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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

September 10, 2001

SUBJECT: **Propanil** Poultry Feeding Study and Independent Laboratory Validation; PC code 028201; Rereg. Case 0226; DP Barcodes D253336 and D253337; MRID No. 44748201 and 44748202.

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INTRODUCTION

In response to the Propanil Registration Standard (12/87), the Propanil Task Force has submitted a poultry feeding study (1998; MRID 44748201) depicting residues of propanil in hen tissues and eggs, and an Independent Laboratory Validation (ILV) trial for a GC method used to determine residues of propanil in rice (1999; MRID 44748202). These data are reviewed here to determine their adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to analytical methodology (plants and animals) and the storage stability and magnitude of the residue in poultry commodities.

Attached is the residue chemistry reviews of the Propanil Task Force poultry feeding study depicting magnitude of the residue propanil in hen tissues and eggs, and the ILV trial for a GC method used to determine residues of propanil on rice. This information was compiled by Dynamac Corporation under supervision of RRB2. This review has undergone secondary review by RRB2 and has been revised to reflect current HED and Office of Pesticide Programs (OPP) policies.

EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES

- The proposed GC/nitrogen-phosphorus detection (NPD) enforcement method (EN-CAS Method No.ENC-9/90) used to determine residues of propanil in/on crops has undergone an acceptable ILV trial; however, the stated method LOQ should be raised to an appropriate level (e.g., 0.05 ppm) unless the method can be validated to 0.01 ppm, as written, by an independent laboratory.
- The GC/NPD method (EN-CAS Method No.ENC-9/90, modified) is adequate for collecting data on residues of propanil in poultry commodities. Should the registrant wish to propose this method for tolerance enforcement, it should be radiovalidated and subjected to an ILV trial in accordance with PR Notice 98/7.

RECOMMENDATIONS

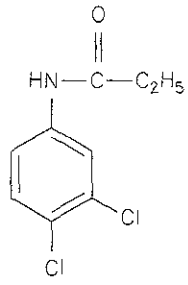
The proposed GC/nitrogen-phosphorus detection (NPD) enforcement method (EN-CAS Method No.ENC-9/90) will be forwarded to the Analytical Chemistry Branch for Agency validation.

The submitted data indicate that the established 0.1 ppm tolerance for propanil residues in poultry meat byproducts (mbyp) should be increased to 0.2 ppm, and the 0.1 ppm tolerance for residues in fat and meat may be lowered to 0.05 ppm; the established 0.05 ppm tolerance for residues in eggs is appropriate.

cc: Sherrie L. Kinard (RRB2), Propanil Reg. Std. File, Propanil Subject File, RF, LAN. RD/I: Propanil Team Review (9/5/2001).

7509C: RRB2: S. Kinard: CM#2:Rm 722B: 703-305-0563: 9/10/2001.

PROPANIL



PC Code 028201; Case 0226

(DP Barcodes D253336 and D253337)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to the Propanil Registration Standard (12/87), the Propanil Task Force has submitted a poultry feeding study (1998; MRID 44748201) depicting residues of propanil in hen tissues and eggs, and an Independent Laboratory Validation (ILV) trial for a GC method used to determine residues of propanil in rice (1999; MRID 44748202). These data are reviewed here to determine their adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to analytical methodology (plants and animals) and the storage stability and magnitude of the residue in poultry commodities.

The nature of the residue in animals and plants is adequately understood based upon metabolism studies on rice, wheat, poultry, goats, and crayfish. The HED Metabolism Committee (DP Barcode D222631, C. Swartz, 2/20/96) has concluded that the residue of concern in plant and animal commodities is propanil and its metabolites convertible to 3,4-dichloroaniline (3,4-DCA) and calculated as propanil.

Tolerances are established for the combined residues of the herbicide propanil (3′,4′-dichloropropionanilide) and its metabolites (calculated as propanil) in or on barley grain (0.2 ppm); barley straw (0.75 ppm); cattle, goats, hogs, horses, poultry and sheep, (fat, meat, meat byproducts), 0.1 ppm; eggs (0.05 ppm); milk (0.05 ppm); oat grain (0.2 ppm); oat straw (0.75 ppm); rice (2 ppm); rice straw (75 ppm); wheat grain (0.2 ppm); and wheat straw (0.75 ppm) [40 CFR §180.274]. In addition, tolerances are established for the combined residues of propanil in rice bran, hulls, mill fractions, and polishings at 10 ppm.

Adequate methods are available for enforcing the established propanil tolerances in animal commodities. The preferred method, cited in the Pesticide Analytical Manual (PAM) Vol. II as Method I, uses base hydrolysis to convert propanil and its metabolites to 3,4-DCA, which is detected using GC/ECD; residues are reported as propanil. PAM II also lists a colorimetric method (Method II) for rice and animal commodities which is no longer considered acceptable for enforcing tolerances. The FDA PESTDATA database (Rev. 10/97) indicates that propanil is completely recovered (>80%) using FDA Multiresidue Protocol D (PAM I, Section 232.4).

CONCLUSIONS AND RECOMMENDATIONS

Analytical Methodology

1a. The proposed GC/nitrogen-phosphorus detection (NPD) enforcement method (EN-CAS Method No.ENC-9/90) used to determine residues of propanil in/on crops has undergone an acceptable ILV trial. The validated limit of quantitation (LOQ) for residues in/on rice straw is 0.2 ppm. In rice grain, acceptable recoveries were obtained at the established tolerance of 2.0 ppm (72 and 76%), but were only achieved at the stated LOQ (0.01 ppm) by subtracting substantial apparent residues in controls (0.022 and 0.023 ppm); therefore, the reported method LOQ could not be reproduced in the trial. [HED notes that FDA laboratories cannot correct for apparent residues as they do not have access to untreated control samples.] Given the relatively high tolerance level for rice grain, this problem will not effect the suitability of the method for tolerance enforcement. However, the stated method LOQ should be raised to an appropriate level (e.g., 0.05 ppm) unless the method can be validated to 0.01 ppm, as written, by an independent laboratory.

1b. The proposed tolerance enforcement method for crops has been previously deemed adequate for collecting data on propanil residues in/on rice and wheat commodities, and has been successfully radiovalidated using ^{14}C-labeled samples from the [^{14}C]propanil confined rotational crop study. The method, as noted above, is considered to be acceptably validated by an independent lab. The method should be forwarded to the Analytical Chemistry Branch for Agency validation.

2. The GC/NPD method (EN-CAS Method No.ENC-9/90, modified) is adequate for collecting data on residues of propanil in poultry commodities. Acceptable method validation data were provided with the current submission. Overall method recoveries were 73-121% from tissue (liver, muscle, and fat) fortified with propanil at 0.05-0.20 ppm, and 70-131% from eggs fortified with propanil at 0.01-0.10 ppm. The LOQ for residues of propanil are 0.05 ppm in tissues and 0.01 in eggs. Should the registrant wish to propose this method for tolerance

enforcement, it should be radiovalidated and subjected to an ILV trial in accordance with PR Notice 98/7.

Storage Stability Data

3. The submitted storage stability data are adequate and indicate that residues of propanil are stable frozen in liver, muscle, and fat for at least 83 days, and in egg for at least 118 days. These data support the frozen storage intervals (up to 51 days for tissues and up to 118 days for eggs) incurred by samples in the subject feeding study.

Magnitude of the Residue in Poultry

4a. The submitted poultry feeding study is adequate. In the current study, four groups of laying hens (10 hens/treatment group) were dosed for 28 consecutive days with either rice-based rations containing field-aged residues at 3.7 ppm (propanil equivalents) or gelatin capsules at levels equivalent to 5, 15, and 50 ppm propanil *per se* in the diet. These feeding levels correspond to 1x, 1.4x, 4.1x, and 13.5x the maximum theoretical dietary burden for poultry (3.7 ppm).

4b. Residues of propanil in eggs plateaued by Day-7. Maximum propanil residues observed were 0.016 ppm in eggs from hens dosed at 3.7 ppm (1x) with rice-based rations bearing aged residues of propanil, and 0.050, 0.212, and 0.372 ppm, respectively, in eggs from hens dosed with propanil *per se* by capsule at 5 (1.4x), 15 (4.1x), and 50 ppm (13.5x).

4c. Residues of propanil in liver were 0.080-0.163 ppm in hens fed rice-based rations (1x). Residues in liver from hens in the 5 (1.4x), 15 (4.1x), and 50 ppm (13.5x) dose groups were 0.077-0.156, 0.183-0.236, and 0.824-1.755 ppm, respectively. Residues were <0.05 (<LOQ) in muscle from the 1x (rice-fed) and 1.4x dose groups, and <0.050-0.076 and 0.087-0.161 ppm, respectively, from the 4.1x and 13.5x dose groups. In fat, propanil residues were <0.05 (<LOQ) at the 1x (rice-fed), 1.4x, and 4.1x feeding levels, and <0.139-0.348 ppm at 13.5x.

4d. The submitted data indicate that the established 0.1 ppm tolerance for propanil residues in poultry meat byproducts (mbyp) should be increased to 0.2 ppm, and the 0.1 ppm tolerance for residues in fat and meat may be lowered to 0.05 ppm; the established 0.05 ppm tolerance for residues in eggs is appropriate.

DETAILED CONSIDERATIONS

Residue Analytical Methods - Plants

The registrant has submitted data (MRID 44748202) pertaining to the independent laboratory validation of the analytical method EN-CAS Method No. EN-9/90, used to determine residues of propanil in rice grain and rice straw. The method has been previously reviewed by the Agency and deemed adequate for data collection on rice and wheat (DP Barcode D205676, C. Swartz, 9/8/94 and DP Barcode D203514, C. Swartz, 9/22/94). The method was also successfully radiovalidated using ^{14}C-labeled samples from the confined rotational crop study (DP Barcode D196301, C. Swartz, 10/24/95).

Briefly, residues of propanil in rice grain and straw samples are hydrolyzed with sodium hydroxide, which results in conversion of propanil and metabolites containing the 3,4-DCA moiety to 3,4-DCA. The hydrolysate is steam distilled for 16 hours using a Nielsen-Kryger apparatus, and the hexane and water fractions separated. The hexane fraction is then cleaned up on a silica gel column which has been pre-conditioned with hexane. The aqueous phase is washed with hexane, and the hexane wash added to the column. Residues are eluted from the column using hexane/ethyl acetate [75/25, v/v]. Residues are quantitated using a GC equipped with a DB-17 or DB-1701 column and a nitrogen/phosphorous (N/P) detector. Residues are determined as 3,4-DCA, and calculated as the parent, propanil. In earlier studies on rice, the validated LOQ was 0.01 ppm for residues of propanil in/on both rice grain and straw.

The ILV trial was conducted by PTRL East, Inc. (Richmond, KY). Duplicate control samples of rough rice grain and straw were fortified with propanil at the LOQ (0.01 ppm) and at tolerance levels of 2.0 ppm (grain) and 75.0 ppm (straw). The initial trial gave highly variable recoveries in rice grain samples, low recoveries for the 75 ppm fortified straw samples, and apparent residues above the LOQ in the unfortified control straw samples. In the second trial, the control straw samples were fortified at 0.20 ppm rather than at 0.01 ppm, due to the lack of control straw samples without background interference. In addition, a stronger eluant (1:1 instead of 75:25 hexane-ethyl acetate) was used to compensate for a modification in the silica SPE column. Again, recoveries were low in the 2.0 ppm fortified rice grain samples and very low in rice straw in the 75 ppm fortification level.

A third, successful trial was conducted following consultation with the sponsor and incorporation of minor modifications to the method. The principal changes were (1) use of a 2g silica SPE column due to the unavailability of the 2.5 gram silica bond Elut® SPE column specified in the original method, and using a stronger eluant (1:1 instead of 75:25 hexane:ethyl acetate), and (2) use of a more concentrated fortification solution to minimize the amount of methanol added to the test system.

The laboratory indicated that a set of six samples required ~16 person-hours for completion of extraction (2 calendar days); GC analysis of the six samples extracts, together with six external

standards, required ~5 hours of automated instrument time, for a total 3 calendar days to complete analysis.

The results of the successful trial are presented in Table 1. Apparent residues of propanil in /on two control samples each of rough grain rice and rice straw were 0.022-0.023 ppm and 0.009-0.012 ppm, respectively. Recoveries were corrected for apparent residues in controls. Adequate recoveries were obtained at all fortification levels.

Conclusions: The proposed GC/NPD enforcement method (EN-CAS Method No.ENC-9/90) used to determine residues of propanil in/on crops has undergone a successful ILV trial. The validated LOQ for residues in/on rice straw is 0.2 ppm. In rice grain, acceptable recoveries were obtained at the established 2.0 ppm tolerance (72 and 76%), but were only achieved at the lowest fortification level (0.01 ppm) by subtracting substantial apparent residues in controls (0.022 and 0.023 ppm); therefore, the reported method LOQ of 0.01 ppm could not be reproduced during the trial. [HED notes that FDA labs cannot correct for apparent residues as they do not have access to untreated control samples.] Given the relatively high tolerance level for rice grain, this problem will not effect the suitability of the method for tolerance enforcement. However, the stated method LOQ should be raised to an appropriate level (e.g., 0.05 ppm), unless the method can be validated to 0.01 ppm, as written, by an independent laboratory.

Table 1. Independent laboratory validation of the proposed GC/NPD tolerance enforcement method (EN-CAS Method No. EN-9/90) using fortified untreated rough rice grain and rice straw samples.

Matrix	Fortification Levels (ppm)	# Samples	% Recovery [a]
Rough rice grain	0.01	2	81, 103
	2.00	2	76, 72
Rice straw	0.20	2	112, 83
	75.00	2	74, 73

[a] Values were corrected for apparent residues in control samples.

Residue Analytical Methods - Animals

In conjunction with the poultry feeding study (1998; MRID 44742801), the registrant submitted a method description and method validation data for a GC/NPD method used to detect residues of propanil in poultry commodities. The method is based on EN-CAS Method No. ENC-9/90, described above for crop matrices, with modifications for use in detecting residues of propanil in poultry commodities.

Briefly, residues of propanil in fat and eggs are hydrolyzed with 40% sodium hydroxide (NaOH) solution under reflux (overnight), cooled, and partitioned into hexane. The residues are

partitioned into 2N HCl, adjusted to pH 11, re-partitioned into hexane, and concentrated. The residues are then purified on a silica SPE column eluted with hexane:ethyl acetate (1:1, v/v) prior to analysis. Residues in muscle and liver are base hydrolyzed, steam distilled (overnight) into iso-octane, and cleaned-up on a silica gel SPE column eluted with hexane:ethyl acetate (1:1, v/v). Residues are determined as 3,4-DCA using a GC/NPD equipped with a DB-17 column, and calculated as the parent compound. The LOQ for residues of propanil are 0.05 ppm in tissues (liver, muscle, and fat) and 0.01 in eggs. The limits of detection are reported as 0.045 ppm in tissue and 0.009 ppm in egg based on the lowest standard used for quantitation.

Method validation and concurrent recovery data are presented in Table 2. For method validation, control samples of fat, liver, and muscle were fortified with propanil at 0.05-0.20 ppm, and egg samples were fortified with propanil at 0.01-0.10 ppm. Overall method validation recoveries were 88-131% (n=12) in eggs and 73-121% (n=39) in tissue; only two recoveries, one each from samples of egg and fat, were unacceptable. Overall concurrent recoveries were 70-119% (n=42) in eggs and 77-119% (n=12) in tissue samples. Apparent residues of propanil were <0.05 ppm (<LOQ) in control samples of tissue (except one muscle sample bearing apparent residues at 0.052 ppm), and <0.01 ppm (<LOQ) in all control egg samples. Adequate sample calculations, raw data, and representative chromatograms were provided. Sample analyses were conducted by PTRL East, Richmond, KY.

Conclusions: The GC/NPD method (EN-CAS Method No.ENC-9/90, modified) is adequate for collecting data on residues of propanil in poultry commodities. Acceptable method validation data were provided with the current submission. Should the registrant wish to propose this method for tolerance enforcement, it should be radiovalidated and subjected to an ILV trial in accordance with PR Notice 96-1.

Table 2. Method recoveries of propanil from fortified control samples of hen tissues and eggs using the GC/NPD data collection method (EN-CAS Method No. ENC-9/90, modified).

Matrix	Fortification level (ppm)	Number of samples	% Recovery	
			Range [a]	Mean (±SD)
Method Validation Recoveries				
Egg	0.01-0.10	12	88-131 (1)	109 ± 12
Liver	0.05-0.20	15	73-118	102 ± 13
Muscle		12	95-114	106 ± 7
Fat		12	77-121 (1)	102 ± 14
Concurrent Method Recoveries				
Egg	0.01-0.10	42	70-119	93 ± 14
Liver	0.05-0.20	4	77-108	
Muscle		4	89,119	
Fat		4	77-93	

[a] Values in parentheses represent the number of recoveries outside the acceptable range (70-120%).

Storage Stability Data

In conjunction with the poultry feeding study (MRID 44748201), the registrant submitted data depicting the storage stability of propanil in animal commodities stored frozen (temperature unspecified) for up to 4 months.

Control samples were fortified with propanil at 0.5 ppm (liver, muscle, and fat) or at 0.1 ppm (egg), and stored frozen. At three sampling intervals ranging from 0-83 days for tissues and 0-118 days for egg, a control sample, two freshly-fortified samples and two stored fortified samples were analyzed for each matrix using the analytical method described above. Apparent residues of propanil were <LOQ in all control samples of fat (<0.05 ppm) and egg (<0.01 ppm). Apparent residues of propanil were 0.119 and 0.168 ppm in two control samples of liver (Day-0 and Day-49 analyses, respectively) and 0.058 ppm in one control sample of muscle (Day-49 analysis); fresh fortification recoveries were corrected for residues in controls. Adequate representative chromatograms, raw data, and sample calculations were provided.

The results of the storage stability study are presented in Table 3. These data indicate that residues of propanil are stable in frozen hen liver, muscle, and fat for at least 83 days and in egg for at least 118 days.

Conclusions: The submitted storage stability data are adequate and indicate that residues of propanil are stable frozen in liver, muscle, and fat for at least 83 days, in egg for at least 118 days. These data support the frozen storage intervals (maximum of 51 days for poultry tissues and 118 days for eggs, from sampling to analysis) depicted in the current feeding study.

Table 3. Stability of propanil fortified in hen liver, muscle, fat and egg and stored frozen for up to 4 months

Matrix	Storage Interval (days)	Fortification Level (ppm)	Fresh Fortification Recovery (%)	Stored Sample Recovery (%)	Stored Sample [a] Corrected Recovery %
Liver	0	0.5	76.2, 97.2	109.5, 106.9	--
	49	0.5	99.7, 83.5	93.1, 94.6	103
	83	0.5	95.1, 94.4	88.4, 88.0	93
Muscle	0	0.5	103.6, 102.3	101.0, 83.3	--
	49	0.5	105.7, 92.3	84.3, 103.1	95
	83	0.5	114.8, 114.7	104.7, 113.7	95
Fat	0	0.5	107.8, 94.0	73.5, 112.3	--
	50	0.5	112.6, 86.1	104.8, 108.3	107
	79	0.5	86.5, 94.5	102.9, 86.2	105
Egg	0	0.1	78.2, NS [b]	78.9, 72.3	--
	50	0.1	107.2, 89.1	95.6, 118.8	109
	118	0.1	105.7, 83.5	99.0, 81.9	96

[a] Represents the average of two corrected recoveries (corrected recovery = %stored recovery ÷ average %fresh recovery).

[b] NS = sample lost during extraction procedure.

Poultry Feeding Study.

In response to the Propanil Registration Standard (12/23/87), the Propanil Task Force submitted a poultry feeding study (1998; MRID 44748201) depicting residues of propanil in poultry tissue and eggs. The study was conducted by PTRL East, Richmond KY.

Groups of White Leghorn laying hens (10 hens/group) were dosed orally for 28 consecutive days with either rice-based rations containing field-aged residues at 3.7 ppm (propanil equivalents) or gelatin capsules fortified with propanil at dose levels equivalent to 5, 15, or 50 ppm in the diet. Dose groups were further divided into three subgroups of 3 or 4 hens each, facilitating the collection of three, separate, composite samples of tissues and eggs from each dose group. One group of 10 hens served as the control. The feeding levels depicted in the study approximate 1x (rice-fed), 1.4x, 4.1x, and 13.5x, the maximum theoretical dietary burden (MTDB) for poultry of 3.7 ppm (Table 4).

The rice-based ration was prepared using rough rice treated postemergence at the maximum label rate (6 lb ai/A) and harvested 63 days posttreatment. The registrant stated that as poultry are fed field-aged residues in their diets and metabolism data show that propanil *per se* is not expected to be a residue in rice commodities at harvest, feeding of propanil treated rice grain containing field-aged residues to poultry is the appropriate route of exposure. In its review of the ruminant feeding study protocol (DP Barcode D224402, C. Swartz, 4/11/96), the Agency indicated that data from a study conducted using field-aged residues in the diet will be taken into consideration during risk assessment, but may not enable the determination of appropriate tolerance levels for livestock commodities. In the subject poultry study, maximum residues were similar in tissues and eggs from the rice-fed group and propanil-fed group at the ~1x dose level.

Table 4. Calculation of the maximum theoretical dietary burdens of poultry for propanil.

Feed Commodity [a]	% Diet [b]	Tolerance (ppm)	Dietary Contribution (ppm) [c]
rice, grain	60	2.0	1.2
bran	25	10	2.5
TOTAL BURDEN	85		3.7

[a] Rice hulls (15% of poultry diet) and bran are poultry feed items; however, it is assumed that both bran and hulls would not be fed to the same birds simultaneously with rice grain (rough rice). Propanil is also registered on other small grains used in poultry diets (wheat, barley, and oats). As the percent of small grain crop treated with propanil is <1% (per registrant), and the contribution of small grains to the MTDB is negligible compared to rice, these commodities were not included in calculating the MTDB.

[b] Table 1 (August 1996).

[c] Contribution = tolerance × % diet.

Hens in the rice-based rations group were fed specially formulated rice-based rations containing rough rice and other ingredients needed for a complete ration. Before study start, these hens

were fed untreated (control) rice diet. Hens in the control and capsule groups were fed a commercially available laying mash throughout the study.

Animals were observed daily throughout the study for mortality and moribundity. Feed consumption for each hen was measured daily, and used to compute the mean daily feed consumption levels. Individual animals were weighed at receipt and prior to sacrifice. There was no apparent effect of propanil dosing on overall animal health and feed consumption at any dose level. Egg production in hens treated with capsules was comparable with production levels during acclimation, but egg production in hens in the rice-based ration dose groups were lower when compared with the production levels during acclimation.

Eggs were collected twice a day (morning and evening) in the 24-hour period following dosing. Composite egg samples were prepared for each of the control and treated subgroups daily throughout the treatment period. The composite egg samples were homogenized and frozen until analysis. The sampling-to-analysis interval for egg samples was 6-118 days.

Control and treated hens were sacrificed within 16-20 hours of receiving the final dose, and samples of liver, composite muscle (thigh and breast), and fat were collected, composited by subgroup, and frozen. No significant conditions, gross abnormalities or gross pathological findings were noted at necropsy that was dose-related. The frozen samples were processed within 10 days of collection and stored frozen (temperature not specified) for 12-51 days prior to analysis.

For analysis of whole eggs, a composite sample collected from each of three subgroups was analyzed from study days 0 (pre-dose), 1, 3, 7, 11, 14, 18, 21, 24, and 27 for each dose group. For analysis of residues in tissues, a composite sample of each matrix was analyzed for each subgroup in each dose group.

Residues of propanil were determined using the GC/NPD method described above. Adequate concurrent recoveries of propanil were obtained from each poultry commodity. Apparent residues of propanil were <LOQ (<0.01 ppm in egg; <0.05 ppm in tissue) for all control samples analyzed for egg, liver, muscle and fat, except for one muscle sample which contained residues of 0.052 ppm. Sample analyses were performed by PTRL East, Richmond, KY. Results from the analyses of egg and poultry tissues are presented in Tables 5 and 6, respectively.

Residues of propanil in eggs plateaued after 7 to 11 days of treatment. Maximum propanil residues observed were 0.016 ppm in eggs from hens dosed at 3.7 ppm (1x) with rice-based rations bearing aged residues of propanil, and 0.050, 0.212, and 0.372 ppm, respectively, in eggs from hens dosed with propanil *per se* by capsule at 5 (1.4x), 15 (4.1x), and 50 ppm (13.5x).

Residues of propanil in liver were 0.080-0.163 ppm in hens fed rice-based rations (1x). Residues in liver from hens in the 5 (1.4x), 15 (4.1x), and 50 ppm (13.5x) dose groups were 0.077-0.156, 0.183-0.236, and 0.824-1.755 ppm, respectively. Residues were <0.05 (<LOQ) in muscle from

the 1x (rice-fed) and 1.4x dose groups, and <0.050-0.076 and 0.087-0.161 ppm, respectively, from the 4.1x and 13.5x dose groups. In fat, propanil residues were <0.05 (<LOQ) at the 1x (rice-fed), 1.4x, and 4.1x feeding levels, and <0.139-0.348 ppm at 13.5x.

Conclusions: The submitted poultry feeding study is adequate and indicates that the established 0.1 ppm tolerances for residues of propanil in poultry fat, meat, and mbyp should be reassessed. The tolerance for residues in mbyp should be increased to 0.2 ppm, and the tolerances for residues in fat and meat may be lowered to 0.05 ppm; the established 0.05 ppm tolerance for residues in eggs is appropriate.

Table 5. Residues of propanil in **eggs** from hens dosed daily for 28 days with either rice-based rations bearing field-incurred residues at 3.7 ppm (propanil equivalents) or gelatin capsules fortified with propanil equivalent to 5, 15 or 50 ppm in the diet (1x, 1.4x, 4.1x, and 13.5x, the MTDB for poultry).

Sampling Day	Residues (**ppm**)[a]			
	Dose level			
	Rice-based Ration 3.7 ppm (1x)	5 ppm (1.4x)	15 ppm (4.1x)	50 ppm (13.5x)
0	<0.010, <0.010, <0.010	<0.010, <0.010, <0.010	<0.010,<0.010,<0.010	<0.010, <0.010, <0.010
1	<0.010, <0.010, <0.010	<0.010, 0.013, <0.010	0.010, 0.011, <0.010	0.027, 0.021, 0.032
3	<0.010, <0.010, <0.010	<0.010, <0.010, <0.010	0.059, 0.054, 0.037	0.217, 0.143, 0.152
7	<0.010, <0.010, 0.014	0.019, 0.017, <0.010	0.100, 0.050, 0.056	0.167, 0.250, 0.277
11	<0.010, <0.010, <0.010	0.020, 0.027, 0.025	0.074, 0.153, 0.137	0.212, 0.163, 0.339
14	<0.010, 0.010, <0.010	0.025, 0.026, 0.028	**0.212**, 0.064, 0.073	0.269, 0.236, 0.344
18	<0.010, 0.010, 0.013	0.022, 0.019, 0.026	0.106, 0.094, 0.094	0.324, 0.29, 0.356
21	<0.010, <0.010, <0.010	0.022, 0.018, 0.023	0.119, 0.098, 0.082	0.283, 0.229, **0.372**
24	<0.010, < 0.010, 0.012	**0.050**, 0.022, 0.023	0.087, 0.061, 0.072	0.290, 0.240, 0.318
27	NS [b], **0.016**, <0.010	0.026, 0.023, 0.025	0.092, 0.066, 0.057	0.217, 0.271, 0.337

[a] Each residue value represents a composite sample from 3-4 subgroup hens. **Bolded** values indicate the maximum residue for each dose group.

[b] No sample produced.

Table 6. Residues of propanil in **edible tissues** from hens dosed daily for 28 days with either rice-based rations bearing field-incurred residues at 3.7 ppm (propanil equivalents) or gelatin capsules fortified with propanil equivalent to 5, 15 or 50 ppm in the diet (1x, 1.4x, 4.1x, and 13.5x, the MTDB for poultry)

Matrix	Residues (**ppm**) [a]			
	Rice-based Ration 3.7 ppm (1x)	5 ppm (1x)	15 ppm (4.1x)	50 ppm (13.5x)
Liver	0.153, 0.163, 0.080	0.079, 0.077, 0.156	0.236, 0.199,0.183	1.755, 0.824, 1.168
Muscle	<0.050, <0.050, <0.050	<0.050, <0.050, <0.050	0.076, <0.050, <0.050	0.161, 0.087, 0.103
Fat	<0.050, <0.050, <0.050	<0.050, <0.050, <0.050	<0.050, <0.050,<0.050	0.348, 0.229, 0.139

[a] Each residue value represents a composite sample from 3-4 subgroup hens.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: 14030
DP Barcode: D205676
Subject: Propanil Task Force Submission to Upgrade a Rice Metabolism Study [Guideline Ref. No. 171-4(a)] and Rice Field Trials [Guideline Ref. No. 171-4(k)].
From: C. Swartz
To: W. Waldrop
Date: 9/22/94
MRID(s): 43285401 and 43282801

CBRS No.: 13729
DP Barcodes: D203514 and D222631
Subject: Propanil. Rohm and Haas Submission of Wheat Residue and Method Validation Data.
From: C. Swartz
To: W. Waldrop
Date: 9/22/94
MRID(s): 43196001 and 43196002

CBRS Nos.: 12739 and 14594
DP Barcodes: D196301 and D208552
Subject: Propanil Task Force Submission of a Confined Rotational Crop Study, and a Method Radiovalidation Study for Rotational Crop.
From: C. Swartz
To: W. Waldrop
Dated: 10/24/95
MRID(s): 42963001 & 43355201

CBRS No.: 16777
DP Barcode: D222631
Subject: Propanil. Outcome of the 1/16/96 meeting of the HED Metabolism.
From: C. Swartz
To: HED Metabolism Committee
Dated: 02/20/96
MRID(s): None

CBRS No.: 17053
D Barcode: D224402
Subject: Protocol: Propanil Task Force Proposal to Satisfy GLN 171-4(j), Magnitude of the Residue in Meat and Milk.
From: C. Swartz
To: K. Davis
Dated: 04/11/96
MRID(s): None

MASTER RECORD IDENTIFICATION NUMBERS

44748201 Gibson, N.; Johnson, T. (1998) Magnitude of the Residue in Meat and Eggs from Laying Hens fed Propanil per se or Field-Aged Propanil Residues: Lab Project Number: 1087: 2013: 1006. Unpublished study prepared by PTRL East, Inc. 302 p. {OPPTS860.1480}

44748202 O'Neal, S. (1999) Second Party Validation of the Analytical Methodology for Propanil in Rough Rice Grain and Straw: Lab Project Number: 1045: 1999. Unpublished study prepared by PTRL East, Inc. 73 p. {OPPTS 860.1340}