of the pesticide chemical in the animal and in the plant have not yet been received, this paragraph does not apply in this case.

2. Neither Codex, Canada, nor Mexico has established a tolerance for the combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6- trichloroisophthalonitrile on almonds. There will be no compatibility problem.

Recommendations

RCB recommends against the establishment of a conditional tolerance for residues of chlorothalonil and 4-hydroxy-2,5,6-trichloroisophthalonitrile on almonds (0.05 ppm) and almond hulls (0.2 ppm) because of reasons given above under RCB's Comments/Conclusions to the Petitioner's Response to Deficiency No's 2a, 2c, 3b, 6a, and 6b. Deficiency 4b is resolved provided that chlorothalonil and 4-OH chlorothalonil are the only residues of toxicological concern.

cc: R.F., Circu., C.D., TOX, EEB, EAB, PP #3F2875, FDA, Robert Thompson (RTP)
RDI: JHO, 11/9/84: R.D. Schmitt: 11/13/84
TS-769: RCB: C.D.:B.J.: CM#2:RM:810:12/7/84:557-3043

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Chlorothalonil

CCPR NO. 81

PETITION NO. 3F2875

Reviewer: C. Deyrup / ND 9/24/84

Codex Status

[ ] No Codex Proposal Step 6 or above

Residue (if Step 9):

Chlorothalonil

Crop(s)	Limit (mg/kg)
None (on almonds or almond hulls)	

Proposed U.S. Tolerances

40 CFR 180.275

Residue: chlorothalonil and 4-hydroxy-2,5,6-trichloro-isophthalonitrile

Crop(s)	Tol. (ppm)
almonds	0.05 ppm
almond hulls	0.2 ppm

CANADIAN LIMIT

Residue:

tetrachloroisophthalonitrile

Crop	Limit (ppm)
None (on almonds or almond hulls)	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
None	

NOTES: