UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 6/14/02

Subject: DCPA. PP#0E3883 and PP#2E6442. IR-4 Petitions for Tolerances and Proposals for Registration of the 75% WP (EPA Reg. No. 5481-490) for Use on Parsley, Oriental Radish, Basil, Coriander, Dill, Marjoram, Ginseng, Chives, Celeriac, Chicory, and Radicchio. Review of Analytical Chemistry and Residue Data.

DP Barcode:	D280398; D280400; D281320; D282898	Case No.:	N/A
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40 CFR 180.	185		

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To: Hoyt Jamerson/Robert Forrest (PM-5) Registration Division (7505C)

Executive Summary

USDA/IR-4 has proposed tolerances with regional registrations for combined residues of DCPA and its currently regulated metabolites in/on parsley grown in CA (PP#0E3883) and in/on several other minor crops (PP#2E6442) grown in CA (oriental radish, basil, coriander, dill, marjoram, chives, celeriac, chicory, and radicchio) and NC/WI (ginseng). The 75% WP (EPA Reg. No. 5481-490) has been proposed to be amended to include these minor crop use sites. The tolerances are intended to regulate DCPA residues in/on these crops resulting from either direct application or off-site, inadvertent movement independent of the application event itself. This off-site movement appears to be largely due to wind-blown soil particles to which DCPA

residues have adsorbed.

DCPA is registered for use as a selective herbicide for pre-emergence application to control crabgrass and certain broad-leafed weeds in cole crops, bulb vegetables, cucurbits, potatoes, fruiting vegetables, strawberries, ornamentals, and turf. DCPA is proposed to be applied at 4.5-10.5 lb ai/A to the soil prior to crop seed germination. DCPA is applied at 4.5-10.5 lb ai/A to registered crop sites at seeding or at transplant for early season weed control and/or over the top for later season control. Typically, only one application is made but a second application may be made at layby to cotton, garlic, onions, potatoes, strawberries, sweet potatoes, and yams; thus, these crops may have a seasonal application rate of \leq 21 lb ai/A. Soil incorporation of DCPA is not recommended on seeded cucurbits, garlic, horseradish, onions, potatoes, radish, sweet potatoes, and yams. Detectable residues of DCPA and its regulated metabolites will result in/on treated crops, rotational crops, and, occasionally, on adjacent or even distant untreated crops via inadvertent off-site movement of residues adsorbed to wind-blown soil particles, particularly in California.

In addition to the parent compound, the mono- and di-desmethylated metabolites (MTP and TPA, respectively) resulting from hydrolysis of one or both methyl ester groups require regulation (MARC: W. Hazel, D282838, 5/15/02). Refer to Figure A for structures of regulated residues. The relative ratios of these three residues vary greatly and depend on crop, timing of application and harvest, location, etc. Tolerances for combined residues of DCPA, MTP, and TPA have been established in/on numerous plant crop commodities at 0.05 ppm in corn grain to 15 ppm in radish tops (40 CFR 180.185). Since DCPA is largely a preemergence herbicide applied early season, most residues are likely to be within the tissue although some inadvertent, wind-blown residues may reside on the surface in some locations. Tolerances have not been established for DCPA residues in livestock commodities although ruminant metabolism and poultry feeding studies suggest that tolerances may be necessary; these studies will be used to estimate anticipated residues. A ruminant feeding study and a poultry metabolism study have been required (W. Smith, 3/8/95, D208554).

Although there are tolerances, there are no registered corn, soybean, lettuce, or rutabaga uses; however, the registrant wishes to retain these tolerances to cover inadvertent crop rotational residues while large-scale field rotational crop studies are being conducted.

Adequate methodology is available to enforce existing and proposed tolerances in/on plant commodities. Three tolerance enforcement methods for plant commodities are published in FDA's Pesticide Analytical Manual (PAM), Vol. II (Section 180.185), as Methods A, B, and C. Residue data submitted in response to the 6/88 Guidance Document were collected using GC/EC methods similar to the PAM, Vol. II methods. These methods are adequate for collection of DCPA, HCB, MTP, and TPA residue data from crops (including processed commodities). The limits of detection (LOD) are 0.01 ppm each for DCPA, MTP, and TPA, and 0.0005 ppm for HCB. These methods are suitable candidates for validation procedures as enforcement methods for plant commodities.

Another GC/EC method, similar to those submitted for plants, is available for determining DCPA, MTP, and TPA in milk and beef fat. Recoveries of each compound using 12 samples

each of milk and beef fat fortified at 0.01-5 ppm were acceptable. The LOD is 0.01 ppm. This method is suitable for Agency validation and inclusion in PAM, Vol. II pending successful independent laboratory validation. The registrant has indicated that independent laboratory validation of the method is underway. The registrant must submit independent laboratory validation data for enforcement method(s) for animal commodities and submit the method(s) for Agency validation and inclusion in PAM, Vol. II. Representative samples from adequate animal metabolism studies must be analyzed by preferred enforcement method(s) to ascertain their ability to adequately recover and quantify DCPA, MTP, and TPA.

DCPA *per se* is completely recovered using PAM, Vol. I Multiresidue Protocols D and E (PESTDATA, PAM, Vol. I, Appendix, 8/93). Data submitted by the registrant indicate that TPA is not recovered by Protocols B and C. Multiresidue testing data on MTP are still required.

In parsley field trials (PP#0E3883), the 75% wettable powder (WP; Dacthal® W75 Herbicide; EPA Reg. No. 5481-490) was applied at 10-10.5 lb ai/A in 1986 to seeded parsley as a single preemergence treatment at four CA sites. Parsley was harvested at normal crop maturity (66-111 days posttreatment) and samples were frozen until analyzed by the GC/EC method described above. Adequate storage stability data are available on a variety of crops indicating stability of residues in samples for at least 4 years of frozen storage. These field trial data have already been reviewed by HED in 1990 (W. T. Chin. PP#0E3883. 9/12/90). The resulting combined residues of DCPA, MTP, and TPA were 0.38-3.1 ppm with DCPA being the major residue. HCB was nonquantifiable (<0.003 ppm) in three samples but detected at 0.004 ppm in one sample; however, as HCB was also found at 0.003 ppm in the untreated control, this may be due to contamination from another source. There are no deficiencies associated with these field trials that would impact registration of the 75% WP DCPA product on parsley grown in CA. The proposed tolerance of 5 ppm for residues of DCPA in/on Parsley, leaves is appropriate. The data are adequate for use in dietary risk assessment.

In the processing/drying study, the calculated concentration factors upon drying fresh parsley are 3.3x, 3.4x, and 4.3x at three respective cuttings made 126, 175, and 231 days posttreatment; the average concentration factor is 3.7x. Considering the somewhat limited database and the level of variability in the residue values and concentration factors, HED recommends that the IR-4 revise their tolerance proposal from 15 ppm to 20 ppm in Parsley, dried leaves.

The tolerances for DCPA residues in/on the following minor crops proposed in PP#2E6442 are deemed by HED to be appropriate: 2 ppm in/on Celeriac, Ginseng, and Radish, oriental; and 5 ppm in/on Basil, fresh leaves, Chive, Dill, Marjoram, and Coriander, leaves. The 5-ppm tolerance proposed for residues in/on "Chicory" has been revised to: Chicory, roots (2 ppm) and Chicory, tops (5 ppm). The 2-ppm tolerance proposed for DCPA in/on Radicchio has been revised to 5 ppm. In addition, a tolerance was not proposed by IR-4 for residues in dried basil; based on dried parsley data summarized above, a 20-ppm tolerance should be proposed in Basil, dried leaves at 20 ppm.

Percent crop treated data were updated by F. Hernandez of BEAD on 5/22/02. Cole crops (6-24%), onions (15%), sweet peppers (5%), and radishes (5%), represent the crops having the highest average percent crop treated. For the following crops, 100% of crop treated will be

assumed: hot peppers, Brussels sprouts, garlic, horseradish, turnips, and upland cress. Less than 1% of crop treated will be assumed for the following crops: cotton, green and succulent beans and peas, peaches, potatoes, sweet potatoes, honeydew melons, watermelons, winter squash, and yams. These data reflect USDA figures and 1995-2000 EPA information.

Field trial data are available for all crops (or translated to the minor crops to support tolerances proposed by IR-4 under PP#2E6442) with an LOQ of 0.01 ppm. Field trial residues are generally detectable and the range of values for a given crop is usually fairly small. Although FDA and PDP monitoring data are available for DCPA, the two regulated metabolites (MTP and TPA) were not sought by these agencies. Since the ratios of parent to metabolite residues are so variable, ratios from metabolism studies or field trials cannot be applied to monitoring data to permit dietary exposure refinement. The percentages of monitoring samples bearing quantifiable residues are typically 5-50%. Some California monitoring data are available but it appears that only the parent compound was analyzed in virtually all samples. Anticipated residue calculations, generally making use of field trial data and correcting for percent crop treated data, will be provided in a separate memorandum. An acute dietary risk assessment is not required because no toxic effects attributable to a single dose have been observed. Anticipated residues to be used in chronic (cancer and noncancer) dietary risk assessments will generally be calcuated as average field trial values corrected by percent crop treated.

Chemical name	Chemical structure
DCPA Dimethyltetrachloroterephthalate	O Cl Cl Cl Cl Cl Cl Cl Cl Cl Cl Cl Cl Cl
MTP Monomethyltetrachloroterephthalic acid	O Cl Cl Cl Cl Cl Cl Cl Cl Cl Cl

Figure A. The Chemical Structure of DCPA and its Metabolites of Concern.



Residue Chemistry Deficiencies

No residue chemistry deficiencies impacting the establishment or reassessment of tolerances exist. The following confirmatory data are necessary to permit refinement of dietary exposure and risk to DCPA: (i) rotational crop field trials and labeling proposals (crops to be rotated and PBIs); (ii) sample storage temperature and duration to confirm the stability of residues in samples collected and analyzed as part of certain field trials conducted prior to 1995; (iii) a ruminant feeding study; (iv) a poultry metabolism study; and (v) livestock method validation. Please see specific topics below for details of these data needs.

Background

DCPA, a selective terephthalate herbicide, is an active ingredient in products registered to control crabgrass and certain broad-leafed weeds on brassica vegetables, bulb vegetables, cucurbits, potatoes, fruiting vegetables, strawberries, ornamentals, and turf. DCPA is proposed by IR-4 to be used on minor crops in CA (leafy vegetables, herbs, and root crops) and in WI and NC (ginseng). The 75% WP (EPA Reg. No. 5481-490) is proposed to be applied once per season at 4.5-10.5 lb ai/A to the soil prior to crop seed germination. When used on currently registered crops, DCPA can be applied at seeding or at transplant for early season weed control and can be applied over the top for later season control. The single application rates for registered crops also are 4.5-10.5 lb ai/A. Typically, only one application is made but a second application can be made at layby to cotton, garlic, onions, potatoes, strawberries, sweet potatoes, and yams. Soil incorporation of DCPA is not recommended on seeded cucurbits, garlic, horseradish, onions, potatoes, radish, sweet potatoes, and yams. Detectable residues of DCPA and its regulated metabolites will result in/on treated crops and, occasionally, on adjacent or even distant untreated crops via inadvertent off-site movement of residues adhered or adsorbed to wind-blown soil particles, particularly in California.

Tolerances are currently established for residues of DCPA, MTP, and TPA, calculated as DCPA, in or on: cottonseed at 0.02 ppm; corn grain and sweet corn kernels at 0.05 ppm; corn forage and fodder at 0.4 ppm; cantaloupes, cucumber, eggplant, garlic, honeydew melons, onions, summer and winter squash, tomatoes, and watermelons at 1 ppm; dry field and mung beans, succulent beans, horseradish, lettuce, southern (black-eyed) peas, peppers, pimentos, potatoes, radish roots,

rutabagas, soybeans, strawberries, sweet potatoes, turnips, and yams at 2 ppm; upland cress, turnip greens, and brassica leafy vegetables at 5 ppm; and radish tops at 15 ppm (40 CFR 180.185). Petition 0E3883 proposes tolerances of 5 and 15 ppm in or on fresh and dried parsley, respectively. Petition 2E6442 proposes tolerances of 2 ppm in or on oriental radish, ginseng, and radicchio and tolerances of 5 ppm in or on basil, coriander, dill, marjoram, chives, celeriac, and chicory. The MARC has determined that the residue of concern for purposes of both regulation (tolerance expression) and risk assessment continues to be combined residues of DCPA, MTP, and TPA calculated as DCPA (W. Hazel. 6/5/02. D282838).

Table 1. Summary of Directions for Use of DCPA.							
Commodity	Applic. Timing, Type, and Equip.	Formu- lation [EPA Reg. No.]	Applic. Rate (lbai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Basil, celeriac, chicory, chives, coriander, dill, ginseng, marjoram,	Preemer- gence spray	75% WP [5481-	4.5- 10.5	1	10.5	None	<i>Ginseng:</i> For use in NC and WI only. <i>All other crops:</i> For use in CA only.
oriental radish	using ground, air, or irrigation equip- ment	490]					<i>All crops:</i> Apply to weed- free soil prior to crop seed germination. Soil incorporation is not recommended. Do not graze or harvest foliage for livestock feed.

860.1200 Proposed Directions for Use

860.1300 Nature of the Residue - Plants

MARC Decision Memo: W. Hazel. 6/5/02. D282838.

From the 7/13/95 HED chapter of the RED, the qualitative nature of the residue in plants is adequately understood based on acceptable studies on onions, turnips, and tobacco. The residues of concern in plants are DCPA and its metabolites MTP and TPA which are the parent compound and the two demethylated metabolites that are currently regulated (Figure A). The metabolism of DCPA in plants is via ester hydrolysis. Studies conducted with onion and turnip indicate that the impurity HCB is not metabolized appreciably in these plants.

Total radioactive residues (TRR) were 0.548 ppm in mature onion bulbs and 6.458 ppm in onion tops treated with ¹⁴C-DCPA at 1x. DCPA and its metabolites MTP and TPA accounted for 66% and 79% of the TRR in onion tops and mature bulbs, respectively. TRR in mature turnip roots and tops were 4.732 and 2.015 ppm from 1x treatment with ¹⁴C-DCPA. Combined residues of DCPA, MTP, and TPA accounted for 78-89% of the TRR in turnip roots and tops. In tobacco

treated with ¹⁴C-DCPA, TRR in whole plants were 21-23 ppm. DCPA, MTP, and TPA accounted for 91-98% of the radioactivity in tobacco.

Based on these plant metabolism studies, the MARC has determined that the residue of concern for purposes of both regulation (tolerance expression) and risk assessment continues to be combined residues of DCPA, MTP, and TPA calculated as DCPA (W. Hazel. 6/5/02. D282838).

860.1300 Nature of the Residue - Livestock

MARC Decision Memo: W. Hazel. 6/5/02. D282838

Ruminants. The nature of the residue in ruminants is adequately understood. DCPA, MTP, and TPA are the residues of concern. A lactating goat was dosed with ¹⁴C-DCPA for 4 days. The daily dose was equivalent to 10 ppm in the diet, 1x the theoretical maximum DCPA intake for dairy cattle and 2x the maximum beef cattle intake. Total radioactive residues (TRR) were less than or equal to 0.01 ppm in milk with 38.5% organosoluble (0.004 ppm). Milk residues were not further characterized. Residues in tissues were 0.0057 ppm in loin muscle, 0.0109 ppm in leg muscle, 0.0168 to 0.0179 ppm in fat, 0.0333 ppm in liver, and 0.1007 ppm in kidney. MTP was the predominant residue in kidney, liver, leg muscle, and fat, accounting for 80-98% of the TRR. The parent compound DCPA was detected only in fat at 10-15% of TRR. TPA was found only in omental fat at 5% of TRR. Until adequate cattle feeding studies are available, the data from this metabolism study will be used for estimating residues in meat and milk commodities.

Poultry. The requirement for a poultry metabolism study has not been met, and remains in effect. Until these data are generated, EPA will use the existing poultry feeding studies for exposure/risk assessment based on the assumption that the residues of concern in poultry tissues and eggs are the same as those delineated in meat and milk from the acceptable ruminant metabolism study.

Rats. In 6 separate metabolism studies, ¹⁴C-DCPA was given as single or multiple oral gavage doses to rats at 1 or 1000 mg/kg/day. There were no significant sex differences in any of the studies. Absorption was rapid and essentially complete by 48 hours. Absorption was more efficient at 1 mg/kg/day (79%-86% of administered dose) than at 1000 mg/kg/day (6-9%). Urine was the major route of excretion. The major compound found in urine was MTP. TPA was a minor metabolite representing approximately 1% of radioactivity in urine. No DCPA was found in urine. Less than 1% of radiolabel was found in bile, so radioactivity in feces represents unabsorbed compound.

Radiolabel did not bioaccumulate in rat tissues following repeated treatment. Although a high percentage of the administered dose was found in fat 12 hours after discontinuance of dosing (12% of dose in low-dose animals), radiolabel had rapidly depleted by 168 hours (0.03%). Concentration of radiolabel in the thyroid increased at 36 hours postdosing when compared to the 12 hour time period; however, radiolabel in the thyroid rapidly depleted by 168 hours. By 168 hours, the highest concentration of radiolabel in both dose groups was in the kidney.

Based on the above metabolism studies, the MARC has determined that the residue of concern for

purposes of both regulation (tolerance expression) and risk assessment continues to be combined residues of DCPA, MTP, and TPA calculated as DCPA (W. Hazel. 6/5/02. D282838).

860.1340 Residue Analytical Methods

DER Reference List: W.Smith. 5/9/95. D211599; 3/16/95. D208554.

The crop field trial residue data were generated using GC/EC or GC/MC methods similar to the methods published in PAM Vol. II (Sec. 180.185, Methods A, B, and C). Briefly, in the GC/EC methods, residues are extracted, selectively partitioned into an organic solvent, and filtered. Two separate aliquots of filtrate are prepared for separate DCPA/HCB and MTP/TPA analyses. Residues from the DCPA/HCB sample are partitioned into an organic solvent and separated and cleaned-up by column chromatography prior to quantitation by GC/EC. Residues from the MTP/TPA sample are also partitioned into an organic solvent, then derivatized with diazopropane to the propyl and dipropyl esters. The derivatized residues are then cleaned up by column chromatography prior to quantitation by GC/EC. The GC/MC methods are similar to the above described methods except that in the GC/MC methods, separate procedures are used for extraction of DCPA and its two metabolites (MTP and TPA); in addition, MTP and TPA are not derivatized prior to analysis. Unless otherwise noted, the limits of detection in plant commodities are 0.01 ppm each for DCPA, MTP and TPA, and 0.0005 ppm for HCB.

The submitted GC/EC method for determining DCPA, MTP, and TPA in milk and beef fat is adequate for data collection. Recoveries of each compound from 12 samples of each matrix fortified with each compound at 0.01-5 ppm were 70-114%, except that a recovery of 130% was obtained from one sample of milk fortified with TPA at 0.01 ppm. The limit of quantitation was reported as the lowest concentration for which validation data were obtained, i.e., 0.01 ppm. This method is a suitable candidate for tolerance enforcement, provided that the method successfully undergoes independent laboratory validation prior to submission for Agency validation and inclusion in PAM, Vol. II. This enforcement method must be validated using liver, kidney and muscle tissues as well as milk and fat. Representative samples from adequate animal metabolism studies must be analyzed by preferred enforcement method(s) to ascertain their ability to adequately recover and quantify DCPA, MTP, and TPA.

860.1360 Multiresidue Methods

DER Reference List: K. Boyle. 7/13/95. HED RED Chapter

DCPA *per se* is completely recovered using PAM, Vol. I Multiresidue Protocols D and E (PESTDATA, PAM, Vol. I, Appendix, 8/93). Data submitted by the registrant indicate that TPA is not recovered by Protocols B and C. Multiresidue testing data on MTP are still required.

860.1380 Storage Stability

DER Reference List: W. Smith. 8/6/96. D226131.

ISK Biosciences Corporation submitted the final report for a 4-year storage stability study on DCPA. The data provided therein support the conclusion that residues of DCPA, MTP, TPA and HCB are stable in frozen samples of broccoli, onion bulbs, celery, snap beans, bell peppers, and sweet potatoes stored for 4 years. However, the registrant must simply submit storage intervals and conditions for field trial samples analyzed in MRIDs 00017975, 00018299, 00033087, 00038919, 00058377, 00058378, 00072099, 00090259, 00114643, 00114678, 00114679, 00114680, 00114681, 00121864, and 00130562. This information has been recommended by HED numerous times since 1995. If it can be confimed that samples from these earlier field trials had been stored frozen and for durations not significantly longer than 4 years, these field trial data will be considered to be fully validated by the 4-year storage stability study.

860.1400 Water, Fish, and Irrigated Crops

Based on the current and proposed use patterns, direct exposure of aquatic sites, fish, and irrigated crops is not expected.

860.1460 Food Handling

Based on the current and proposed use patterns, treatment of food handling facilities will not occur.

860.1480 Meat, Milk, Poultry, and Eggs

DER Reference List: W. Smith. 5/9/95. D211599.

A ruminant feeding study conducted in 1963 (MRID 00114643) is of limited usefulness because most edible tissues were not analyzed and data for milk and fat are inconsistent with the results of a more recent goat metabolism study indicating detectable residues in milk, fat, muscle, liver, and kidney from a 10 ppm dosing level (see 860.1300, Nature of the Residue in Livestock). The 10 ppm dosing level represents 1x the theoretical maximum DCPA intake for dairy cattle and 2x the maximum beef cattle intake. The goat metabolism study indicates that tolerances are needed and new ruminant feeding studies have been required. In the meantime, we will estimate transfer of DCPA residues to livestock commodities based on total radioactive residues (TRR) detected in the goat metabolism study. Residues reached a plateau in the milk at a feeding rate of 10 ppm in the diet by the second day of the four-day feeding period. The bulk of the TRR in tissues was comprised of MTP with lesser amounts of DCPA and TPA. The TRR in milk at plateau and residues in goat tissues at sacrifice will be used for dietary exposure assessment.

A poultry feeding study was conducted in 1973 (MRID 00058378) in which laying hens were fed a 1:1 mixture of DCPA (containing 0.3 ppm HCB) and TPA for 30 consecutive days. The test compounds were fed at concentrations in the diet of 4 ppm, 12 ppm, and 40 ppm. Eggs were

collected prior to, during, and after dosing. At the end of dosing and at 15 and 30 days after dosing, 5 hens from each group were sacrificed. Neither DCPA nor TPA were detectable in eggs during the feeding and withdrawal periods but MTP was detected in egg yolks of all groups. Maximum residues were reported to be 0.06, 0.13, and 0.41 ppm in yolks from hens receiving 2, 6 and 20 ppm DCPA, respectively. No residues of MTP, TPA, or HCB were reported in any tissues from any dosing level. No DCPA was reported in white meat, dark meat, or selected internal organs; however, dose-related residues were reported in the fat after the 30-day feeding period. A maximum residue of 0.26 ppm was reported in the groups fed 6 and 20 ppm DCPA. The utility of this study is questionable due to the limited nature of supporting information provided, variability in residue determinations both in controls and treated samples, and the unexpected result with HCB, i.e., no accumulation was apparent in fat. A decision as to the need for a new feeding study will be made on submission of an acceptable poultry metabolism study. In the meantime, the accumulation of DCPA residues in poultry tissues and eggs will be estimated using the data from this study. It appears that the accumulation factors resulting from this approach are in line with those from similar tissues in ruminants.

Livestock data are supported by storage stability studies. The analytical method appears to be adequate for the analysis of the residues of concern contingent on the conduct of an independent laboratory validation and Agency validation. The appropriate residues of concern were sought. The ruminant metabolism study and the poultry feeding study (pending confirmation by a poultry metabolism study) were conducted with the appropriate chemicals in light of plant metabolism data and the residues of concern. Tolerances in livestock commodities cannot be recommended at this time but their establishment is likely based on available studies.

860.1500 Crop Field Trials

DER Reference List: W. Hazel, 5/13/02, D281001.

In parsley field trials (PP#0E3883), the 75% wettable powder (WP; Dacthal® W75 Herbicide; EPA Reg. No. 5481-490) was applied at 10-10.5 lb ai/A (1x) in 1986 to seeded parsley as a single preemergence treatment at four CA sites. Parsley was harvested at normal crop maturity (66-111 days posttreatment) and samples were frozen until analyzed by the adequate GC/EC method described above. Recoveries of DCPA, MTP, and TPA spiked into fresh parsley at 0.03-4.0 ppm were 76-123%. HCB recoveries were 65-100% from fresh parsley spiked at 0.01-0.05 ppm. Adequate storage stability data are available on a variety of crops indicating stability of residues in samples for at least 4 years of frozen storage. These field trial data have already been reviewed by HED in 1990 (W. T. Chin. PP#0E3883. 9/12/90). The resulting combined residues of DCPA, MTP, and TPA were 0.41-3.14 ppm with DCPA being the major component of the residue (Table 2). HCB was nonquantifiable (<0.003 ppm) in three samples but detected at 0.004 ppm in one sample; however, as HCB was also found at 0.003 ppm in the untreated control, this may be due to contamination from another source. There are no deficiencies associated with these field trials that would impact registration of the 75% WP DCPA product on parsley grown in CA. The number and location of the subject field trials are adequate; HED supports the proposed tolerance of 5 ppm for residues of DCPA in/on parsley with a regional registration in CA. The field trials reflect the proposed use pattern. The data are adequate for use in dietary risk assessment.

Table 2. Summary of Parsley Field Trial Data on DCPA from California.							
Location	Appl. rate PHI Residue level (ppm) (avg. of duplicate samples)					5)	
	(lb ai/A)	(days)	DCPA	MTP	TPA	Total	HCB
Salinas	10.0	85	0.34	0.02	0.02	0.38	< 0.003
Fresno	10.5	111	0.30	0.02	0.15	0.47	< 0.003
Greenfield	10.5	73	1.31	0.02	0.12	1.45	< 0.003
Modesto	10.5	66	2.88	0.02	0.20	3.10	0.004

Considering the minor crop status, regional registrations, and the expert opinion of B. A. Schneider, Ph.D., the tolerances for DCPA residues in/on the following minor crops proposed in PP#2E6442 are deemed by HED to be appropriate: 2 ppm in/on Celeriac, Ginseng, and Radish, oriental; and 5 ppm in/on Basil, Chive, Dill, Marjoram, and Coriander, leaves. The 5-ppm tolerance proposed for residues in/on "Chicory" has been revised to: Chicory, roots (2 ppm) and Chicory, tops (5 ppm). The 2-ppm tolerance proposed for DCPA in/on Radicchio has been revised to 5 ppm. Input from B.A. Schneider (HED, 4/15/02) is presented below:

The 2-ppm tolerance in/on oriental radish, celeriac and ginseng can be translated from the established tolerances in/on horseradish, potato, rutabaga, turnip, sweet potato, and yams. Potatoes and sweet potatoes are representative commodities of Subgroups 1C and 1D. Horseradish, turnip, and rutabaga are in the same crop subgroups as oriental radish and ginseng. Celeriac has a bulbous root that is similar in exposure to rutabagas at harvest by both being partially uncovered from the soil.

The 5-ppm on basil, coriander, dill, and marjoram can be translated from the established tolerances in/on upland cress (5 ppm), lettuce (2 ppm), and Brassica leafy vegetables (5 ppm). The 5 ppm is a more conservative number than the 2-ppm tolerance in/on leaf lettuce. Basil, coriander, and marjoram are similar in growth to the leafy cress and Brassica leafy vegetables. Dill has a more open fine-fern leaf structure and, although the surface area is expected to be less, the relative magnitude of residues to expect is difficult to predict; therefore, the more conservative 5 ppm is recommended for dill as well.

The 5-ppm tolerance in/on chives can be translated based on the established tolerances in/on upland cress (a leafy vegetable) at 5 ppm. Chives are most similar in growth to onions which have an established tolerance of 1 ppm; although conservative, the 5-ppm tolerance is recommended for this minor crop since the chive leaves are hollow, potentially resulting in higher residues than in/on onions which have a solid base (white portion).

The 2-ppm tolerance in/on chicory, roots can be translated from the existing tolerances on horseradish (2 ppm), potatoes (2 ppm), rutabagas (2 ppm), sweet potato (2 ppm), turnips (2ppm), and yams (2ppm).

The 5-ppm tolerance in/on chicory, tops and radicchio can be translated from the existing tolerances on cress, upland (5ppm), lettuce (2ppm), and Vegetables, leafy brassica (cole) (5ppm). Both radicchio and chicory, tops are leafy vegetables.

The second to last paragraph of Section D is recommended to be revised to state: "The proposed use pattern in Section B is similar to the existing registered uses on the translatable crops as indicated in Section A (Specimen Label). As the proposed use pattern is similar for all commodities listed in this proposal, as there is similarity in culture and growth between crops, and as the tolerances in/on translatable crops do not vary

by a factor of more than five, then the tolerances in/on the proposed commodities are possible with no additional residue data."

RECOMMENDED REVISIONS TO SECTION G:

Last two paragraphs should be revised to eliminate mention of crop groups, i.e.:

"The proposed use pattern in Section B is similar to the existing registered uses on the translatable crops as indicated in Section A (Specimen Label). As the proposed use pattern is similar for all commodities listed in this proposal, as there is similarity in culture and growth between crops, and as the tolerances in/on translatable crops do not vary by a factor of more than five, then the tolerances in/on the proposed commodities are possible with no additional residue data."

"Based on the above information the establishment of the commodity tolerances would protect the public health, and would not expose man or the environment to unreasonable adverse effects."

860.1520 Processed Food and Feed

DER Reference List: W. Hazel, 5/13/02, D281001.

In 1995, a parsley plot in Salinas, CA was treated with a single, postplant, preemergence application of the 75% WP at 10.5 lb ai/A (1x) using ground equipment. Three cuttings were made at 126, 175, and 231 days posttreatment. Samples were analyzed fresh as well as dried (following dehydration to a moisture content of 3-6%). Samples were stored frozen at <-18 C until analysis using an analytical method very similar to the acceptable method described above. LOQs were as follows: DCPA - 0.1 ppm in fresh/0.5 ppm in dried; MTP and TPA - 0.1 ppm in fresh/0.2 ppm in dried; and HCB - 0.001 ppm in fresh/0.003 ppm in dried. Recovery studies involved spiking fresh and dried parsley with DCPA, MTP, and TPA at 0.05-10 ppm and HCB at 0.001-0.005 ppm. Recoveries were 84-112% from fresh parsley and 71-125% from dried parsley. Freezer storage stability studies were apparently conducted concurrently using the duration and temperatures of frozen storage of field trial samples: <-18 C for 119-161 days. Samples were fortified with DCPA, MTP, and TPA at 1.0 ppm each and with HCB at 0.05 ppm. By comparing concentrations in fresh parsley on the day of spiking and after frozen storage for 119-125 days, recoveries were 81-97% for all four analytes. In dried parsley, recoveries of DCPA, TPA, and HCB were 91-99%; recoveries of MTP were 68-74% which is considered adequate. The following residue values in fresh and dried parsley are averages of duplicate analyses. Combined residues of DCPA, MTP, and TPA in fresh parsley were 1.63 ppm at cutting 1 (126-day PHI), 0.72 ppm at cutting 2 (175-day PHI), and 0.375 ppm at cutting 3 (231-day PHI); the corresponding combined residues in dried parsley were 5.32 ppm at 126 days, 2.45 ppm after 175 days, and 1.6 ppm after 231 days. The calculated concentration factors upon drying parsley, respectively, are 3.3, 3.4, and 4.3x; the average concentration factor is 3.7x. Although adequate for this minor crop given that use is to be restricted to CA, the field trial data are somewhat limited and variable (Table 2) which is a major reason HED has decided to recommend in favor of the 5-ppm tolerance in fresh parsley. Also, given the range in residue values at the three cutting times of the processing study and the variability between concentration factors at the cuttings (range of 3.3 to 4.3), HED recommends that the IR-4 revise their tolerance proposal from 15 ppm to 20 ppm in dry parsley. This is based on multiplying the average concentration factor of 3.7x by the proposed RAC tolerance of 5 ppm to arrive at 18.5 ppm and then rounding up to 20 ppm.

A tolerance was not proposed by IR-4 for residues in dried basil. The dried parsley study described above has been translated to Basil, dried leaves. IR-4 is requested to propose a 20-ppm tolerance for combined residues of DCPA, MTP, and TPA in/on Basil, dried leaves.

860.1850 Confined Accumulation in Rotational Crops

DER Reference List: W. Smith. 10/23/95. D211773.

The confined rotational crop study is adequate. Carrots, lettuce, and green beans were planted in soil treated 11 weeks previously with [¹⁴C]DCPA. TPA accounted for the majority (52%) of the soil radioactivity after aging, DCPA comprised 41%, and MTP accounted for <1%. ¹⁴C-Residues identified in rotated crops were also DCPA, TPA, and MTP; these residues of concern generally comprised 60-100% of the TRR. The predominant residue in rotated crops was TPA (generally 60-80% of the TRR) followed by MTP at 2-20 % TRR and then DCPA at <3% of the TRR. Residues of concern in rotational crops and target crops are the same. Based on the results of the confined accumulation study, field accumulation in rotational crop studies are needed (see below).

860.1900 Field Accumulation in Rotational Crops

DER Reference List: W. Smith. 10/23/95. D211773.

The limited field rotational crop studies indicate that rotational crop tolerances and plantback restrictions on labels will be required. The submitted tests, which were conducted in soil that had been treated at 0.5x the maximum seasonal rate, show that significant levels of DCPA and metabolite residues can occur in rotated crops at plantback intervals of 30-220 days. At a PBI of 30 days, combined residues of DCPA, MTP, and TPA ranged from <LOQ (0.01 ppm for each analyte) in corn grain to as high as 2.7 ppm in lettuce. At a PBI of about 200 days, combined residues of concern were as high as 0.15 ppm (in carrot roots). Carrot roots and tops, corn fodder and silage, oat forage, and turnip tops from plants sowed at a 1-year plantback interval in soil treated at 10.5 lb a.i./A bore quantifiable residues in one or more samples. These data indicate that tolerances are needed for residues of DCPA and metabolites in some crops if they are rotated to fields that have been treated at even half the maximum seasonal label rate (the maximum seasonal rate would be 21 lb a.i./A (i.e., two applications of 10.5 lb a.i./A). The petitioner/registrant has not proposed any restrictions that obviate the need for rotational crop tolerances.

Large-scale rotational crop field trials are required to determine the appropriate tolerance levels for rotated crop commodities. The scope of the required tests is dependent upon the petitioner's/registrant's intent with respect to the crops to be allowed in rotation and the desired plantback interval(s) for these crops.

Any crop without a registered use, for which the petitioner/registrant wishes to allow rotation, requires field trial data to determine a suitable tolerance level. A crop group approach, requiring data on representative commodities, may be appropriate if several crops within a group are to be

rotated. For individual crops, the standard number of trials needed to support direct crop treatment tolerances are required, e.g., 20 trials for wheat.

The petitioner/registrant must clarify their intentions as to specific crops to be allowed in rotation with the crops on the label(s) and the desired plantback intervals for rotated crops. The requirements for field trials for purposes of rotational crop tolerances are the same as those to establish primary tolerances on crops or crop groups; these requirements are covered in EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances (6/2/94).

860.1550 Proposed Tolerances

The MARC has determined that the residue of concern for purposes of both regulation (tolerance expression) and risk assessment continues to be combined residues of DCPA, MTP, and TPA calculated as DCPA (W. Hazel. 6/5/02. D282838). Tolerances are listed at 40 CFR 180.185. There are no Codex MRLs for DCPA residues. However, there are Canadian MRLs ranging from 1-5 ppm in/on leafy crops, cole crops, cucurbits, legumes, root crops, fruiting vegetables, bulb vegetables, and strawberries; the Canadian MRLs appear to include only the parent compound but, numerically, they are identical to U.S. tolerances.

Table 3. Tolerance Summary for Combined Residues of DCPA, MTP, and TPA.					
Commodity (as proposed)	Proposed Tolerance (ppm)	Correct commodity definition ^a	Recommended Tolerance (ppm) ^a		
Oriental radish Basil Coriander Dill Marjoram Chives Ginseng Celeriac Chicory Radicchio Parsley (Fresh) Parsley (Dried)	2 5 5 5 5 5 5 5 2 2 2 5 2 5 15	Radish, oriental Basil, fresh leaves Basil, dried leaves Coriander, leaves Dill Marjoram Chive Ginseng Celeriac Chicory, roots Chicory, tops Radicchio Parsley, leaves Parsley, dried leaves	2 5 20 5 5 5 5 5 2 2 2 2 2 2 5 5 5 5 20 5 5 5 5		

^aCorrections/recommendations in bold.

Tolerance Reassessment

All of the DCPA tolerances established at 40 CFR 180.185 are considered by HED to be reassessed. Please refer to the dietary exposure and risk assessment prepared by W. Hazel (6/13/02; D283580).

cc: W.Hazel; Registration Standard File; SF; RF 7509C:W.Hazel:RRB1:CM2:Rm722J:703- 305-7677:06/10/02 RDI:RRB1 reviewers (C.Swartz&C.Olinger):5/30/02:W.Phang:6/12/02