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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

Subject: PP#3F2875 Chlorothalonil in or on almonds, rice, wheat, meat, milk, poultry and eggs.

From: Martin F. Kovacs, Jr., Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: Henry Jacoby, Product Manager #21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Diamond Shamrock Corporation proposes tolerances for the combined residues of the fungicide, chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-tetrachloroisophthalonitrile be established on the following commodities:

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

Chlorothalonil tolerances are established for several commodities ranging from 0.05 ppm for the edible pulp of bananas to 15 ppm for celery and papayas (40 CFR 180.275). A

temporary tolerance for chlorothalonil and its 4-OH metabolite on almonds at 0.05 ppm is currently in effect. Tolerances are pending for peaches (PP#3E2815); oranges, grapefruit and citrus oil (PP#OF2405) and for coffee and cocoa beans (PP#2E2744). Currently, no tolerances for chlorothalonil or its 4-OH metabolite have been established in meat, milk, poultry and eggs.

Conclusions IMPURITY INFO IS NOT INCLUDED

1a. Following the proposed use of Bravo 500 (containing [redacted] PCBN) essentially no detectable residues of either impurity was found on the rac's almonds (nutmeats and hulls) and wheat grain, however, residues of PCBN were detected in 90% of the rice grain samples analyzed at levels up to 0.053 ppm. Residues of HCB and PCBN were not determined in rice straw but were detected in wheat straw at levels up to 0.08 and 0.09 ppm respectively.

1b. The label restriction regarding the feeding of treated rice straw to livestock should be modified in a revised Section B as follows: "Do not graze or feed treated forage to livestock. Do not bale or use rice straw from chlorothalonil-treated fields for feed or bedding."

1c. The petitioner should offer an explanation for the terminology "Feekes 8, 10.1 and 10.5." Does this term have a meaning or relevance to the pesticide applicator as it relates to the timing of wheat applications? If it does not it should be deleted from the wheat label. We (RCB) do not consider the imposed label restriction against feeding treated wheat straw to livestock to be a valid restriction. Wheat straw can be baled and sold by the grower and, in addition, the practical economics of wheat production would tend to encourage the feeding of wheat straw to livestock.

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.

2b. We conclude that the nature of the residue in animals (rats, dogs) is adequately understood. The residue of concern is the parent plus its 4-OH metabolite.

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.)

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).

3a. Adequate analytical methodology is available for enforcement of the proposed tolerance in terms of chlorothalonil and 4-OH chlorothalonil on almonds (nutmeats and hulls), rice and wheat. However, the petitioner should provide an explanation for abnormally high control values for chlorothalonil on wheat (0.47 ppm) in a 1978 Cheneyville, LA residue trial and for chlorothalonil (0.66 ppm) and 4-OH chlorothalonil (0.11 ppm) on wheat straw in a 1978 Experiment GA residue trial.

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.

4a. Combined residues of chlorothalonil and its 4-OH metabolite are not likely to exceed the proposed tolerance on almonds of 0.05 ppm.

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.

4c. The proposed tolerance of 4.0 ppm for combined residues of chlorothalonil and its 4-OH metabolite on rice is not adequate to cover residues resulting from the proposed use. A more appropriate tolerance proposal would be 5.0 ppm. The rice tolerance when established should be expressed in terms of rice (grain).

4d. The submitted residue data for wheat grain are insufficient to support the proposed tolerance for combined residues of chlorothalonil and 4-OH chlorothalonil at 0.1 ppm. Samples were stored for up to five years prior to analysis. For a favorable tolerance recommendation on wheat grain 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. 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 wheat grain. The wheat tolerance when established should be expressed in terms of wheat (grain).

4e. A tolerance proposal for wheat (straw) is needed to cover maximum residues expected from the proposed use. Additional residue data on wheat straw is requested to reflect residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN resulting from the maximum proposed application rate at the minimum proposed PHI. Sampling to analysis intervals should be kept to a minimum and the submitted residue data accompanied by documented storage stability data for the above residues.

5a. The rice processing study submitted with this petition was inadequate in part since it did not address the concentration of PCBN residues in rice hulls. The petitioner should submit a new processing study for whole rice grain with the processing method outlined in detail. For this processing study the petitioner should, if possible, retrieve the unhulled rice grain samples from the Beaumont, TX residue trial bearing residues of chlorothalonil at 2.72 ppm and PCBN at 0.053 ppm (Sample No. 79-194-23) and subject these samples to a processing study to primarily ascertain whether PCBN residues concentrate, if at all, in the rice hull fraction to the same or greater extent than has been demonstrated for chlorothalonil and its 4-OH metabolite. If the above sample is not available, then comparable unhulled rice grain samples containing field treated detectable residues of PCBN at or near 0.05 ppm must be utilized in the requested processing study. The results of this requested processing study will have direct bearing on RCB/TOX Branch's determination as to the need for a poultry metabolism study and EPA's timely initiation of a MTO on meat, milk, poultry and eggs.

5b. The wheat processing study submitted with this petition was inadequate. No finite residues of chlorothalonil or its 4-OH metabolite were present initially on the rac (wheat grain) prior to processing, therefore, no accurate judgement can be made concerning concentration of these residues in the processed products. The petitioner should submit a new processing study with whole wheat grain bearing finite or detectable field treated residues at or near the proposed 0.1 ppm tolerance. To obtain finite residues on whole wheat grain, wheat should be treated with the Bravo 500 formulation (with the % HCB and PCBN inpurities specified) at 1x-2x application rates and at short PHI's. Residues of chlorothalonil, its 4-OH metabolite and the impurities HCB and PCBN should be determined in the milling fractions obtained.

The results of this requested processing study (in part) will have a bearing on RCB/TOX Branch's determination as to the need for a cattle metabolism study and EPA's timely initiation of a MTO on meat, milk, poultry and eggs.

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 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.

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 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.

7. The International Tolerance Sheet is attached. There are no Canadian or Mexican tolerances for chlorothalonil residues for the commodities addressed in this petition; however, a Codex tolerance of 0.2 ppm for the group "cereal grains" is at Step 9. This Codex IRL tolerance is incompatible with and not supportable by the residue data submitted in conjunction with the uses proposed in this petition. It would be useful for the Agency to address the possibility of U.S. compatibility in terms of the group limit although compatibility of individual members of the group may not be possible.

Recommendations

We recommend that the proposed tolerances not be established for the reasons given in conclusions 1a, 1b, 1c, 2a, 2c, 2d, 3a, 3b, 4b, 4c, 4d, 4e, 5a, 5b, 6a, 6b, 6c, 6d and 7. 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).

Finite residues of the impurities HCB and PCBN were found in some of the rac's analyzed in this petition following the proposed use of chlorothalonil. Residues of HCB (<0.005 ppm) or PCBN (<0.008 ppm) were not detected on almond nutmeats, shells and hulls following application of Bravo 500 formulation (containing [redacted] HCB and [redacted] PCBN). On the other hand, following application of Bravo 500 (containing [redacted] HCB and [redacted] PCBN) to rice, residues of PCBN were detected in 90% of the 64 unhulled rice grain samples examined at levels up to 0.053 ppm whereas no HCB (<0.005 ppm) was detected in any of the samples analyzed. Essentially, no residues of PCBN (<.009 ppm) or HCB (<0.004 ppm) were detected in 318 wheat grain samples following application of Bravo 500 (containing [redacted] PCBN and [redacted] HCB). Maximum residues of HCB and PCBN at 0.03 and 0.09 ppm respectively were detected in wheat straw following application of the same Bravo 500 formulation cited above also at the maximum proposed use rate. Details of both the analytical methodology and residue analyses for HCB and PCBN on the rac's in this petition are discussed in the appropriate sections below.

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. Another registered formulation used for some of the residue studies, Bravo 6F, contains 6 lb. active chlorothalonil per gallon.

Proposed Use

Almonds

For control of brown rot and twig blight on almonds, apply 6-8 pts. Bravo 500/A (3.1-4.2 lb. ai/A) in 400 gal. water/A for a dilute spray. For concentrate sprays (50 to 200 gal./A) or when treating non-bearing or immature trees, the lower rate of 6 pts. Bravo 500/A (3.1 lb. ai/A) may be used. Application through ground equipment is recommended. Bravo 500 (4-1/2 pts/A or 2.3 lb. ai/A) can also be co-applied with Benlate® 50WP (1 lb/A) for control of brown rot blossom and twig blight. Application for brown rot blossom blight should be made at the pink bud stage with a second application made at half-to-full bloom stage if conditions favor severe disease. For control of Coryneum blight (shothole) on almonds apply Bravo 500 at the same rates as described above, however, apply only once at petal fall. Use the high rate of Bravo 500 in orchards with a history of severe shothole or if weather conditions favor infection.

Rice

For control of Leaf and Sheath: narrow brown leaf spot, brown blotch, leaf smut, brown spot, blast and Panicle: panicle blight, apply Bravo 500 at 2 to 3 pts./A (1.0 to 1.6 lb ai/A) at panicle differentiation (1/2 inch panicle) via either ground or aircraft methods of application and repeat approximately 14 days later at beginning of heading. Do not harvest within 4 weeks following the last application of Bravo 500 and do not allow runoff of water from treated areas within 7 days following application. Do not feed treated straw to livestock. (We consider this restriction practical; see PP #0F2401, memo of April 17, 1981, C. Trichilo). However, this restriction should be revised as follows: "Do not graze or feed treated forage to livestock. Do not bale or use rice straw from chlorothalonil-treated fields for feed or bedding."

Wheat

For control of Septoria leaf spot, glume blotch, leaf rust, stripe rust and Helminthosporium leaf spot (tan spot), apply 1-1/2 to 2 pts./A (0.75 to 1.0 lb. ai/A) via either ground or aircraft methods of application at flag leaf emergence (Feekes 8) and approximately 14 days later at beginning of head emergence (Feekes 10.1). If conditions favor continued infection of glumes and leaves, make a third application at end of heading (Feekes 10.5). Do not harvest within 4 weeks following the last application of Bravo 500. Do not feed treated straw to livestock or allow livestock to

graze in treated areas. The petitioner should offer an explanation for the terminology "Feekes 8, 10.1 and 10.5." Does this term have any meaning or relevance to the pesticide applicator as it relates to the timing of application? If it does not, it should be deleted from the wheat label. We (RCB) do not consider the imposed label restriction against feeding treated wheat straw to livestock to be a valid restriction. Wheat straw can be baled and sold by the grower and in addition the practical economics of wheat production would tend to encourage the feeding of wheat straw to livestock.

Nature of the Residue

Plants

No new plant metabolism studies were submitted with the 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 6G1871).

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 uses on almonds, rice and wheat. 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 uses all involve multiple foliar applications of chlorothalonil in crops 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. Accordingly, we will require that the petitioner submit a 14_C chlorothalonil wheat metabolism study the results of which can be translated to the additional proposed uses on rice and almonds. Labeled 14_C chlorothalonil 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.

For the purpose of establishing tolerances on the rac's almonds, rice and wheat as proposed in this petition, we therefore conclude that the nature of the residue is not adequately understood.

Animals

A study entitled "Balance Study of the Distribution of Radioactivity Following Oral Administration of ^{14}C-chlorothalonil (^{14}C-DS-2787) to Rats," Report No. 000-4AM-81-0209-001 was submitted with this petition.

In this study, uniformly benzene ring labeled ^{14}C chlorothalonil was orally administered to male Sprague-Dawley rats at 3 dose levels (5, 50, and 200 mg/kg of body weight) to determine the distribution of radioactivity in rats at 2, 9, and 24 hours after dosing. The percent recovery of radioactivity at all times and at all dose levels was equal to or greater than 86% and ca. 80% of the administered dose was found in the small intestinal contents at 2 hours, 90% in the large intestinal contents at 9 hours, and 95% in the large intestinal contents at 24 hours after dosing. The accumulation of radioactivity in all tissues except the GI tract was less than 1% of the dose and the rate of absorption from the intestine was rapid. Total ^{14}C levels in the blood were lower than those in liver and kidneys at 2 hours after dosing for all 3 dose levels and at 9 and 24 hours after dosing for only the 5 mg/kg dose.

As cited above, the metabolism of chlorothalonil in animals has been reviewed in earlier petitions. As with plants, the parent compound and the 4-hydroxy metabolite constitute the residue of concern. In animals (rats, dogs) the 4-hydroxy metabolite is a minor component of the residue but is of concern because of its transfer potential to meat and milk (see W. S. Cox 5/23/72 review of PP #2F1230 re a dairy cattle feeding study with unlabeled chlorothalonil and 4-OH chlorothalonil). However, the dairy cattle feeding studies cited in that review and also in the W.S. Cox 1/6/71 review of PP#1F1024 were conducted by Industrial Bio-Test Laboratories, Inc. (IBT Report No. J6629 in PP#1F1024 and IBT Report No. J179 in PP#2F1230). The residue data generated by the IBT studies are not presently useful in assessing an appropriate tolerance level for residues of chlorothalonil and 4-OH chlorothalonil in meat and milk, because laboratory tests conducted by IBT are currently under investigation. The tests discussed here (IBT Report Nos. J-6629 and J-179) have been validated in Canada; however, EPA is in the process of reviewing these reports (see Chlorothalonil Registration Standard Initial Draft Report dated 9/15/83, Residue Chemistry Chapter, Magnitude of the Residue in Meat, Milk, Poultry, and Eggs).

Nothwithstanding validation of the aforecited unlabeled dairy cattle feeding studies conducted by IBT we will also need a lactating ruminant (dairy cattle or goat) 14_C metabolism study utilizing both chlorothalonil and its hydroxy 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 on the requested residue studies then the requested C^{14} cattle metabolism studies must contain these impurities in the 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).

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.

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.

In a conference between RCB and representatives of Diamond Shamrock Corp. (see P. Errico's 9/24/81 memo of conference) we recommended to the petitioner that a radio-labeled poultry metabolism study should be performed prior to a poultry feeding study that they were contemplating in connection with a use on alfalfa. In the submitted metabolism study, a mixture of parent and impurities in the same ratio as is present on treated rac's can be used and in addition the petitioner can also run separate metabolism studies on parent and impurities. Poultry should be fed enough radio-labeled material to allow detection of residues in the tissues and if no residues are detected in eggs then data on tissues would suffice. In the same conference, we informed the petitioner that for a poultry feeding study that 3 groups of chickens should be fed at 1x, 3x and 10x levels of chloro-thalonil in the diet, the chlorothalonil used in the feeding study should be analyzed for HCB and PCBN and that chickens should be fed for 3-4 weeks or until a plateau is reached in the eggs.

In the current petition, the petitioner has submitted two poultry feeding studies, one with 14_C labeled chloro-thalonil and the other with the 14_C labeled 4-hydroxy metabolite of chlorothalonil. The results of these feeding studies are discussed in detail below under "Residues in Meat, Milk,

Poultry and Eggs." These studies do not satisfy the requirement for a poultry metabolism study per se, as we have previously discussed above. 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 the 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).

Analytical Methodology

Almonds, Rice and Wheat (including processing fractions)

The method of enforcement contained in PAM II for determination of chlorothalonil and its 4-hydroxy-metabolite (DS-3701) involves extaction of the parent and metabolite with acidified acetone, separation of the two compounds on a Florisil column, methylation of the metabolite, and determination of the derivative and parent by MC- or EC-GLC. This method is validated in PAM II for potatoes.

The PAM II method with modifications for extraction of oily crops such as peanuts has been validated by EPA on peanuts (PP #1F1024, memos of May 18, 1971 and August 10, 1972; modifications in letter from Diamond Shamrock dated 9/14/70). The residue is extracted with acetonitrile. Hexane is added to allow partitioning of the parent and the hydroxy-metabolite into the acetonitrile. The acetonitrile is evaporated. Separation of the parent and metabolite are undertaken by column chromatographic cleanup as described in PAM II under "Column Chromatographic Clean-up and Separation."

For almonds, unhulled rice grain, wheat grain (including its milling fractions) and wheat straw, residues of chlorothalonil, 4-OH chlorothalonil HCB and PCBN were extracted from the crop with acidified acetone and selectively partitioned into an organic solvent. The residues of chlorothalonil, HCB and PCBN were separated by column chromatography prior to subsequent quantitation by electron capture gas chhromatography. The residue of 4-OH chlorothalonil was derivatized to its methyl ether prior to quantitation. If required, the residue of derivatized 4-OH chlorothalonil was cleaned up by column

chromatography prior to quantitation. For the rice milling fractions; hulls, bran, brown rice and white rice and for rice straw, the same procedure described above was used, however, only residues of chlorothalonil and 4-OH chlorothalonil were determined. Details of the analytical methodology employed for the crop analyses in this petition have previously been described in the N. Dodd 11/17/81 review of PP #1G2471 (chlorothalonil on almonds).

The following check and recovery values are submitted for the rac's analyzed:

Almond (nutmeats)	Check (ppm)	Fort. (ppm)	Range (%)	Avg (%)
Chlorothalonil	<0.03	0.05-1.00	60-100	76
4-OH Chlorothalonil	<0.03	0.05-0.50	60-96	79
HCB	<0.005	0.01-0.05	70-120	91
PCBN	<0.008	0.02-0.10	65-104	86
Almond (shells & hulls)				
Chlorothalonil	<0.03	0.05-1.00	76-110	92
4-OH Chlorothalonil	<0.03	0.05-0.50	60-80	74
HCB	<0.005	0.01-0.05	60-95	82
PCBN	<0.008	0.02-0.10	64-98	84
Rice (Grain)				
Chlorothalonil	<0.01-0.13	0.02-10.0	40-150	94
4-OH Chlorothalonil	<0.01-0.03	0.02-0.5	57-100	80
HCB	<0.003-0.005	.005-.05	60-140	98
PCBN	<0.005-0.009	.01-0.1	65-160	101
Rice (Milling Fractions)				
Chlorothalonil	<0.01-0.15	0.1-0.2	33-167	86
4-OH Chlorothalonil	<0.01-0.03	0.1-0.2	32-117	92
Wheat (Grain)				
Chlorothalonil	<0.01-0.47	0.03-1.00	64-143	89
4-OH Chlorothalonil	<0.01-0.03	0.03-0.50	60-120	89
HCB	<0.004	0.01-0.05	60-100	81
PCBN	<0.008-0.009	0.02-0.10	75-110	92
Wheat (Milling fractions)				
Chlorothalonil	<0.03	0.05-1.00	89-99	93
4-OH Chlorothalonil	<0.03	0.05-0.50	70-96	82
HCB	<0.004	0.01-0.05	90-98	93
PCBN	<0.008	0.01-0.05	83-94	90

Wheat (Straw)

Chlorothalonil	<0.03-0.66	0.10-10.0	80-180	101
4-OH Chlorothalonil	<0.03-0.11	0.05-0.50	74-134	96
HCB	<0.004-0.042	0.01-0.05	78-140	100
PCBN	<0.008-0.020	0.02-0.10	75-125	98

We consider the sensitivity of the method to be about 0.03 ppm for both chlorothalonil and 4-OH chlorothalonil, 0.004 ppm for HCB and 0.008 ppm for PCBN in all of the rac's analyzed. Accompanying chromatograms support these limits of detection. Although control values for chlorothalonil on wheat were generally below 0.03 ppm, one value from a 1978 Cheneyville, LA residue trial was reported as 0.47 ppm which far exceeds the proposed 0.1 ppm tolerance. The petitioner should provide an explanation for this abnormally high control value. In addition, the petitioner should provide an explanation for the high control values reported for the chlorothalonil (0.57, 0.66 ppm) and 4-OH chlorothalonil (0.09, 0.11 ppm) on wheat straw obtained in the 1978 Experiment, Georgia residue trial. We conclude that adequate analytical methods are available to enforce the proposed tolerances on almonds, rice and wheat.

Meat, Milk, Poultry and Eggs

Meat and Milk

A method try-out was conducted on Diamond Shamrock's methods "Daconil, 4-hydroxy metabolite (DAC 3701) in meat" and "Daconil, 4-hydroxy metabolite (DAC 3701) in milk" (PP #2F1230, B. Puma memo of 6/27/72). (The hydroxy metabolite accounts for the majority of the residue in meat and milk.) Beef kidney was fortified with 0.2 ppm DAC 3701 and milk was fortified with 0.4 ppm DAC 3701. Reported recoveries were 61-76% for milk and 65-72% for beef kidney. The method is satisfactory for analysis of the hydroxy-metabolite in kidney and milk.

We conclude that adequate analytical methology is available to detect residues of 4-OH chlorothalonil *per se* in milk and meat. However, the tolerances proposal in the current petition for meat and milk is expressed as combined residues of chlorothalonil and its 4-OH metabolite. Although the dairy cattle feeding study submitted in conjunction with PP #2F1230 (*see* W. S. Cox 5/3/72 review) indicated very little transfer of the parent compound to meat and milk, the data were generated by an invalid IBT study, therefore the possibility exists that finite residues of chlorothalonil may occur in meat and milk as a result of the proposed use. The

initiation and conduct of the additional MTO for residues of chlorothalonil and its 4-OH metabolite in meat and milk 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) and wheat straw. If toxicologically significant residues of HCB and PCBN are found in these cattle feed items then these residues may need to be included in the tolerance and also undergo a MTO.

Poultry and Eggs

The petitioner has submitted a method for the gas chromatographic determination of chlorothalonil (DS-2787) and DS-3701 residues in chicken egg and tissue samples (Document No. 596-HMD-82-0183-001) 3/2/83. This method, a modification of the method used for crop samples, determines residues of chlorothalonil and its 4-OH metabolite in poultry tissue and egg samples. The modifications employed involve the use of acetone acidified with diluted HCl as an extraction solvent which also precipitates protein during egg analysis. In addition, the fat in the extracts can be removed by cooling the extracts for 10 minutes in an acetone dry ice bath followed by filtration.

The following check and recovery values are submitted for the egg and tissue samples analyzed:

Poultry (Meat, fat, heart, skin)	Check (ppm)	Recovery Fort. (ppm)	Range (%)	Avg (%)
Chlorothalonil	<0.010	.050-1.00	79-104	95
4-OH Chlorothalonil	<0.020	.050-1.00	89-105	95
(Liver)				
Chlorothalonil	<.010	.050-1.00	85-100	94
4-OH Chlorothalonil	<.020	.050-1.00	88-98	93
(Eggs)				
Chlorothalonil	<.010	.050-1.00	80-100	92
4-OH Chlorothalonil	<.020	.050-1.00	89-98	93

We consider the sensitivity of the method to be 0.01 ppm for chlorothalonil and 0.02 ppm for 4-OH chlorothalonil for all poultry tissue and egg samples. Accompanying chromatograms support these limits of detection.

We cannot arrive at a final conclusion regarding the adequacy of the submitted analytical method to enforce the proposed tolerances on poultry and eggs until an additional MTO is conducted for residues of chlorothalonil and its 4-OH metabolite in poultry tissue and eggs. The initiation and conduct of this additional MTO, however, must await the results of the requested additional studies for residues of PCBN and HCB on wheat (grain and processed fractions) 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 poultry feed items then these residues may need to be included in the tolerance and also undergo a MTO.

Residue Data

Storage Stability Studies

No storage stability studies for chlorothalonil its metabolite 4-OH chlorothalonil or the potential impurities HCB and PCBN were submitted for the rac's for which a tolerance is proposed in this petition; almonds, almond hulls, rice grain, wheat grain and straw or the animal products meat, milk, poultry and eggs.

In a storage stability study submitted in conjunction with PP #1F1024, 81% and (82-100%) of chlorothalonil and 4-OH chlorothalonil respectively were recovered in milk following 1 month storage at 0°C at fortification levels ranging from 0.05 to 0.85 ppm. A storage stability study with passion fruit (PP #5E1569) amended with 0.1 ppm of chlorothalonil and 4-OH chlorothalonil following 6 months of storage ct -15°C indicated chlorothalonil recoveries of 85 and 71% respectively in the peel and pulp and 4-OH chlorothalonil recoveries of 78 and 83% respectively. Recoveries of chlorothalonil from mint hay (PP #1E2473) stored for 14 months at -20°C were 84-89%. 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 (Northover, J., and B. Ripley. 1980. J. Agr. Food Chem., Vol. 28, No. 5, pp. 971-974).

Residue Data

almonds

Residue data in support of a temporary tolerance on almonds were previously submitted in conjunction with PP #1G2471 and evaluated in the N. Dodd 11/17/81 review of that petition. Samples submitted in those studies and also submitted in the current petition were stored at 0°F prior to analysis for periods ranging from 3 to 22 months. From the results of the storage stability data presented above we can conclude that chlorothalonil residues are stable in frozen storage for up to at least 14 months. Therefore, since almond nutmeat

and hull samples were generally stored in a frozen condition for 1 year or less, we are not raising any questions with respect to the accuracy of the residue data for almond nutmeats and hulls.

In those studies Bravo 500 or Bravo W-75 was applied to almond trees in California over a three-year period from 1978 through 1980, and samples of almond nutmeats and shells and hulls from these tests were assayed for residues of chlorothalonil, 4-OH chlorothalonil HCB and PCBN. Following 1-3 applications of Bravo 500 or Bravo W-75 at 0.25 to 2.0x the maximum proposed use rate with PHI's ranging from 162-210 days (normal harvest is 162-198 days) no residues of chlorothalonil, 4-OH chlorothalonil, HCB (all at <0.03 ppm) or PCBN (<0.007 ppm) were detected on almond nutmeats, residues of chlorothalonil in shells and hulls ranged from <0.03 to 0.66 ppm, 4-OH chlorothalonil from <0.03 to 0.06 ppm, and no residues of HCB <0.005 ppm or PCBN <0.008 ppm were detected.

In 1981 residue trials conducted at two California locations and reported in this petition,, Bravo 500 containing [redacted] PCBN was applied in two applications with ground equipment at rates varying from 4.5 to 16 pts/A (2.34 to 8.34 lbs ai/A) ca 0.5x to 2x the maximum proposed use rate to almond trees and residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN determined on almond nutmeats and almond shell and hull samples obtained at PHI's of 197 or 208 days. Following all treatment rates and PHI's, no detectable residues of chlorothalonil (<0.03 ppm) were found in almond nutmeats and no detectable residues of 4-OH chlorothalonil (<0.03 ppm), HCB (<0.004 ppm) or PCBN (<0.008 ppm) were found in either almond nutmeats or almond shells and hulls. Following two applications at the 2x application rate of Bravo 500 and at a PHI of 208 days, residues of chlorothalonil on almond shells and hulls ranged from 0.04 to 0.07 ppm and averaged 0.05 ppm for almonds.

We conclude that residues on almond nutmeats are not likely to exceed the proposed tolerance of 0.05 for almonds.

We also conclude that the proposed tolerance of 0.1 ppm for almond hulls is not adequate to cover residues resulting from the proposed use. In the 11/17/81 N. Dodd review of PP #1G2471, it was concluded that the then requested 0.2 ppm temporary tolerance proposed for almond hulls was not adequate to cover residues resulting from the proposed use, based on one residue trial in which residues of chlorothalonil in almond shells and hulls ranged from 0.05 to 0.66 ppm and averaged 0.37 ppm following 1 application of Bravo 500 at 16 pts/A (2x) at a 198 day PHI. In light of the latter 1981 residue trial indicating residues of chlorothalonil on almond shells

and hulls <0.1 ppm following 2 applications at a 2x application rate but considering the earlier residue trial cited above which indicated chlorothalonil residues averaging ca 0.4 ppm following 1 application at a 2x application rate. We consider that an appropriate tolerance level for combined residues of chlorothalonil and its 4-OH metabolite on almond hulls would be 0.2 ppm.

Rice (Grain)

Samples submitted in these studies were stored at 0°C prior to analysis for periods ranging from 4 to 5 months. For the reasons cited above for almonds we are not raising any questions with respect to the accuracy of the residue data for rice grain.

Residue experiments (21) were carried out in Texas, Louisiana, Arkansas, Mississippi, California, Puerto Rico, and Minnesota over a 5 year period (1976-1980). Rice was treated with either Bravo W-75 in 1 to 2 applications for a total of 2.66 to 5.32 lbs ai/A or Bravo 6F in 1 to 4 applications at 1 to 3 pts/A/Appl (0.75 to 2.25 lbs ai/A/Appl) for a total of 1.25 to 6.75 lbs ai/A or Bravo 500 in 1 to 3 applications at 1 to 4 pts/A/Appl (0.52 lb to 2.08 lbs ai/A/Appl) for a total of 1.04 to 4.16 lbs ai/A (0.33 to 1.33x the maximum recommended rate) via aerial applications or ground applications utilizing hydraulic boom sprayers or backpack mistblower sprayers. The PHI's for all studies varied between 23 and 96 days. A PHI of 28 days is recommended.

Residues of chlorothalonil and its 4-OH metabolite on unhulled rice following both the Bravo 6F and W-75 treatments ranged between (<0.01 and 1.80 ppm) and (<0.01 to 0.24 ppm) respectively. The highest residues reflected treatment of rice with Bravo 6F following a total of 6.75 lbs ai/A in a Texas trial following a 26 day PHI. Residues of chlorothalonil and its 4-OH metabolite on unhulled rice ranged from (<0.03 to 4.20 ppm) and (<0.03 to 0.14 ppm) respectively following treatment with Bravo 500. The highest residue reflected a 1x treatment rate in a Texas trial following a 31 day PHI.

In Texas and Louisiana residue trials when rice was treated with Bravo 500 (containing [redacted] PCBN) at 2.08 to 4.16 lbs ai/A (0.67 to 1.33x) the maximum recommended rate at PHI's of 26 to 50 days, residues of chlorothalonil, HCB, and PCBN ranged from (<0.01 to 2.72 ppm) (<0.003 ppm) and (<0.005 to 0.053 ppm) respectively. The highest chlorothalonil and PCBN residues reflected a 1x application rate following a 26 day PHI in a Texas trial.

We conclude that the submitted residue data will not support the proposed tolerance on rice. A more appropriate tolerance proposal (as suggested by the petitioner in Section D) would be 5.0 ppm for combined residues of chlorothalonil and its 4-OH metabolite on rice. We furthermore conclude that residues of PCBN up to 0.05 ppm would result on unhulled rice grain following the proposed use of Bravo 500 formulations on rice. No residuees of HCB would result on unhulled rice as a result of the proposed use.

Rice Processing Study

A rice processing or milling study was submitted with this petition. Although the petitioner indicates that the rice milling operation was conducted at the Texas Agricultural Experiment Station, Texas A&M Univ. System, Beaumont, Texas 77706, no details are given (as contrasted to the wheat milling study discussed later in this petition) as to the procedure or methodology utilized in the processing of unhulled rice grain to the rice hull, rice bran, brown rice and white rice fractions.

Unhulled rice grain bearing residues of 0.31 ppm chlorothalonil and 0.09 ppm 4-OH chlorothalonil or 2.16 ppm chlorothalonil and 0.05 ppm 4-OH chlorothalonil resulting from field treatment of rice with Bravo 6F and Bravo 500 respectively, were processed into rice hulls, bran, brown rice and white rice. Residues of chlorothalonil and 4-OH chlorothalonil in all processed fractiot rice hulls were all <0.06 ppm. For Bravo 6F treated rice, residues of chlorothalonil and 4-OH chlorothalonil concentrated 1.8x (0.55 ppm) and 1.6x (0.14 ppm) in the rice hulls, for Bravo 500 treated rice the comparable values were 6.5x (14.10 ppm) and 4.8X (0.24 ppm) in the rice hulls. This study indicates that combined residues of chlorothalonil and 4-OH chlorothalonil (at a maximum of 5 ppm in unhulled rice grain) have the potential to concentrate in the poultry feed item, rice hulls, to approximately 32 ppm. We can tentatively conclude that the petitioner should submit a food additive proposal to cover residues expected in the poultry feed item rice hulls. However, before we can arrive at a final conclusion regarding the necessity for a food additive tolerance, the petitioner should submit a new rice processing study for RCB's evaluation. In this processing study the petitioner, if possible, should retrieve the unhulled rice grain samples from the Beaumont, Texas residue trial bearing residues of chlorothalonil at 2.72 ppm and PCBN at 0.053 ppm (Sample No. 79-194-23) and subject these samples to a processing study

to ascertain whether PCBN residues concentrate in the rice hulls to the same extent as chlorothalonil and 4-OH chlorothalonil. If the above sample is not available, then comparable unhulled rice grain samples containing field treated detectable residues of PCBN at ca 0.05 ppm must be utilized in the requested processing study.

Wheat (grain)

Wheat grain samples submitted in the following studies were usually stored at 0°C prior to analysis (although in a few instances were stored at ambient temperature) for periods of time ranging from 3 to 5 years. Since the previously submitted storage stability studies for chlorothalonil and its metabolite 4-OH chlorothalonil indicate storage stability at 0°F for periods of time up to ca 14 months only, we seriously question the validity of the residue data submitted for wheat grain. We are also uncertain as to the stability of PCBN and HCB residues, if any, on wheat grain when stored over a period of time from 3 to 5 years.

Residue experiments (35) were conducted over a period of 6 years (1975-1980) in the following locations: MD, IL, TN, AL, GA, MN, LA, NE, AK, SD, ND, VA, MD, OK, TX and OR. Wheat was treated with either Bravo 6F in 1 to 3 applications at 1 to 3 pts/A/ Appl (0.75 to 2.25 lbs ai/A/Appl) for a total of 1.12 to 6.75 lbs ai/A or with Bravo 500 in 1 to 3 applications at 1 to 5 pts/A/Appl (0.52 lb to 2.60 lbs ai/A/Appl) for a total of 1.04 to 4.16 lbs ai/A (0.33 to 1.33X the maximum recommended rate) via aerial or ground applications. The PHI's for all studies varied between 22 and 77 days. A PHI of 28 days is recommended.

Residues of chlorothalonil and its 4-OH metabolite on wheat grain following Bravo 6F treatments both ranged between (<0.01 to 0.05 ppm). The highest residue of chlorothalonil reflected treatment of wheat with Bravo 6F following a total of 4.50 lbs ai/A in a Maryland trial with a 40 day PHI. The highest residue of the 4-OH metabolite reflected treatment of wheat with Bravo 6F following a total of 6.75 lbs ai/A in an Arkansas trial with a 34 day PHI. Residues of chlorothalonil and its 4-OH metabolite on wheat grain ranged from (<0.01 to 0.06 ppm) and (<0.03 to 0.04 ppm) respectively following treatment with Bravo 500. The highest chlorothalonil residue reflected a 0.75X treatment rate in a North Dakota trial at a 30 day PHI and the highest 4-OH metabolite residue reflected a 1.33X treatment rate in a Georgia trial at a 26 day PHI.

In residue trials conducted over a 4-year period in 12 of the 16 states cited above, when wheat was treated with Bravo 500 (containing [redacted] PCBN) at 1.04 to 4.16 lbs ai/A (0.33 to 1.33X) the maximum recommended rate at PHI's of 22 to 77 days, residues of HCB and PCBN were (<0.004-0.004 ppm) and (<0.008 ppm) respectively. Of the 42 residue trials reported only one resulted in a finite residue of HCB which was at the limit of detection (0.004 ppm) and which in turn reflected an Oklahoma trial at a 0.75X application rate with a 37 day PHI.

We conclude that the submitted residue data for wheat grain are insufficient to support the proposed tolerance for combined residues of chlorothalonil and 4-OH chlorothalonil at 0.1 ppm. Only 3 of the 42 residue trials conducted (ND and GA (2)) reflected, applications at or above the maximum proposed use rate and at or near the proposed 28-day PHI. In addition, as we have pointed out above, wheat grain samples were stored (in some cases presumably under ambient storage conditions) for periods of time up to 3 to 5 years before analysis. Under these conditions the stability of chlorothalonil and its 4-OH metabolite let alone the stability of HCB and PCBN residues (if any) are not known.

For a favorable tolerance recommendation on wheat grain the petitioner should provide additional residue data (chlorothalonil, 4-OH chlorothanonil, HCB and PCBN) reflecting the maximum proposed application rate at the minimum proposed PHI. 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 wheat grain.

Wheat Straw

Wheat straw samples submitted in the following studies were usually stored at 0°C prior to analysis (although in a few instances like wheat grain were stored at ambient temperature) for periods of time from 4 to 5 years. For the reasons cited above we question the validity of the residue data obtained on wheat straw for residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN.

Residue experiments were conducted at a total of 17 locations in ND, NE, AK, OK, MO, TN, LA, TX, MN and GA over a 2-year period. Wheat was tested aerially or via ground equipment, and wheat straw was harvested at grain maturity. Following application of Bravo 6F or Bravo 500 (containing 0.01% HCB and 0.3% PCBN) to wheat at 1.04 to 4.16 lbs ai/A (0.33 to 1.33X) the maximum recommended rate at PHI's of 22 to 65 days, residues of chlorothalonil, its 4-OH metabolite, HCB and PCBN

ranged from [(<0.03 - 18.0 ppm; Bravo 6F)(<0.03 - 7.53 ppm Bravo 500)], [(<0.03 - 1.80 ppm; Bravo 6F)(<0.03 - 0.88 ppm: Bravo 500)], [(<0.004-0.041 ppm; Bravo 6F) (<0.004 - 0.074 ppm; Bravo 500)] and [(<0.008 - 0.43 ppm; Bravo 6F)(<0.008 - 0.088 ppm; Bravo 500] respectively. The maximum chlorothalonil and 4-OH metabolite residue from Bravo 500 applications reflected a 1 1/3 X rate with a PHI of 26 days in a GA trial; the maximum PCBN residue reflected a 1X rate in a GA trial at a 38 day PHI and the maximum HCB residue reflected a 2/3X rate in an AK trial at a 54 day PHI.

The petitioner has imposed a label restriction against feeding treated wheat straw to livestock. We do not consider this restriction to be practical (see our discussion above under Proposed Use) and accordingly the petitioner should propose a tolerance for wheat straw to cover maximum residues expected from the proposed use. This proposed tolerance should be based on additional wheat straw residue data we are requesting. As we have pointed out above the submitted wheat straw residue data is invalid in that samples were stored for an excessively long (4-5 year) period prior to analysis. The submitted residue data (chlorothalonil, 4-OH chlorothalonil, HCB and PCBN) should reflect the maximum proposed application rate at the minimum proposed PHI. The sampling to analysis intervals should be kept to a minimum and the submitted residue data must be accompanied by documented storage stability data for residues of chlorothalonil, 4-OH chlorothalonil, HCB and PCBN on wheat straw.

Wheat Processing Study

A wheat processing or milling study was submitted with this petition. Wheat grain bearing field treated residues (North Dakota trial with Bravo 6F at 4.50 lbs ai/A) of chlorothalonil, its 4-OH metabolite, HCB and PCBN at (<0.03 ppm), (<0.03 ppm) (<0.004 ppm) and (<0.008 ppm) respectively was milled by the Buhler milling method (AACC Approved Methods 7th Ed. rev. 1962) which produced 53% reduction flour, 13% break flour, 11% shorts and 20% bran. No residues of chlorothalonil (<0.03 ppm), its 4-OH metabolite (<0.03 ppm) HCB (<0.004 ppm) and PCBN (<0.008 ppm) were detected in any of the milling products analyzed.

We consider the submitted processing (milling) study deficient, in that no finite residues were present initially on the rac (wheat grain) prior to processing. It could also be pointed out that the wheat foliage in that same study bore low residues of chlorothalonil (0.15 to 0.20 ppm) and 4-OH chlorothalonil (0.07 ppm). Additional wheat residue trials showed residues of chlorothalonil ranging up to ca 6 ppm and 4-OH Chlorothalonil ranging up to 0.6 ppm on wheat straw at

the proposed use rates. If grain from those studies was fractionated, it is quite possible that contaminative residues would show up in the outer layer of the wheat grain. Before RCB can render a judgement in regard to the need for a food additive proposal, we request that the petitioner submit a new wheat processing study for RCB's evaluation. In the submitted processing study, the rac (wheat grain) to be milled should bear finite or detectable field treated residues at or near the proposed 0.1 ppm tolerance. In addition, wheat should be treated with the Bravo 500 formulation (with the % HCB and PCBN impurities specified) at 1X or exaggerated application rates and the concentration of residues of chlorothalonil, its 4-OH metabolites and the impurities HCB and PCBN determined in the milling fractions.

Meat, Milk, Poultry and Eggs

Meat and Milk

No additional large animal (beef cattle, dairy cattle, goat, swine) feeding studies were submitted in this petition. Diamond Shamrock previously submitted residue data for chlorothalonil in milk (PP#1F1024, memo of W. Cox, 1/6/71). Cows were fed 25, 75, and 250 ppm chlorothalonil for 30 days. Residues were as high as 0.04 ppm chlorothalonil at each feeding level, but were below the limit of detection of the method (i.e., <0.02 ppm) in most cases. The controls registered levels as high as 0.03 ppm.

A second Diamond Shamrock study (PP#1F1024) determines residues of the hydroxy-metabolite in milk. The three feeding levels were 0.2 ppm DS-3701 (4-OH chlorothalonil) and 25 ppm DS-2787 (chlorothalonil) , 0.6 ppm DS-3701 and 75 ppm DS-2787, and 2.0 ppm DS-3701 and 250 ppm DS-2787. Residues of DS-3701 during the 30 days in which the chemicals were fed are as high as 0.30 ppm, 0.70 ppm, and 1.34 ppm, respectively. The sensitivity of the method is 0.03 ppm.

In a third Diamond Shamrock study on the hydroxy-metabolite (PP#1F1024), dairy cows were fed DS-2787 at 25 ppm and DS-3701 at 0.2 ppm for 30 days. Cows were also fed 75 ppm DS-2787 and 0.6 ppm DS-3701, and 250 ppm DS-2787 and 2.0 pm DS-3701. Half of the animals were slaughtered at the end of the 30 days to allow determination of residues in tissues. Residues of DS-2787 either at the end of the 30-day feeding period or at the end of a 32-day withdrawal period at the lowest treatment level were as high as follows: <0.05 ppm in muscle, 0.16 ppm in fat, 0.10 ppm in kidney, and 0.12 ppm in liver. Residues of DS-2787 in tissues after treatment at the middle feeding level were as high as <0.05 ppm in muscle, 0.34 ppm in fat, <0.05 ppm in kidney, and 0.09 ppm in liver. Residues

of DS-2787 at the highest feeding level were as high as 0.35 ppm in muscle, 0.22 ppm in fat, <0.05 ppm in kidney, and 0.08 ppm in liver. Residues of DS-3701 at the lowest treatment rate were as high as 0.12 ppm in muscle, 0.34 ppm in fat, 0.76 ppm in kidney, and 0.15 ppm in liver. Residues of DS-3701 at the middle treatment rate were 0.27 ppm in muscle, 1.1 ppm in fat, 1.47 ppm in kidney, and 0.50 pm in liver. Residues of DS-3701 at the highest treatment rate were 1.1 ppm in muscle, 2.7 ppm in fat, 4.40 ppm in kidney, and 1.80 ppm in liver. The sensitivity of the analytical method was 0.1 ppm.

The hydroxy-metabolite rather than the parent comprises the majority of the residue in meat, fat, and milk. Residues in milk from feeding chlorothalonil at 25 ppm for 30 days were a maximum of 0.04 ppm DS-2787. Residues of DS-3701 were as high as 0.30 ppm. This would indicate that combined residues of DS-2787 and DS-3701 would be <0.01 ppm in milk from feeding cows 25 ppm DS-2787 plus 0.2 ppm DS-3701 in 25% of the diet. Combined residues of DS-2787 plus DS-3701 from feeding cows 25 ppm of DS-2787 plus 0.2 ppm DS-3701 for 30 days were 0.17 ppm in muscle, 0.50 ppm in fat, 0.86 ppm in kidney, and 0.27 ppm in liver.

However, as we have previously mentioned under Nature of the Residue above, the aforecited dairy cattle feeding studies were conducted by IBT and therefore the residue data generated are not presently useful in assessing an appropriate tolerance level for residues of chlorothalonil and 4-OH chlorothalonil in meat and milk. Validation of the IBT studies must be accomplished and in addition a 14_C lactating ruminant metabolism study must be conducted in order for RCB to recommend an approporiate tolerance level in meat and milk.

Almond hulls can comprise up to 25% of the diet of beef and dairy cattle. Rice grain w/hulls can comprise up to 25% of the diet of beef and dairy cattle. Although rice straw is a potential feed item for beef cattle (10% of diet) a label feeding and grazing restriction imposed by the petitioner obviates the need to consider this rac as a feed item in this petition. Wheat grain and its milled byproducts can comprise up to 50% and 25% respectively of the diet of both beef and dairy cattle. Wheat straw can comprise up to 10% of the diet of both beef and dairy cattle.

Wheat grain and its milled byproducts can comprise up to 50%, 70% and 90% of the diet for laying hens, turkeys and broilers and swine, respectively. Rice (grain with hulls) can comprise up to 40% and 20% of the diet for turkeys and broilers and laying hens respectively. RCB considers rice hulls a poultry feed item including rice mill feed which is a

2:1 blend of rice hulls and rice bran (see 5/6/81 letter from W.E. Rogers, Elanco Products Co. to H. M. Jacoby PM#21 in RCB's Cultural Practices File under Rice). Rice hulls can comprise up to 12% and bran up to 40% of the diet of both turkeys and broilers and laying hens. We take issue with the petitioner's statement in the Crop Residue Chemistry Summary portion of the petition "that rice hulls themselves are not used as either food or feed supplement."

Although currently no other tolerances are pending for chlorothalonil on rac's and their processed byproducts that are feed items, permanent tolerances have been established for chlorothalonil on the following livestock feed items: cull carrots (1.0 ppm), mint hay (2.0 ppm), peanuts (0.3 ppm), potatoes (0.1 ppm) and tomatoes (5.0 ppm). Based on data submitted by the petitioner (letter of 8/9/76 submitted in conjunction with PP#0F01024) that virtually all the residues (over 99%) of chlorothalonil are removed during the normal processing (alkaline detergent wash) of tomatoes, it was concluded in the W. S. Cox 11/17/76 review of that petition that RCB has no further concern as to the concentration of residues in processed tomato byproducts (tomato pomace) or the impact of treated tomatoes on secondary residues of chlorothalonil in meat or milk. Mint hay can comprise up to 25% and 60% respectively of the diet of both beef and dairy cattle, peanut meal; 15% for beef cattle, 25% for dairy cattle and 10% for poultry and swine, potatoes; 20% for poultry, 50% for swine, and 30% for both beef and dairy cattle and carrots; 30% for beef cattle and 20% for dairy cattle. In conjunction with PP#1E2473 a label restriction was imposed against feeding treated mint hay to livestock. The remaining livestock feed items cited above (carrots, peanuts, and potatoes) for which tolerances have been established, must be considered, in addition to the feed items addressed in this petition when appropriate tolerances are established by the petitioner for residues of chlorothalonil and its 4-OH metabolite in milk and in the meat, fat and meat byproducts of cattle, goats, hogs, horses, sheep and poultry. However, in the following Tables calculating the maximum potential for secondary residues of chlorothalonil and its 4-OH meabolite to transfer to meat, milk, poultry and eggs we have not considered the feed contribution of carrots, peanuts and potatoes (for which tolerances have been established) since for those feed items residues of 4-OH chlorothalonil were either not detected or analyzed for (see PP#7F0599 (carrots), PP#9F0743 (Potatoes) and PP#1F1024 (peanuts)).

The following feed items would provide a diet highest in potential for secondary residues of chlorothalonil and its 4-OH metabolite in the meat and milk of beef and dairy cattle:

	% of diet	Max. Residues Expected (ppm) DS-2787 (Chlorothalonil)	DS-3701 4-OH met.)	ppm in diet DS-2787	DS-3701
Almond hulls	15	0.2	-	.030	-
Rice w/hulls	25	5.0	0.14	1.250	.035
Wheat (grain)	50	0.1[1]	0.05	.050	.025
Wheat (straw)	10	10.0[2]	1.0	1.000	.100
				2.330	.160

1 Proposed tolerance level not supported by submitted residue data (see our discussion under Sec. D above)

2 Maximum estimated value based on our evaluation of residue data.

Based on an analysis of the aforecited (albeit invalid) livestock feeding studies we can calculate that the feeding of 2.330 ppm chlorothalonil to dairy cattle would result in a transfer of 0.005 ppm of this residue to milk combined with a transfer of ca 0.08 ppm of the 4-OH metabolite to milk (from an ingestion of 0.100 ppm of this residue) resulting in a total transfer of 0.085 ppm combined residues to milk.

It should be noted, however, that residues of PCBN were detected at levels up to 0.053 ppm on rice w/hulls, up to levels of 0.88 ppm in wheat straw and residues of HCB detected up to 0.07 ppm on wheat straw and dependent upon the results of the additional wheat (grain) residue and processing studies we are requesting, residues of HCB and PCBN any also be present at finite levels in wheat grain and processed fractions. Therefore, until the requested additional residue studies on wheat (grain and straw) and processed fractions 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 studies then the requested 14_C cattle metabolism studies should also determine the potential of these residues to transfer to meat and milk and the tolerance proposal for meat and milk amended to include these residues in the tolerance expression. Additionally, prior to the establishment of a revised tolerance for meat and milk an additional MTO will be conducted for residues of both chlorothalonil and its 4-OH metabolite and contingent upon the results of the requested residue studies on HCB and PCBN described above, to include these residues in the MTO (see our discussion under Analytical Methodology above).

Based on the data submitted in this petition and contingent upon the results of the requested residue, storage stability, IBT validation and 14_C lactating ruminant metabolism studies and a successful MTO of the proposed milk methodology, 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.

We cannot arrive at a final conclusion regarding the adequacy of the proposed tolerance of 0.1 ppm for combined residues of chlorothalonil and its 4-OH metabolite in milk 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 conducted by EPA in milk for the significant residues of toxicological concern detected in the aforementioned studies.

The following feed items would provide a diet highest in potential for secondary residues of chlorothalonil and its 4-OH metabolite in hogs:

		Max. Residues Expected (ppm)		ppm in diet	
	% of diet	DS-2787 (Chlorothalonil)	DS-3701 4-OH met.)	DS-2787	DS-3701
Rice w/hulls	50	5.0	0.14	2.500	0.070
Wheat (grain)	50	0.1[1/]	0.05	.050	.025
				2.550	.095

Based on an analysis of the aforecited (albeit invalid) livestock feeding study we calculate that the feeding of 2.550 ppm chlorothalonil and 0.095 ppm 4-OH chlorothalonil to hogs would result in total residues of chlorothalonil and 4-OH chlorothalonil at 0.05 ppm in each of liver and muscle, less than 0.1 ppm in fat and in the range of 0.2 to 0.4 ppm in kidney tissue.

Furthermore, based on our analysis of the same livestock feeding study we calculate that the feeding of 2.330 ppm chlorothalonil to dairy cattle including 0.160 ppm 4-OH chlorothalonil would result in total residues of slightly

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1/ Proposed tolerance level not supported by submitted residue data (see our discussion under Sec. D above).

less than 0.1 ppm in each of liver, muscle and fat and at approximately 0.5 ppm in kidney tissue.

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, 14_C lactating ruminant metabolism studies and a successful method tryout on the same substrates for significant residues of toxicological concern have been obtained. Based on the data submitted in this petition and contingent upon the results of the requested residue studies including 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 proposed at a level of at least 0.2 ppm and for kidney at a level of at least 0.5 ppm.

Poultry and Eggs

Two poultry feeding studies were submitted by the petitioners. The first "Poultry and Egg Residue Study with (14_C-DS-2787) (DOC No. 596-4AM-82-0122-002) and the second Poultry and Egg Residue Study with (14_C-DS-3701) (DOC. No. 596-4AM-82-0013-002). The chickens employed in these studies were young adult (27 wk old) Leghorn hens. In the first study the birds were dosed daily for 21 days with 0, 2, 6 and 20 ppm ^{14}C-DS-2787 (uniformly labeled in the benzene ring) and DS-2787 (in a 1:8 ratio) and in the second study birds were dosed daily for 21 days with 0, 0.1, 0.3 and 1.0 ppm ^{14}C-DS-3701 and DS-3701 (in a 1:8 ratio). The unlabeled DS-2787 contained 4% unidentified impurities and the unlabeled DS-3701 contained 1% unidentified impurities. Eggs from each dose group were collected daily throughout the investigation, separated into whites and yolks and frozen prior to residue analysis. At the scheduled sacrifice (6 hrs, 3 days and 7 days after final dose) pooled samples of muscle (adductor, cardial and pectoral), liver, fat and skin from the birds in each test level were collected and subjected to residue analysis. Egg yolk and skin and cardial tissue were blended in a Sorvall Omni-Mixer and egg white and samples of adductor, pectoral, liver and fat were homogenized in a Waring Blender. Levels of radioactivity in all processed egg and tissue samples were determined by combustion of 0.1 g subsamples in a Harvey OX-300 biological oxidizer. Evolved $^{14}CO_2$ from combusted samples was counted in 15 ml of carbon 14 cocktail and samples were routinely counted for 10 min. in a Tracor Model 6882 Mark III liquid scintillation spectrometer.

In the first study no detectable (<0.03 ppm) ^{14}C-residues were found in egg whites at any dose level of ^{14}C-DS-2787. No detectable (<0.03 ppm) ^{14}C residues were found in egg yolks at the 2 ppm or 6 ppm dose level at any sampling interval. At a dose of 20 ppm yolks contained .035 to .047 ppm ^{14}C. The only detectable (>0.04 ppm) ^{14}C residues were present in liver tissue. A ^{14}C-residue of .098 ppm was present in liver following the 6 ppm dose.

In the second study no detectable (<0.03 ppm) ^{14}C residues were found in egg whites at any dose level of ^{14}C-DS-3701. The mid dose (0.3 ppm) and high dose (1.0 ppm) egg yolks showed maximum total ^{14}C residues of 0.12 and 0.42 ppm respectively, the low dose 0.1 ppm. Egg yolks showed residues of 0.04 ppm. No detectable (<0.03 ppm) ^{14}C residues were found in fat, adductor and pectoral tissue at any dose level. Skin contained a detectable residue, 0.037 ppm, only at the high (1.0 ppm) dose level. ^{14}C residues detected in liver were .056 ppm, .269 ppm and .782 ppm following the 0.1, 0.3 and 1.0 ppm dose levels. ^{14}C residues in cardial tissues were <0.03 ppm, 0.055 ppm and 0.154 ppm respectively following the 0.1, 0.3 and 1.0 ppm dose levels. The results of the above feeding studies clearly indicate that as has already been demonstrated in the dairy cattle feeding studies submitted earlier that the 4-OH metabolite of chlorothalonil (DS-3701) rather than the parent compound DS-2787 is the primary secondary residue transferred from animal feed to the meat, milk, and eggs of livestock. We also note that the petitioner has not analyzed the chlorothalonil used in the above feeding study for HCB and PCBN impurities as originally requested in P. Errico's 9/24/81 memo of conference with Diamond Shamrock Corp.

The following feed items would provide a diet highest in potential for secondary residues of cholorothalonil and its 4-OH metabolite in poultry (turkey and broiler) tissues.

		Max. residues expected (ppm)		ppm in diet	
	% of diet	DS-2787 (Chlorothalonil)	DS-3701 (4-OH met)	DS-2787	DS-3701
Rice w/hulls	40	5.0	0.14	2.00	.060
Rice hulls	12	31.59[1/]	0.67[1]	3.79	.080
Wheat grain	48	0.1[2/]	0.05	.05	.024
				5.84	.164

[1/] Based on 6.5X conc. factor for DS-2787 and 4.8X conc. factor for DS-3701.

[2/] Proposed tolerance level not supported by submitted residue data (see our discussion under. Sec. D above)

For laying hens, such a diet would be as follows:

	% of diet	Max-residues expected (ppm) DS-2787 (Chlorothalonil)	DS-3701 (4-OH met)	ppm in diet DS-2787	DS-3701
Rice w/hulls	20	5.0	0.14	1.00	.028
Rice hulls	12	31.59[1/]	0.67[1/]	3.79	.080
Wheat grain	50	0.1[2/]	0.05	.05	.025
Rice (milled byproduct)	18	0.06	-	.01	-
				4.85	.133

[1/] and [2/] Same as above for (turkeys and broilers)

Based on an analysis of the aforecited poultry feeding studies, we calculate that the feeding of 4.85 ppm chlorothalonil and 0.133 ppm of its 4-OH metabolite to laying hens would result in the transfer of ca 0.04 ppm of the combined residue to eggs. Feeding of 5.84 ppm chlorothalonil and 0.164 ppm of its 4-OH metabolite to turkeys and broilers would result in the transfer of ca 0.29 pm of the combined residue to poultry tissue.

It should be noted, however, that residues of PCBN were detected at levels ranging up to 0.053 ppm on rice w/hulls, assuming a concentration factor varying from 4.8 to 6.5X for concentration of the impurity in rice hulls (see results of rice milling study cited under Residue Data for residues of chlorothalonil and 4-OH chlorothalonil) we calculate that residues of PCBN could vary between 0.25 and 0.34 ppm in the poultry feed item rice hulls. Our final conclusion regarding the concentration of PCBN residues in rice hulls must await the results of the processing study we have requested on unhulled rice grain bearing finite residues of PCBN (see Rice processing study under Residue Data above). The metabolism of PCBN by poultry or its potential transfer to poultry tissue or eggs has not been considered in the poultry feeding studies submitted above. Additionally, RCB's final assessment of the magnitude of PCBN and possibly HCB residues in the poultry diet must await the results of the requested additional (validated with storage stability data) wheat (grain and processed fractions) residue studies to include analysis of HCB and PCBN residues. If significant levels of these residues are found in both rice hulls as a result of the requested rice processing study and in addition in wheat (grain) and processed fractions as a result of the requested additional residue studies, then a poultry metabolism study will need to be initiated in order to determine the potential of these residues to transfer to the meat and eggs of poultry and the tolerance proposal for meat and eggs amended to include these residues

in the tolerance expression. Additionally, prior to the establishment of a revised tolerance for meat and eggs an additional MTO will be conducted for residues of both chlorothalonil and its 4-OH metabolite and contingent upon the results of the requested residue studies on HCB and PCBN described above, to include these residues on the MTO (see our discussion under Analytical Methodology above).

Based on the data submitted in this petition and contingent upon the results of the requested residue, storage stability and poultry metabolism study (if warranted) and a successful MTO of the proposed methodology for eggs, we tentatively conclude that the proposed 0.1 pm 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 in almonds, rice and wheat.

We cannot arrive at a final conclusion regarding the adequacy of the proposed tolerance of 0.1 ppm for combined residues of chlorothalonil and its 4-OH metabolite in eggs 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 these additional residue studies submitted, and a successful MTO conducted by EPA on eggs for the significant residues of toxicological concern detected in the aforementioned studies.

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. Based on the data submitted in this petition and contingent upon the results of the requested residue (including processing), storage stability and metabolism studies and a successful MTO of the proposed methodology on 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.

Other Considerations

The International Residue Limit (IRL) Status sheet is attached. According to it, there are no Canadian or Mexican tolerances for chlorothalonil residues for the commodities addressed in this petition.

A review of the residue data in this petition indicates that the Codex IRL of 0.2 ppm for the group "cereal grains" would not be supportable in conjunction with the uses proposed in this petition. However it would be useful for the Agency to address the possiblity of U.S. compatability in terms of the group limit allthough compatability of individual members of the group may not be possible.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Chlorothalonil

PETITION NO 3F 2875

CCPR NO. 81

Codex Status

/_____/ No Codex Proposal
Step 6 or above

Proposed U.S. Tolerances

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

(Crop(s)	Limit (mg/kg)
Cereal grains	0.2 [1]/

Residue: Combined residues Chlorothalonil and 4-hydroxy-2,5,6-Trichlorophthalonitrile

Crops(s)	Tol. (ppm)
Almonds	0.05
Rice	4.0
Wheat	0.1
Almond Hulls	0.1
Meat	0.05
Milk	0.1
Poultry	0.1
Eggs	0.1

CANADIAN LIMIT

Residue:_____

_____

Crop	Limit (ppm)
none (on these commodities)	

MEXICAN TOLERANCIA

Residue:_____

_____

Crop	Tolerancia (ppm)
none	(on these commodities).

Notes: [1]/ It would be useful to address the possibility of U.S. compatibility in terms of the group limit and for the individual members of the group.

cc: R.F.
Circu
Kovacs
TOX
EEB
EAB
Petition No. 3F2875
RDI:Section Head:RSQ:Date:9/23/83:RDS:Date:9/23/83
TS-769:MFK:pjb:RM:810:CM#2:Date:9/28/83
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