CEB201

12-3-79

(10)

Some toxicity studies Attached

EEE BRANCH REVIEW

DATE: IN 2/22/79 OUT 12/3/79 IN _____ OUT _____ IN _____ OUT _____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 707-75

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, D, (H), F, N, R, S Herbicide

DATA ACCESSION NO(S). 095187

PRODUCT MGR. NO. Mountfort (25)

PRODUCT NAME(S) STAMPEDE 3E

COMPANY NAME Rohm & Haas Co.

SUBMISSION PURPOSE Addition of wheat to existing label on rice

CHEMICAL & FORMULATION		
	Propanil: 3,4-Dichloropropionanilide	33.8%
	Inerts	66.2
		100.0%

Propanil

100 Pesticide Label Information

100.1 Pesticide Use

Selective postemergent herbicide for the control of green and yellow foxtail (wild millet or pigeongrass) and specific broadleaf weeds in hard red spring wheat in upper Midwest (North & South Dakota, Minnesota and Montana).

100.2 Formulation Information

Stampede 3E (emulsifiable concentrate)

Propanil	33.8%
Inerts	66.2%
	100.0%

(equiv. to 3 lb. AI/gal.)

100.3 Application Methods, Directions, Rates

TIMING OF APPLICATION

For maximum weed control, it is important that wheat fields be inspected frequently prior to the STAMPEDE application to ensure that emerging foxtail grass and susceptible broadleaf weeds are treated with STAMPEDE at the proper stage of growth.

FOXTAIL GRASS AND BROADLEAF WEED CONTROL

When foxtail grass and broadleaf weeds are present in the same field, time the application to the foxtail leaf stage. A single application of STAMPEDE 3E should be timed to occur when the majority of the foxtail grass seedlings are in the 2-4 leaf stage and the wheat is in the 2 leaf to early tillering stage. Application of STAMPEDE at this time will provide effective control of foxtail grass as well as susceptible broadleaf weeds in the 1 to 4 leaf stage. Since the height of foxtail grass plants bears no relationship to leaf stage, it is important to judge the susceptibility of foxtail grass to STAMPEDE only by leaf stage. The effectiveness of STAMPEDE in controlling foxtail grass declines rapidly as the fifth leaf emerges and tillering begins. Applications of STAMPEDE made after the fifth leaf stage of wheat may be less effective on foxtail grass and broadleaf weeds because crop cover will interfere with spray coverage of the weeds.

TIME OF SPRAYING

Although successful applications of STAMPEDE have been made at any time of the day when wind conditions remained favorable, early morning or late evening application is usually preferable. At

this time winds are generally at a lower velocity and humidity is higher.

DOSAGE RECOMMENDATIONS

STAMPEDE 3E should be applied in a single application at the rate of 2 quarts (1.5 pounds active ingredient) per acre when the majority of the foxtail seedlings are in the 2 to 4 leaf stage and when the wheat is in the 2 leaf to early tillering stage. At this growth stage of foxtail grass, most susceptible broadleaf weeds should be in the 1 to 4 leaf stage and will be effectively controlled. Time the application to the foxtail leaf stage. STAMPEDE has no residual herbicidal effect and, therefore, will not control foxtail grasses and broadleaf weeds which emerge from the soil after application.

100.4 Target Organisms

Green Foxtail (Wild Millet or Pigeongrass) (Setaria viridis)

Yellow Foxtail (Wild Millet or Pigeongrass) (Setaria lutescens)

Wild Buckwheat (Polygonum convolvulus)

Redroot Pigweed (Amaranthus retroflexus)

Prostrate Pigweed (Amaranthus blitoides)

Lambsquarters (Chenopodium album)

Wild Mustard (Brassica kaber)

100.5 Precautionary Labeling (as proposed)

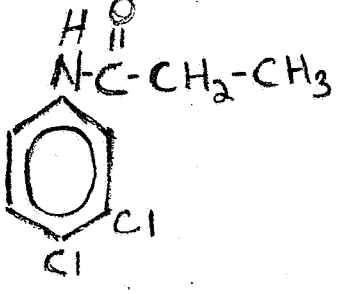
TOXIC TO FISH: Keep out of lakes, streams and ponds.

101 Physical and Chemical Properties

101.1 Chemical Name

3,4-Dichloropropionanilide

101.2 Structural Formula



101.3 Common Name

Propanil

101.4 Trade Names

Stampede 3E (Stam F-34, Rogue, Surcopur)

101.5 Molecular Weight

218.08

101.6 Physical Properties

Pure propanil (99+%) - odorless white powder

Technical propanil (85%) - black to brown crystalline solid

101.7 Solubility

Solvent	Percent	Source
Hexalene glycol	>25	Herbicide Handbook (1974)
Isophorone	>25	
Isopropyl alcohol	>25	
Methyl ethyl ketone	>25	
Toluene	>25	
Xylene	>25	
Water	0.05 (500 ppm)	
Ethanol	54 at 25°C	Martin (1971)
Isophorone	60 at 25°C	
Water	225 ppm	
	Grams/100 ml	
Acetone	170	Gordon et al. (1964)
Benzene	7	
Water	0.02	
Methanol	Very soluble	
Water	500 ppm	Bailey and White (1965)

102 Behavior in the Environment

102.1 Soil

(Taken from reviews by E.L. Gunderson 6/4/70 and G. J. Beusch 11/22/71 of Residue Chemistry Branch and by R.E. Ney. 3/3/70 of Environmental Fate Branch.)

Half-lives of propanil in soil range from 30 days, after a single application, to 40 days, after two applications at 4 lb. AI/acre 10 days apart. It is metabolized to 3,4-dichloroaniline which in turn recombines to form small amounts of 3,3',4,4'-tetrachloroazobenzene (TCAB) and 3,3',4'-trichloro-4-(3,4-dichloroanilino)-azobenzene, both (and particularly the former) potential carcinogens.

102.2 Water

(Taken from review by A. O. Schlosser 10/29/75 of Environmental Fate Branch.)

At pH 5.1 over 56% of propanil was hydrolyzed in buffered solutions to 3,4-dichloroaniline after 28 days at ca. 25°C. Under similar conditions over 99% of propanil was still present at pH 7.2 and 8.9. No TCAB was detected.

102.3 Plant

(Taken from review by E. L. Gunderson 6/4/70 of Residue Chemistry Branch.)

Propanil is metabolized in rice to 3,4-dichloroaniline and propionic acid. In weeds and other susceptible plants, it is metabolized into 3,4-dichlorolactanilide.

102.4 Animal

(Taken from reviews by F. Sanders 2/6/74 and R.E. Ney. 3/3/70 of Environmental Fate Branch.)

Technical propanil was continuously fed into four tanks, two containing crayfish at 0.05 ppm and 1.0 ppm calculated propanil and two containing catfish also at 0.05 ppm and 1.0 ppm calculated propanil. Exposure lasted 28 days followed by 28 days in clean water. Both crayfish and catfish were sampled for analyses regularly during both 28 day periods and water during the exposure period. Results are tabulated below: (level of sensitivity 0.1 ppm).

Residues in Water (ppm calc. as propanil)

Exposure Day	0.05 ppm aquaria		1 ppm aquaria	
	Crayfish	Catfish	Crayfish	Catfish
0	0.04	0.10	—	—
3	0.06	0.08	1.4	1.5
7	0.06	0.06	1.7	1.7
10	0.10	0.15	1.7	1.2
14	0.15	0.15	1.4	1.7
21	0.08	0.08	0.9	1.0
28	0.08	0.05	1.5	1.2
Ave.	0.08	0.09	1.4	1.4

Residues in Animals (ppm calc. as propanil)

Exposure Day	0.05 ppm exposure			1.0 ppm exposure		
	Crayfish Tails	Catfish (Edible Tissue)	Viscera	Crayfish Tails	Catfish (Edible Tissue)	Viscera
3	0.17	1.43		1.70	11.8	
		1.46				
7	0.29	1.52		1.66	9.6	
		1.64				
10	0.33	2.08	3.3	0.67	7.4	
	0.51	1.50		1.67	10.6	44.5
	0.25	1.78		1.33	7.5	
14	0.50	1.67		3.54	9.0	
21	0.18	2.00		2.86	9.6	
28	0.71	1.17		3.43	11.4	
	0.87	1.51	8.50	2.92	13.3	127
	0.95	1.17		2.72	11.6	

6

Withdrawal Day	Crayfish Tails	Catfish (Edible Tissue)		Crayfish Tails	Catfish (Edible Tissue)	Viscera
3	0.54	1.10		1.40	1.31	
7	0.13	0.83		0.86	0.89	
14	0.09	0.19	NDR	0.18	0.63	3.7
28	NDR	NDR	NDR	NDR	0.60	0.63
	"	"		"	0.44	
	"	"		"	0.53	
	"	"		"	0.55	
	"	"		"	0.45	
	"			"	0.43	

In summary, bioaccumulation ratios for crayfish tails were as high as 12X and for catfish edible tissue and viscera 30X and 170X, respectively.

In a field test, crayfish were placed in rice fields 127 days after 2 treatments both at 3 lb. AI/acre. After 374 days, crayfish were analyzed for residues. No propanil was found in shell or edible meat (level of sensitivity 0.025 ppm).

103 Toxicological Properties

103.1 References from Toxicology Branch

Acute Oral LD_{50}

Rat	1384 mg/kg	Technical
Rat	1.87 ml/kg	STAM F-34 (36.5%)
Dog	1217 mg/kg	Technical
Rat	560 mg/kg	STAM EC
Rabbit	520 mg/kg	STAM ED

Subacute

Rat no effect level (NOEL) in diet <0.1%

chronic

Rat	NOEL	400 ppm	STAM
Dog	NOEL	600 ppm	STAM

Reproduction

Rat	NOEL	<1000 ppm	STAM F-34

103.2 Fish and Wildlife Minimum Requirements

All of the previously submitted Fish and Wildlife Minimum Requirements have been previously validated as Supplemental by F. Betz, (10/10/78), either because of non-standard test methods, non-standard statiscal methods, use of formulated product, test duration too short or use of non-standard species. The following are the results of these reports recalculated (if non-standard statistical methods were used), corrected into terms of AI (if originally calculated in terms of total formulated product) and extrapolated to 96-hr (if only 24- and 48-br data were available) as necessary (see Appendix I):

Tag No.	Species	Test Type	Final Results (in AI)
20	Mallard (Anas platyrhynchos)	Acute Oral LD_{50} 10X multidose	116.8 mg/kg/day
21	Japanese Quail (Coturnix coturnix japonica)	Acute Oral LD_{50} 10X multi dose	58.4 mg/kg/day
22	European Starling (Sturnus vulgaris)	Acute Oral LD_{50} 10X multi Dose	1095 mg/kg/day
22	English Sparrow (Passer domesticus)	Acute Oral LD_{50} 10 X multi dose	68.4-136.9 mg/kg/day
23	Rainbow Trout (Salmo gairdneri)	48-hr LC_{50}	4.0 ppm
24	Lake Emerald Shiner (Notropis atherinoides) 36.5%	96-hr LC_{50}	7.5 ppm
25	Goldfish (Carassius auratus) 34.5%	96-hr LC_{50}	6.87 ppm
25	Brown Bullhead (Ictalurus nebulosus) tested with 34.5% ai	96-hr LC_{50}	7.61 ppm
26	Rainbow Trout (Salmo gairdneri) 36.5%	96-hr LC_{50}	1.83 ppm

Tag No.	Species	Test Type	Final Results (in AI)
27	Daphnia pulex	48-hr LC_{50}	4.18 ppm
28	Daphnia magna	26-hr LC_{50}	4.8 ppm

The final avian acute oral LD_{50} results have been converted to the following equivalent 5-day dietary LC_{50} results taking into account average body weight (as reported in experiment) and % body weight eaten per day for that particular weight (see Appendix II):

Species	Equiv. 5-day dietary LC_{50} (in AI)
Mallard	520 ppm
Japanese Quail	117 ppm
European Starling	1825 ppm
English Sparrow	72-144 ppm

103.2.3 Fish Acute LC_{50}'s

Fathead minnow (Pimephales promelas) - (86%)
Flow-Through
24-hr LC_{50} = 11.6 ppm AI
48-hr LC_{50} = 10.2 ppm AI
96-hr LC_{50} = 8.6 ppm AI
192-hr LC_{50} = 3.2 ppm AI

(Note that toxicity increased at a faster rate as the test proceeded.)

Call et al. 1979 (Univ. Wisc.- Superior)
Supplemental - Leitzke (10/18/79) (see attached)
(1st, 2nd & 3rd Quart. Progr. Rept. to EPA, 1978-79; In: EEB Propanil Registration Review File.)

(Note: The following is not a validation)

Static 48-hr LC_{50} to "roaches" is 2.5 ppm at 24°C in well aerated water.

When held for 20 to 30 min. at 4 to 6 ppm (concentrations causing 100% mortality in 48-hr LC_{50} test) and then placed in clean water, fish appeared to fully recover within 2 hours. However, all (8 of 8 fish) died within 2 days.

Popova, G. V. 1973. Changes in morphophysiological indices of fish, induced by propanil. Eksp. Vod. Toks. 4:38-49. (transl. by S. Colten, In: EEB Propanil Registration Review file).

103.4 Additional Aquatic Laboratory Tests

103.4.2 Embryo-Larvae and Life Cycle Studies

Fathead minnow (Pimephales promelas) - (86%)
60-day Egg-to-Fingerling Maximum Acceptable Toxicant Concentration (MATC) = 0.4 - 0.6 ppb AI
Application Factor (96-hr LC_{50}/MATC) = 22,000

Symptoms: 1) swollen yolk-sac in region of heart (pericardial edema) and 2) bloated abdomens streaked with red (personal communication, D. Call, 10/15/79; letter attached to Quarterly Repts).

Results of First Attempt: 1) greater than 50% mortality at 5.6 ppb. 48-hr in newly hatched fry from exposed eggs; 2) no mortality at 5 ppb in newly hatched fry from unexposed eggs (pers. comm., D. Call, 10/15/79).

Call et al., 1979 (Univ. Wisc. - Superior)
Core - Leitzke (10/18/79) (see attached)
(1st, 2nd & 3rd Quart. Progr. Rept. to EPA, 78-79; In: EEB Propanil Registration Review file)

(Note: The following is not a validation)

Daphnia magna Life Cycle - (93%)
21-day adult LC_{50} = 0.4 ppm AI
21-day reproduction EC_{50} = 0.11 ppm AI
(as avg. total production of young per surviving adult)
MATC = 0.07 - 0.28 ppm AI

Terrestrial & Aquatic Biology Laboratory , CBIB, BFSD, 10/15/79; In: EEB Propanil Registration Review file.

103.4.4 Residue Uptake Study

Fathead minnow (Pimephales promelas)
Biocentration Factors at 0.5, 5.0, 5.0 and 50 ppb (nominal) = 69.0, 111.3, 114.4 and 66.3, respectively
Percent Loss at End of Withdrawal - ca. 96%
Call et al., 1979 (Univ. Wisc. - Superior)
Core - Leitzke (10/18/79) (see attached)
(1st, 2nd & 3rd Quart. Progr. Rept. to EPA, 1978-79; In: EEB Propanil Registration Review file.)

103.4.6 Other Studies

Metabolism

Rainbow trout (Salmo gairdneri)
Principal Metabolites are 1) either 3',4'-dichloro-2-hydroxy-propionalide or 3',4'-dichloro-3-hydroxypropionalide and 2) 3,4-dichloroaniline (DCA).

Remaining in bile 24-hr after injection with ^{14}C- labeled propanil was 9-22% of original activity.

Found in Water after 24-hr was 75% of original activity.

Call et al., 1979 (Univ. Wisc. - Superior)

Core - Leitzke (10/18/79) (see attached)

(1st, 2nd & 3rd Quart. Progr. Rept. to EPA, 1978-79; In: EEB Propanil Registration Review File).

Herbicide Stability in Solution

Propanil had a half-life of 65 days in a 194-day test in Lake Superior water. Principal degradate was 3,4-dichloroaniline (DCA).

Call et al., 1979 (Univ. Wisc. - Superior)
Core - Leitzke (10/18/79) (see attached)

(1st, 2nd & 3rd Quart. Progr. Rept. to EPA, 1978-79; In: EEB Propanil Registration Review file).

103.5 Field Test

103.5.3 Aquatic Field Test

(Note: The following is not a validation.)

An enclosed 0.025 ha pond was treated with 7 kg/ha propanil (normal application rate for rice in Russia), and 72 "ides" were introduced. Samples were taken periodically for residue analyses, and over a 60-day period fish were biochemically and histologically examined.

Propanil concentration was 0.2 ppm on day 1 and declined to 0.05 ppm by day 5; only its metabolites were found on the 10th day. By day 10 the following pathological findings were noted: 1) complete loss of hemoglobin from red blood cells and numerous dead white blood cells, 2) disaggregation of liver cells which increased over the remainder of the test, and 3) degeneration and resorption of ovocytes which also continued till the end. After 60 days

control fish had increased in weight 63%, while exposed fish increased by only 14% and had 20% mortality.

Popova, G.V. 1973. Changes in morphophysiological indices of fish, induced by propanil. Eksp. Vod. Toks. 4: 38-49. (transl. by S.Colten; In: EEB Propanil Registration Review file).

104 Hazard Assessment

104.1 Discussion (Residue Profile)

The following residues (in ppm) may be expected on vegetation immediately following application at 1.5 lb. AI/acre:

Short Grass	Long Grass	Leaves & Leafy Crops	Forage
360	165	187	87

104.2 Likelihood of Exposure Adverse Effects

Terrestrial

As noted by Betz (10/10/78) "wheat is one of the most valuable wildlife plants in the whole country (Martin et al., 1960)." Numerous species of waterfowl, upland game birds, songbirds and small mammals occur in wheat fields, and those feeding on young plants would be exposed to the highest propanil residues.

Theoretically calulated equivalent 5-day dietary LC_{50}'s (Sect. 103.2) are generally in the range of or less than expected residues of propanil on vegetation in wheat fields (Sect. 104.1). Although these data indicate potential hazard, they are too theoretical for EEB to use as the basis of a final risk assessment. Because potential hazard is indicated, in this case EEB will require LC_{50}'s from actual dietary tests in its final risk assessment. Therefore, EEB must receive two "Acceptable" 5-day dietary LC_{50} studies on one species of waterfowl (preferably the mallard) and one species of upland game birds (preferably the bobwhite or other native quail, or the ring-necked pheasant) using technical grade propanil before completion of this Hazard Assessment.

Aquatic

Propanil is applied on wheat at 1.5 lb. AI/acre when wheat and weeds are at the 2 to 4 leaf stage and has a half-life in soil of 30 to 40 days (see Sect. 102.1). Taking into account the rate of application, persistence in soil and amount of vegetation in the field at time of application, it is rather unlikely that run-off is a potentially significant route for aquatic contmination. Drift, however, from aerial application is a much more likely route of contamination.

On EEB's TI-59 spray drift program, the critical level for potential acute hazard (as 1/2 the recalculated, corrected and extrapolated 96-hr LC_{50} for rainbow trout (Salmo gairdneri) of 1.83 ppm AI, see Sect. 103.2) was 0.915 ppm. An application rate of 1.5 lb. AI/acre, application height of 12 ft (for aerial application and a windspeed of 5 mph were also used. (Note: Assumptions in this program are no evaporation of droplets and no air turbulence, i.e. droplets fall due to gravity alone). Acute hazard from drift was calculated as minimal.

However, the potential hazard from chronic exposure is much greater. Propanil is stable to hydrolysis in neutral buffered solutions for up to 28 days (see Sect. 102.2), and in Lake Superior water has a half-life of 65 days (see Sect. 103.4.6). Its empirically derived Application Factor (96-hr LC_{50}/MATC) is (8.6 ppm/0.4 ppb =) approx. 22,000 using the fathead minnow, Pimephales promelas (see Sect. 103.4.2). This means that contamination resulting from a single application could easily persist long enough to cause reproductive impairment in fish even at very low levels.

Also more than 50% mortality was observed at 5.6 ppb in newly hatched fry from exposed eggs, while fry at 5 ppb from unexposed eggs had no mortality. It is apparent that in the former case something was affecting developing embryonic tissues in the egg that later expressed itself as mortality. This could have been either propanil, its two principal breakdown products propionic acid and 3,4-dichloroaniline (DCA) or its secondary breakdown product via DCA, the carcinogenic 3,3',4,4'-tetrachlorozobenzene (TCAB) (Sect. 102.1). As a carcinogen TCAB could have very well been responsible for damaging the embryonic tissues and thus have been responsible for propanil's unusually high Application Factor of 22,000.

Dividing the theoretical rainbow trout 96-hr LC_{50} used above by the Application Factor gives a critical level of 0.0000831818 ppm. Calculated lay-off distances to avoid contamination levels causing potential chronic effects are 265, 530 and 800 ft. for windspeeds of 5, 10 and 15 mph. These lay-off distances were calculated because, even though it is applied only once, propanil is very persistent in water. Also, even assuming some degradation in natural waters, Russian laboratory and field data indicate irreversibility and persistence of toxic effects even after fish were no longer exposed to (albeit relatively high levels of) propanil (see Sects. 103.2.3 & 103.5.3, Popova).

However, lay-off distances of such a length are not meaningful for late-spring aerial applications in the northern plain states where windy conditions averaging 11 to 12 mph prevail. Thus, levels of aquatic contamination are expected to be high enough to result in Unreasonable Adverse Effects on local fish populations. Therefore,

EEB does not concur with the registration of propanil on wheat until it is shown either that 1) actual levels of contamination are much lower and less hazardous than theoretically expected levels or 2) local populations would not be affected by expected levels of contamination.

(I.E., EEB will reconsider its position, only if 1) the results of a full-scale field residue and population monitoring study show that chronically hazardous levels of contamination do not occur in aquatic sites at certain distances from wheat fields, or 2) the theoretical 96-hr LC_{50} for rainbow trout and the empirical Application Factor from the Univ. Wisc. - Superior fathead minnow study are not reflective of the toxicity of currently produced propanil.)

If it is shown that currently produced propanil is as toxic as that used in previous tests (2), then it must be shown that hazardous levels are not reached in the field (1).

104.3 Endangered Species Considerations

As noted previously by F. Betz (10/10/78), the whooping crane (Grus americana) is the only Threatened or Endangered Species expected to be exposed to pesticides in northern wheat fields during the spring, and then only briefly. Also it is possible that whooping cranes will have passed through this area before propanil application.

"In summary, the proposed pesticide application appears to present a low probability of hazard to the whooping crane, although the final evaluation must await receipt of complete avian toxicity data."

104.4 Adequacy of Toxicity Data

As noted above, all of the previously submitted Fish and Wildlife Minimum Requirements are Supplemental and are not considered adequate in meeting full registration requirements (see Sect. 103.2).

The recent Univ. Wisc. - Superior study has the following validations (J. S. Leitzke, 10/18/79):

1) Fathead minnow acute LC_{50} - Supplemental (Sect. 103.2.3)
2) Fathead minnow 60-day embryo-larvae - Core (Sect. 103.4.2)
3) Fathead minnow residue uptake - Core (Sect. 103.4.4)
4) Rainbow trout metabolism - Core (Sect. 103.4.6)
5) Herbicide stability in solution - Core (Sect. 103.4.6)

104.5 Additional Data Required

Theoretically calculated equivalent 5-day dietary LC_{50}'s (calculated from "Supplemental" LD_{50} data, Sect. 103.2) are

generally in the range of or less than expected residues of propanil on vegetation in wheat fields (Sect. 104.1). However, such data calculated from "Supplemental" LD_{50}'s are too theoretical for EEB to use in its final risk assessment. Therefore, the registrant must submit two avian 5-day dietary LC_{50} studies on one species of waterfowl (preferably the mallard) and one species of upland game bird (preferably the bobwhite or other native quail, or the ring-necked pheasant) using technical grade propanil prior to consideration of registration of propanil on wheat.

Levels of aquatic contamination from drift (Sect. 104.2) are theoretically expected to be higher than levels calculated (from the extrapolated rainbow trout 96-hr LC_{50}, Sect. 103.2, and from the Univ. Wisc. - Superior fathead minnow embryo-larvae test, Sects. 103.2.3, .4.2, .4.4 & .4.6) to result in Unreasonable Adverse Effects on local fish populations. Therefore, the registrant must show that either 1) actual levels of contamination are much lower and less hazardous than theoretically expected levels (through a full-scale field residue and population monitoring study), or 2) the theoretical 96-hr LC_{50} and Application Factor are not reflective of the toxicity of currently produced propanil (through a coldwater fish 96-hr LC_{50}, quality control bioassays, fully listed contents data sheets, and adequate identification of alleged impurity), prior to consideration of registration of propanil on wheat. (See Sect. 107.5 for fuller details).

106 RPAR Criteria

Levels of aquatic contamination from drift are theoretically expected to be higher than levels calculated to result in Unreasonable Adverse Effects on local fish populations (Sect. 104.2), CFR 162.11. Therefore, information leading to this conclusion will be forwarded to Special Pesticide Review Division for scheduling.

107 Conclusions

The proposed registration of propanil on hard red spring wheat in the northern plains states constitutes a new and substantially dissimilar use compared to the presently registered rice use. Due to vastly increased acreage, different geographical location and different climate, significantly new non-target populations will be exposed to propanil. Therefore, this Incremental Risk Assessment has addressed what the hazards to these new populations are and what information must be supplied to complete this review prior to consideration of registration of propanil on wheat.

107.3 Environmental Hazards Labeling

Although the submitted data are generally insufficient for EEB to complete its Hazard Assessment, there is sufficient information to determine that the proposed caution is inadequate. The following caution from propanil's rice label (EPA Registration No. 707-109) is considered more appropriate:

> This product is toxic to fish. Keep out of lakes, streams and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

107.4 Data Adequacy Conclusions

As noted above, all of the previously submitted Fish and Wildlife Minimum Requirements are Unacceptable (F. Betz, 10/10/78) and are not considered adequate in meeting full registration requirements (Sect. 103.2).

The recent Univ. Wisc. - Superior study has the following validations (J. S. Leitzke, 10/18/78):

1) Fathead minnow acute LC_{50} - Unacceptable (Sect. 103.2.3)
2) Fathead minnow 60-day embryo-larvae - Acceptable (Sect. 103.4.2)
3) Fathead minnow residue uptake - Acceptable (Sect. 103.4.4)
4) Rainbow trout metabolism - Acceptable (Sect. 103.4.6)
5) Herbicide stability in solution - Acceptable (Sect. 103.4.6)

107.5 Data Requests

Theoretically calculated equivalent 5-day dietary LC_{50}'s (calculated from "Supplemental" LD_{50} data, Sect. 103.2) are generally in the range of or less than expected residues of propanil on vegetation in wheat fields (Sect. 104.1). However, such data calculated from "Supplemental" LD_{50}'s is too theoretical for EEB to use in its final assessment. Therefore, the following tests must be submitted prior to consideration of registration of propanil on wheat:

> Avian 5-day Dietary LC_{50}'s using technical grade propanil on one species of waterfowl (preferably the mallard) and one species of upland game bird (preferably the bobwhite or other native quail, or the ring-necked pheasant).

Levels of aquatic contamination from drift (Sect. 104.2) are theoretically expected to be higher than levels calculated (from the extrapolated rainbow trout 96-hr LC_{50}, Sect. 103.2, and from the Univ. Wisc.- Superior fathead minnow embryo-larvae test, Sects. 103.2.3, 4.2, 4.4 & 4.6) to exceed RPAR criteria for

Unreasonable Adverse Effects on local fish populations. Therefore, one or both of the following courses of tests must be submitted prior to consideration of registration of propanil on wheat:

1) Show that actual levels of contamination are much lower and less hazardous than theoretically expected levels. To this end the registrant must conduct a full-scale field residue and population monitoring study. Propanil should be aerially applied, at 1.5 lb. AI/acre on a large wheat field under normal wind speed. Wind speed and direction should be noted. Three to four ponds at varying and noted distances downwind of wheat field should be sampled pre- and post-application for enough time to establish a decline curve. Residue analyses should be conducted for at least the following compounds: propanil, 3,4-dichloroaniline (DCA) and 3,3',4,4'-tetrachloroazobenzene (TCAB). Populations of fish should be measured pre- and post-application with specific reference to reproductive success and growth and survival of fry after application. Effects on future population levels should also be estimated under the assumption of continued use. Such ponds and fish populations must not be downwind of fields sprayed in previous years with propanil.

OR 2) Show that the theoretical 96-hr LC_{50} for rainbow trout and the empirical Application Factor from the Univ. Wisc. - Superior fathead minnow study are not reflective of the toxicity of currently produced propanil. To this end the registrant must submit the following test results: 1) A 96-hr LC_{50} on a coldwater fish (preferably rainbow trout) using technical-grade propanil; 2) Quality control bioassays comparing the toxicity of the older batch of technical propanil used in the Univ. Wisc. - Superior study (lot no. 8771) against all currently produced used batches (including lot no. 9287) on an appropriate test organism such as newly hatched fathead minnow fry. Tests should be of at least an "Acceptable" enough status to make valid comparisons between different batches used and should be run as similarly as possible to Univ. Wisc. - Superior study to make valid comparisons, i.e. continuous exposure of fertilized eggs to fry, flow-through exposure, and results expressed in terms actual concentration measured (and not nominal); 3) Fully listed contents data sheets, listing all components and impurities, in particular TCAB and other possible azobenzenes, "present in quantities of 0.01 percent (of the weight of the product) or more" (CFR 163.61-7; Product Chemistry, Product Analytical Methods and Data, Manufacturing-Use Products), for lot nos. 8771 and 9287 and all other batches on which quality control fathead fry acute bioassays are subsequently run; 4) And in general, enough information to adequately identify the compound present in batch lot no. 8771 and not in currently produced batches (including lot no. 9287) that was responsible

for the Univ. Wisc. - Superior's unusually high Application Factor of 22,000.

Note: If the second option is followed and if it is shown that currently produced propanil is as toxic as that used in previous tests, then the first course must be followed as well.

107.7 Recommendations

EEB objects to the registration of propanil on wheat until all Data Requests have been fulfilled.

John S. Leitzke John S. Leitzke 11/30/79
Section 2
Ecological Effects Branch, HED, (TS-769)

Norm Cook Norman Cook 12/3/79
Head, Section 2
Ecological Effects Branch, HED, (TS-769)

Clayton Bushong Clayton Bushong 12/3/79
Branch Chief
Ecological Effects Branch, HED, (TS-769)

VALIDATION SHEET

FORMULATION:	CHEMICAL NAME	Validator:	Date
% a.i.	3,4-Dichloropropionanilide	J. S. Leitzke	10/18/79
86% (Adler, Rohm & Haas, 10/4/79)		Test Type: Fish Acute LC_{50} - Fathead minnow; 60-day Embryo-Larvae - Fathead minnow; Residue Uptake - Fathead minnow; Metabolism - Rainbow trout; Herbicide Stability in Solution	

CITATION: Accession No. [not assigned yet]; D. J. Call, R. Kent and L.T. Brook, 1979, Estimates of "no effect" concentrations of selected pesticides in freshwater organisms, Univ. Wisc.-Superior, 1st, 2nd & 3rd Quarterly Progress Report to EPA, 1978-1979; In: EEB Propanil Registration Review file. (plus personal communications from D. Call, 10/15/79 & 10/29/79)

VALIDATION CATEGORY:

1) Fish Acute LC_{50} - Supplemental
2) 60-day Embryo-Larvae - Core
3) Residue Uptake - Core
4) Metabolism - Core
5) Herbicide Stability in Solution - Core

RESULTS:

1) Fish Acute Flow-Through LC_{50} - Fathead minnow (Pimephales promelas) - in ppm AI

24-hr.	48-hr.	96-hr	192-hr.
11.6	10.2	8.6	3.2

2) 60-day Embryo-Larvae - Fathead minnow (Pimephales promelas) egg-to-Fingerling Maximum Acceptable Toxicant Concentration (MATC) = 0.4-0.6 ppb AI
Application Factor (96-hr LC_{50}/MATC) = 22,000

3) Residue Uptake - Fathead minnow (Pimephales promelas)

Bioconcentration Factors at 0.5,5.0,5.0 and 50 ppb (nominal) = 69.0, 111.3, 114.4 and 66.3, respectively
Percent Loss at End of Withdrawal = ca. 96%

4) Metabolism-Rainbow trout (Salmo gairdneri)

Principal Metabolites are 1) either 3',4',-dichloro-2-hydroxypropionanilide or 3',4'-dichloro-3-hydroxypropionanilide and 2) 3,4-dichloroaniline (DCA). Remaining in Bile 24-hr after injection with ^{14}C- labeled propanil was 9-22% of original activity.

Found in Water after 24-hr was 75%.

5) Herbicide Stability in Solution

Half-life in Lake Superior water = 65 days

DISCUSSION & VALIDATION RATIONALE:

1) Fish Acute Flow-Through LC_{50}

Two Replicate Tests were run generally according to standard prodedures for flow-through tests, except that the fathead minnow (generally not an accepted test species for acute tests) was used. Some of the test conditions were as follows: temperature 25.0°C (24.1-26.6°C), DO (as % saturation) 90.0 (± 1.4), total hardness (as ppm $CaCO_3$) 51.3 (± 6.7), pH 7.5 (± 0). LC_{50}'s were calculated in terms of actual concentrations in water (and not nominal concentrations) using the trimmed Spearman-Karber method. Replicate and mean LC_{50} values (in ppm) are tabulated below:

	24-hr.	48-hr.	96-hr.	192-hr.
	11.9 (9.9-14.3)	10.0 (8.9-11.3)	8.6 (7.4-9.9)	3.9 (2.8-5.6)
	11.4 (9.6-13.5)	10.5 (9.6-11.5)	8.5 (7.0-10.2)	2.6 (1.7-4.2)
Mean	11.6	10.2	8.6	3.2

Note that toxicity increased at a faster rate as the test proceded.

2) 60-day Embryo-Larvae

A standard proportional-diluter provided continuous exposure to ≤24-hr-old fertilized fathead minnow eggs and subsequently hatching fry surviving fingerlings for 54 days at 5 actual duplicated concentrations (and not nominal concentrations) of 0.0, 0.4, 0.6, 1.2, 2.4 and 3.8 ppb. (In the first attempt more than 50% of hatched fry from exposed eggs died within 48-hr at the lowest concentration 5.6 ppb. On the other hand, newly hatched fry from unexposed eggs had no mortalities at 5 ppb [personal communication, D. Call, 10/15/79; letter attached to Quarterly Repts.]). Eggs were placed in

incubation jars (approx. 50 eggs per jar, 2 jars per replication), and after hatching a total of 30 fry were released into the chamber (later cut back 20; D. Call, pers. comm.)

Some of the test conditions were as follows: temperature 25.3°C (23.6-27.2°C), DO (as % saturation) 73.7 (± 28.9), total hardness (as ppm $CaCO_3$) 57.9 (± 2.1), pH 7.3 (± 0.3). Results were statistically analyzed by one-way analysis of variance with a one-tailed Dunnett's test. Results are tabulated below:

Mean Propanil Concentration (ug/l)

Parameter	0.0	0.4	0.6	1.2	2.4	3.8
Mean percent hatch*	75.9	80.5	70.2	63.4	64.0	56.6#
Mean percent abnormal and dead**	3.0	5.5	10.4	9.4	13.5	65.8##
Mean percent fry survival at 54 days***	93.4	72.5	50.0	16.6##	0##	0##
Mean wet weight at 54 days (g)	0.590	0.558	0.491	0.448	---	---
Mean dry weight at 54 days (g)	0.152	0.132	0.119#	0.113	---	---
Mean total length at 54 days (mm)	38.3	36.7	34.2##	33.1##	---	---

* Live fry/total eggs.
** Abnormal (deformed) + dead fry/total fry at time of transfer.
*** Based on mortality of 30 fish maximum per chamber through day 30 post-hatch and 20 fish maximum per chamber between days 30 and 54 post-hatch.
\# Significantly different from controls ($p<0.05$).
Significantly different from controls ($p<0.01$).

The most common symptoms of poisoning were swelling of yolk-sac around the heart and (pericardial edema) and bloated abdomens streaked with red (pers. comm, D. Call, 10/15/79). The resulting Application Factor (96-hr LC_{50} divided by MATC) is (8.6 ppm/0.4 ppb =) ca. 22,000.

3) Residue Update

Two sets of residue uptake tests were run, at continuous, nominal concentrations 5.0 & 50 ppb and 0.5 & 5.0 ppb ^{14}C-labelled propanil using modified proportional diluters. One-hundred 30-day-old fathead minnows per chamber were used. Two tests were necessary because 14.5 and 16.4% mortality occurred in the 5.0 and 50 ppb nominal concentrations (3.96 and 53.49 ppb actual) chambers over the 21-day exposure period. Depuration in the first run was for 21 days. The second run at 0.5 and 5.0 ppb nominal concentration (0.34 and 5.09 ppb actual) had 17 days exposure and 10 day depuration. The results are tabulated below:

Mean H_2O concentration (ug/1)	Bio-concentration factor	Percent parent compound at end of uptake*	Percent depuration in 24 hr.	Percent depuration at end of test (days of depuration
3.96**	114.4		80.1	95.6 (21)
53.49**	66.3	1.8	76.2	95.9 (21)
0.34***	69.0		80.0	96.4 (10)
5.09***	111.3		80.8	95.4 (10)

* Determined as portion of ether-extractable fraction that chromatographed by TLC as parent compound from fish exposed to higher concentrations of test herbicides.

** First propanil run.

*** Second propanil run.

In all tests both initial uptake and elimination of ^{14}C were rapid.

4) Metabolism

One rainbow trout (100-150 gm) in 10°C water, was injected with ^{14}C- labelled propanil and sacrificed 24-hr. later for analysis of bile and liver. Metabolites were analyzed first by thin layer Chromatography (TLC) on silica gel coated glass plates followed by mass spectral analysis.

TCAB (3,3',4,4'-tetrachloroazobenzene) was found in the mass spectral analysis but not in the TLC and therefore the authors concluded that 3,4-dichloroaniline (DCA) photochemically converted to TCAB prior to mass spectral analysis.

5) Herbicide Stability in Solution

Propanil stability in Lake Superior water was determined over 194 days at 20°C. Duplicate 500 ml stock solutions had initial concentrations of approximately the 96-hr. LC_{50} for fathead minnows. Propanil decreased curvilinearly with a half-life of 65 days. Principal degradate determined by mass spectral analysis was 3,4-dichloroaniline.

Appendix I

Final Results of Previously Submitted Data Recalculated, Corrected and Extrapolated As Necessary

Tag No.	Species	Test	Reported Results	Recal. Results (if nec.)	Material (% AI)	In terms of AI/Form	Corrected Results in AI	Extrapolated Results (if nec.)
20	Mallard (Anas platychnchos)	Mult. Dose Acute Oral LD_{50}	(Betz) 375 mg/kg/day	(Actual) 320 mg/kg/day	36.5%	Form.	116.8 mg/kg/day	
21	Japanese Quail (Coturnix Coturnix japonica)	Mult. Dose Acute Oral LD_{50}	160 mg/kg/day	—	36.5%	Form.	58.4 mg/kg/day	
22	Europ. Strl. (Sturnus vulgaris)	Mult. Dose Acute Oral LD_{50}	3000 mg/kg/day	—	36.5%	(Form.)	1095 mg/kg/day	
22	Engl. Sprr. (Passer domesticus)	Mult. Dose Acute Oral LD_{50}	187.5-375 mg/kg/day	—	36.5%	(Form.)	68.4 - 136.9 mg/kg/day	
23	Rainbow Trout (Salmo gaird-neri)	48-hr LC_{50}	4.0 ppm	—	Tech. (?)	(AI)	—	
24	Lake Emerald Shiner (Notropis atherinoides)	96-hr TLM	7.5 ppm AI	(other) 4-hr - 13.5 24-hr 7.5 48-hr 7.5	STAM F 34 (?)	AI	—	
25	Goldfish (Carassius auratus)	48-hr LC_{50}	22.4 ppm	24-hr 24.03 48-hr 21.27	36.5%	Form.	24-hr 8.77 48-hr 7.76	96-hr 6.87
25	Brown Bullhead (Ictalurus nebulosus)	48-hr LC_{50}	22.2 ppm	24-hr 23.39 48-hr 22.09	36.5%	Form.	24-hr 8.54 48-hr 8.06	96-hr 7.61

Appendix I

Final Results of Previously Submitted Data Recalculated, Corrected and Extrapolated As Necessary

Tag No.	Species	Test	Reported Results	Recal. Results (if nec)	Material (% AI)	In terms of AI/Form	Corrected Results in AI	Extrapolated Results (if nec)
26	Rainbow Trout (Salmo gairdneri)	48-hr LC_{50}	7.4 ppm	24-hr 9.65 48-hr 6.95	36.5%	Form.	24-hr 3.52 48-hr 2.54	96-hr 1.83
27	Daphnia pulex	48-hr LC_{50}	11.8 ppm	24-hr 14.11 48-hr 11.44	36.5%	Form.	24-hr 5.15 48-hr 4.18	
28	Daphnia magna	26-hr LC_{50}	4.8 ppm (3.8-6.6)	—	Tech. (?)	(AI)	—	

Appendix II

Conversion of Acute Oral LD_{50} to Equivalent 5-day Dietary LC_{50}

$$\text{Equiv. 5-day } LC_{50} \text{ (ppm)} = \frac{(LD_{50} \text{ (mg/kg)} \times (100\%)}{(\% \text{ Body Weight eaten per day})} \times \frac{1}{5}$$

Mallard

LD_{50} = 116.8 mg/kg/day
Avg. Body Wt. (in expt.) = 892.3 g
% BW eaten per day (for that weight) = 4.5%
Equiv. 5-day LC_{50} = 520 ppm

Japanese Quail

LD_{50} = 58.4 mg/kg/day
Avg. Body Wt. (in expt.) = 125 g
% BW eaten per day (for that weight) = 10%
Equiv. 5-day LC_{50} = 117 ppm

Starling

LD_{50} = 3000 mg/kg/day
Avg. Body Wt. (in expt.) = 75.16 g
% BW eaten per day (for that weight) = 12%
Equiv. 5-day LC_{50} = 1825 ppm

English Sparrow

LD_{50} = 68.4-136.9 mg/kg/day
Avg. Body Wt. (in expt.) = 25 g
% BW eaten per day (for that weight) = 19%
Equiv. 5-day LC_{50} = 72-144 ppm

Appendix III

List of Wildlife Species Likely to be exposed

Waterfowl

Ducks
Geese

Upland Gamebirds

Greater Prairie Chicken
Ring-necked Pheasant

Songbirds

Rose-breasted Grosbeak
Western Meadowlark
Yellow-headed Blackbird
Red-winged Blackbird
Brewer Blackbird
Lapland Longspur

Small Mammals

Richardson Ground Squirrel
Grasshopper Mouse
Cottontail Rabbit
Jackrabbit

From: Martin et al. (1961) and Gusey and Maturgo (1972).

Appendix IV

References:

Gusey, W. F. and Z. D. Maturgo. 1972. Wildlife Utilization of Croplands. Env. Cons. Dept. Shell Oil Co. 277p.

Martin, A.C., M.S. Zim and A. L. Nelson 1961. American Wildlife and Plants, A Guide to Wildlife Food Habits. Dover Publications, New York, 500p.

Usual Planting and Harvesting Dates, 1972. USDA Agricultural Handbook No. 283. 84p.

```
DRIFT EST.
        0.915        CL
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           12.       HT
            5.        W

            3.
DRIFT MINIMAL
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           12.      AL
          125.      AL
          1.5       AL
           12.      HT
           10.       W

            3.
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162.0561303          M
```

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DRIFT EST.
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          1.5       AL
           12.      HT
            5.       W

            3.
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81.02806515          M
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DRIFT EST.
 .0000831818        CL
          1.5       AL
           12.      HT
           15.       W

            3.
797.5203263         FT
243.0841955          M
```

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Usual Planting and Harvesting Dates, 1972. USDA Agricultural Handbook No. 283. 84p.

02820

15 OCT 1979

PP# 8F2106. Propanil on wheat. Amendment of September 7, 1979.

R. S. Perfetti, Ph.D., Chemist, RCB, HED (TS-769)

Product Manager No. 25 (R. Taylor), FMB, RD (TS-767) and Toxicology Branch, HED (TS-769)

THRU:Chief, RCB, HED (TS-769)

This amendment is in response to our memorandum of August 22, 1979 in which we recommended against the proposed tolerances for wheat grain and straw. Satisfactory resolution of the remaining deficiencies at that time required the following:

(1) Submission of a revised Section F proposing an 0.2 ppm tolerance for residues of propanil and its metabolites in or on wheat grain and an 0.75 ppm tolerance for wheat straw.

(2) Satisfactory resolution of our deferral to TOX regarding tetrachlorazobenzene.

The petitioner has now submitted a revised Section F proposing an 0.2 ppm tolerance for residues of propanil and its metabolites in or on wheat grain and an 0.75 ppm tolerance for wheat straw. We have also obtained a copy of a TOX memorandum (W. Dykstra, 8/28/79) stating that they would not be concerned over residues, if any, of <1.0 ppb tetrachlorazobenzene in wheat grain or straw.

We therefore consider all deficiencies in the subject petition resolved.

Recommendation

TOX Branch considerations permitted. We now recommend that the proposed tolerances for residues of propanil and its metabolites on wheat grain at 0.2 ppm and on wheat straw at 0.75 ppm be established.

RDI:R.Quick:10-2-79:JGCummings:10-2-79
TS-769:RCB:R.Perfetti:JP:X77484:Rm810:10-3-79
CC: EEE,TOX,CHM(3)

028201 EFE

22 AUG 1979 Stan Rogue

PP# 8F2106. Propanil on wheat. Amendment of 2/16/79.

R. B. Perfetti, Chemist, RCB, HED (TS-769)

PM #25 (R. Taylor), Fungicide-Herbicide Branch, Registration Division & TOX, HED (TS-769)

THRU: Chief, RCB, HED (TS-769)

The amendment is in response to our memorandum of 11/22/78 in which several deficiencies in the subject petition were outlined. We will discuss these deficiencies and the petitioner's response to them in the order in which they appeared in our memorandum cited above.

Deficiency 1.

A clearance for the inert ingredient [redacted] for a post emergence - before heads form - use on wheat is needed before any favorable action can be taken on this petition.

Response to 1.

The petitioner has submitted a copy of a Federal Register Notice [redacted]

We consider this deficiency resolved.

Deficiencies 3a, 3b and 4a.

3a. The analytical method used to obtain residue data employed a 4 hr hydrolysis vs a 16 hr minimum hydrolysis time prescribed in the PAM II Method. Also a less concentrated caustic solution was utilized in this method. Since data submitted previously showed that release of 3,4-dichloroaniline from treated rice plants was much lower when a 6 hr hydrolysis was employed (vs the 16 hr hydrolysis), we are concerned that the method used in this petition did not accomplish total release of conjugated 3,4-dichloroaniline. Validation data involving the spiking of samples with parent compound would, of course, not be adequate to demonstrate quantitative release of 3,4-dichloroaniline from its conjugates in wheat grain and straw. Therefore, we will need additional data showing that a 4 hr reflux with 5N sodium hydroxide is sufficient to release quantitative amounts of 3,4-dichloroaniline from its conjugates in wheat grain and straw.

3b. We will reserve judgment on the adequacy of the method for production of residue data and the appropriateness of the validation data at such time as our concerns discussed in 3(a) above are satisfactorily resolved.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

4a. Because of the uncertainties with respect to the ability of the analytical method to determine conjugated 3,4-dichloroaniline we will make a conclusion with respect to the adequacy of the residue data at such time as these uncertainties are satisfactorily resolved.

Response to 3a, 3b and 4a.

The petitioner has submitted analysis of grain and straw from previous residue trails using a 16 hour digestion. These results are compared with data found originally in the same samples using 4 hour digestion. Grain samples which showed <0.05 ppm of 3,4-dichloroaniline with the 4 hour reflux gave the same values on reanalysis with the 16 hour digestion. Samples of straw when analyzed with the 4 hour digestion contained residues ranging from <0.05 to 0.06 ppm these samples showed larger residues of 0.04 to 0.10 ppm of 3,4-dichloroaniline after 16 hours of reflux or a possible 60% increase in observed residues.

The petitioner has also submitted data showing % release of 3,4-dichloroaniline from its glucose conjugate (N-glucosyl-3,4-dichloroaniline) which is considered the major conjugate of 3,4-dichloroaniline. The % increase for the 4 hour digestestion was 80 and 106% and for the 16 hour reflux 86 and 92%.

Therefore, since it is possible that, as was indicated in the reanalyses of the straw samples, only 40% of the actual residues of 3,4-dichloroaniline may have been determined with the 4 hour digestion procedure, it is our judgment that higher tolerance levels for wheat grain and straw are needed to assure that over-tolerance residues are not found in these commodities. Based on the maximum 60% increase in observed residues in the straw and the maximum residues levels found in the grain and straw, appropriate tolerance levels would be 0.2 ppm for wheat grain and 0.75 ppm for wheat straw. The petitioner should be informed that a revised Section F proposing these levels is needed.

We conclude that, using the maximum correction factor discussed above, the 4 hour digestion procedure is adequate for obtaining residue data but not for enforcement purposes. The method of choice for enforcement purposes is the PAM II procedure using a 16 hour digestion and the higher NaOH concentration.

We consider deficiencies 3a and 3b resolved.

We do not consider deficiency 4a resolved.

Deficiency 4b

We defer to TOX the question of whether they are concerned over possible residues (theoretical maximum value of 8 ppm) of tetrachloroazobenzene (TCAB) in wheat. Should TOX express concern over the possibility of TCAB residues occuring in this commodity, we will need, at the least, a radiotracer study on wheat resembling the experiment carried out for rice.

Response to 4b.

The petitioner has submitted residue data for tetrachloroazobenzene in wheat treated with propanil in lieu of the radiotracer study requested above. The stated sensitivity of the of the method used was 1 ppb. The procedure utilized glc and a ^{63}Ni electron capture detector. Recoveries for wheat grain spiked at 1 to 4 ppb ranged from 68 to 100%. Recoveries from straw fortified at 7.5 to 10 ppb ranged from 54 to 70%. We estimate that a reliable limit of detectability would be 2 to 3 ppb.

Residues of tetrachloroazobenzene were <0.1 ppb in all samples of wheat grain and straw analyzed. In all, 19 samples of wheat grain and 15 samples of straw grown in Minnesota, Montana, and North and South Dakota were analyzed. These samples were treated once with 1.5 to 2.0 lb active ingredient/acre and PHIs ranged from 64 to 81 days. In seven of the 15 straw samples, small peaks (1 to 3 mm) were observed at the retention time for TCAB. This would represent, if indeed these peaks were TCAB 0.125 to 0.375 ppb of this compound in wheat straw which is well below the 2 to 3 ppb estimated practical limit of detectability. No such peaks (<1mm in height) at the retention time for TCAB were observed in any of the wheat grain samples.

We defer to TOX the question of whether they are concerned over residues, if any, of <1.0 ppb in wheat grain or straw.

Pending satisfactory resolution of our deferral to TOX, we consider this deficiency resolved.

Deficiency 5.

Without a final determination of the levels of residues to be expected on wheat grain and straw we can make no final judgment with respect to secondary residues in meat, milk, poultry, and eggs.

Response to 5.

No formal response to deficiency 5 was needed. However, now that we have been able to determine appropriate tolerance levels for wheat grain (0.2 ppm) and straw (0.75 ppm) we can now conclude that any secondary residues in meat, milk, poultry and eggs resulting from the feeding of wheat grain and/or straw to livestock will be covered under the existing tolerances for these commodities.

We consider this deficiency resolved.

Recommendations.

We recommend that the proposed tolerance not be granted for the reasons given in our discussions of deficiencies 4a and 4b above. The petitioner should be informed that resolution of these deficiencies will require the following:

3A

1. Submission of a revised Section F proposing an 0.2 ppm tolerance for residues of propanil and its metabolites in or on wheat grain and an 0.75 ppm tolerance for wheat straw.

2. Satisfactory resolution of our deferral to TOX in deficiency 4b above regarding tetrachlorazobenzene.

We also note that EFB has now concluded that the previously imposed rotational crop restriction may now be deleted from the label.

R. B. Perfetti, Ph.D.

TS-769:RCB:RBPERFETTI:sdb:X77484:RM810:CM#2:8/20/79
cc: EEE, TOX, CHM (3)
RDI:RSQUICK:8/16/79:JGCUMMINGS:8/16/79

May 19, 1980

Meeting with Rohm & Haas on Propanil, May 9th

John S. Leitzke, Ecologist, Section #2
Ecological Effects Branch, HED (TS-769)

Richard F. Mountfort
Propanil PM, Team #25
Herbicides-Fungicides Branch, Registration Division (TS-767)

THRU: Norm Cook
Head, Section #2
Ecological Effects Branch, HED (TS-769)

THRU: Clayton Bushong, Chief
Ecological Effects Branch, HED (TS-769)

Attendees: John S. Leitzke & David L. Coppage
Ecological Effects Branch, HED
Richard F. Mountfort, H-F-B, ~~57642~~ 52196
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The purpose of the meeting was to discuss the feasibility of the proposed residue monitoring requirement, and, failing that, other possible avenues for dealing with the potential chronic hazards of propanil on fish from aerial applications on hard red spring wheat.

Major conclusions of this meeting were:

A. Rohm & Haas will encourage ground spraying, and will restrict aerial applications to windspeeds less than 10 mph with a 600 ft buffer zone to the nearest body of water.

B. Rohm & Haas will provide in writing a statement that their current analytical techniques for propanil are sensitive only down to about 10 ppb for biological waters, and will tell us where information on hydrolysis of propanil in natural water is in previous submissions.) PP 9F 2106 Acc No 097297 (Vol 1 of 4)

C. Rohm & Haas should also recognize that the following features of EEB's previous hazard assessments remain:

J.Leitzke: emg 5-14-80,TS-769,CM2, (77725)

1. EEB's level of concern for chronic effects on the most sensitive coldwater indicator species, rainbow trout, is still 0.08 ppb.

2. There is still insufficient information to support the contention by Rohm & Haas that "new" technical batches of propanil are any less chronically toxic to fish than "old" batches of technical.

3. A rainbow trout 96-hr LC50 on the technical is still required as a condition of registration.

4. Two avian 5(+3)-day dieatry LC50, preferably on bobwhite quail and mallards, on the technical are also still required as a condition of registration.

5. If the results of the above tests show that biologically significant levels exist, more tests may be required.

Propanil – Hydrolysis in natural water

Rohm & Haas said info in PP9F2106 (Acc. No. 097297; Vol 1 of 4)

~~E~~ No info in this file; Env chem referenced to PP 0F0932

RCB PP0F0932 – Acc. No. – 116476

Nos 14-16 Rawe data all mixed in one report and series of tables of results from diff fields, ~~states~~ + sta
No exptl procedure explaining sampling or monitoring given at all

Acc. No. – 116473

Summary of results from above data ~~[illegible]~~

Appl to Sampl Int	Propanil (ppm) – lb/A/season 3	4	6	8 (2 appls)
0	1.16	–		N.T
1	–	1.089		–
2	–	0.740		1.77
3	–	–		–
4	0.133	–	0.61	–
7	–	0.094		0.604
10	0.044	–		–
[illegible]	–	–		–