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

JUN 17 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: TPTH Avian Reproduction Studies (MRID No.'s 263193 - 263954) and the Requirement for Estuarine/Marine Acute Toxicity Testing

From: James W. Akerman
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Environmental Fate and Effects Division (H7507C)

Douglas J. Urban 6/14/91

To: Eric Feris, PM Team Reviewer
PM Team 74
Special Review and Reregistration Division (H7508C)

As requested in the Data Package Record the Ecological Effects Branch (EEB) has responded to the avian reproduction study comments and the waiver request on estuarine/marine studies requirements.

EEB's subject response was to William Landis (Landis International, Inc) letter of January 7,1991 for Atochem North America, Inc., American Hoechst Corp. and Griffin Corp. for the subject reproduction studies. Mr. Landis had the laboratory, Wildlife International Ltd. which performed the work, comment on of each EEB's responses. This memorandum will follow the same format, omitting items which will not affect the status of the study.

BOBWHITE QUAIL

EPA Comment 14a.

The laboratory explained that the method of selecting the concentration for each dose level was based on the Fink (1972) study. Fink's study indicated that effects did not occurred at the tested levels of 5 and 25 ppm. As shown in the most recent study, the highest test level (30 ppm) failed to produce statistically significant results. The Guidelines do not suggest using other avian reproduction studies for determining the test levels. The LC_{50} study shows levels as high as 78 ppm with no mortality. Hence the levels higher than 30 ppm are reasonable and likely to show effects. The reproductive parameters are very insensitive (power of the test and difference detected from the control) with the exception of the egg shell thickness portion of the test. Therefore, the choice to use minimal spacing between

the concentrations rather than those suggested by the guidelines reduces the ability of the test to produce statistically significant result and defeats three of the objectives of the test.

1. Establish a no-effect-level
2. Establish a reproductive effect level
3. Identify symptoms which may be useful in field study design and diagnosis of poisonings.

The guidelines indicated the following:

> "Diet preparation. Concentrations for the test substance should be based on measured or calculated residues expected in the diet from the proposed use pattern(s). The concentrations should include an actual or expected field residue exposure level and a multiple level such as five. The highest nonlethal level may be estimated from data developed from the avian dietary LC_{50} (71-2)."

The ASTM support this logic by recommending the following three criteria:

(1) At least one concentration must produce an effect.

(2) The highest test concentration must contain at least 0.1% (1000 ppm).

(3) The highest test concentration must be 100 times the highest measured or expected field concentration.

Based of this the response to EEB initial review is nonpersuasive and the requirement has not been fulfilled.

The laboratory could not explain the high frequency of cracked eggs. Based on this EEB believes that the population of birds used were atypical although phenotypically indistinguishable from wild birds, tendencies such as these can not be overlooked. Unfortunately, this results in a selected population which may affect the results of the other reproductive parameters. This could mask treatment related effects for the other parameters further reducing the power of the test and the ability to detect differences.

EPA Comment 14.a.8:

The Quality Assurance statement under Appendix XV addresses

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only the accuracy of the results. For example, "The final report was determined to be an accurate reflection of the results obtained." The ability of the laboratory to adequately perform the techniques prescribed by the protocol was not discussed.

EPA Comment 14.b:

EEB did not declare that Dunnett's was inappropriate. "There is no basis for transforming the number of eggs laid and the number of hatchlings to percentile values of the maximum number of eggs laid or set in any test group, which were then used in statistical procedures." Otherwise if transformation of data is required the rationale should accompany the those results. EEB prefers the Duncan's multiple range test particularly if an effect appears to have a dose response, the Duncan test allows the dose levels to be compared to each other and separated statistically. Potentially providing a chronic effect level and a no effect level.

MALLARD DUCK

The laboratory explained that the method of selecting the doses was based on the Fink (1972) study. The EEB Data Evaluation Record for the Fink study indicated, "Triphenyltin hydroxide fed at 5 ppm had no effect on the reproductive parameters with the exception of cracked eggshell thickness ($p<0.01$)." This is contrary to your response, "That study indicated that significant effects occurred on all reproductive parameters at the 25 ppm test concentration, while no effects occurred at 5 ppm." In addition, this study was categorized "invalid" due to the lack of individual pen data, photoperiods and pre-treatment interval discrepancies. The Guidelines do not suggest using other avian reproduction studies for determining the concentration test levels. The LC_{50} study shows levels as high as 312 ppm. Hence the higher levels of 80-100 ppm are reasonable and likely to show effects. The reproductive parameters are very insensitive (power of the test and difference detected from the control) with the exception of the egg shell thickness portion of the test. Therefore, the choice to use minimal spacing between the concentrations rather than those suggested by the guidelines reduces the ability of the test to produce statistically significant result and defeats three of the objectives of the test.

1. Establish a no-effect-level
2. Establish a reproductive effect level
3. Identify symptoms which may be useful in field study design and diagnosis of poisonings.

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Therefore the initially suggested test levels which essentially follow the guidelines (see guideline) should have been used.

> "Diet preparation. Concentrations for the test substance should be based on measured or calculated residues expected in the diet from the proposed use pattern(s). The concentrations should include an actual or expected field residue exposure level and a multiple level such as five. The highest nonlethal level may be estimated from data developed from the avian dietary LC_{50} (71-2)."

Based on this EEB will also require a new mallard study as in the initial review.

The registrant has requested a waiver of the estuarine/marine studies because the label has been limited to sugarbeets, potatoes, and pecans. However a review of the 1987 Department of Commerce's Census of Agriculture indicates that the number of acres in coastal counties for these three crops are equal to 105,385 acres. (see Table 1) This is significant particularly when one is aware of the supplemental studies which show effect levels from .57 to 34 ppb are very highly toxic.

Based on this discussion, the following studies are required.

1. §71-4 Avian Reproduction Test for both Bobwhite Quail and Mallard Duck

2. §72-3 Acute toxicity test for estuarine and marine organisms

   a. 96-hour LC_{50} for shrimp and estuarine or marine fish

   b. 48-hour EC_{50} for oyster embryolarvae or 96-hour shell deposition for oyster

If there are any other questions or information needed please contact Dennis McLane (557-1993).

TABLE 1

COASTAL COUNTIES WITH POTATOES PECANS AND SUGARBEETS TPTH

ö PECANS ö					
STATE>	AL	CA	CA	FL	FL
COUNTY	ACRES	COUNTY	ACRES	COUNTY	ACRES
BALDWIN	10872	CONTRA COSTA	D	BAY	69
MOBILE	4876	LOS ANGELES	D	BREVARD	19
				CITRUS	48
				DUVAL	221
				ESCAMBIA	626
				GULF	D
				HERNANDO	13
				HILLSBOROUGH	8
				JEFFERSON	2005
				LEVY	101
				NASSAU	114
				OKALOOSA	236
				PASCO	72
				ST.JOHNS	9
				SANTA ROSA	506
				TAYLOR	10
				WAKULLA	28
				WALTON	647

TOTAL AL ACRES	TOTAL CA ACRES	TOTAL FL ACRES
15748	0	4732

TABLE 1

PECANS (CONT)

STATE>	GA	LA	LA	MS	MS
COUNTY	ACRES	COUNTY	ACRES	COUNTY	ACRES
CAMDEN	31	IBERIA	D	HANCOCK	271
CHARLTON	534	JEFFERSON	D	HARRISON	833
GLYNN		PLAQUEMINE	94	JACKSON	206
		ST. TAMMAN	197		
		TERREBONE	49		
		VERMILLIAN	18		
	TOTAL GA ACRES		TOTAL LA ACRES		TOTAL MS ACRES
	565		358		1310

PECANS(CONT)

STATE>	NC	TX	TX	
COUNTY	ACRES	COUNTY	ACRES	
BEAUFORT	199	BRAZORIA	1347	
BRUNSWICK	187	CALHOUN	D	
CARTER	451	CAMERON	68	
CRAVEN	279	CHAMBER	64	
HYDE	D	GALVESTON	119	
NEWHAVEN	105	JACKSON	519	
PASQUOTANK	71	JEFFERSON	170	PECANS
TYRRELL	17	MATAGOR	1129	TOTAL COASTAL
		NUECES	13	ACRES
	TOTAL NC ACRES		TOTAL TX ACRES	27571

TABLE 1

POTATOES

STATE>	CA ACRES	HI	HI ACRES	LA	LA ACRES
	COUNTY	COUNTY		COUNTY	
HUMBOLDT	541	MAUI	29	LAFOURCHE	D
MENDOCINO	D	OTHER	4	ST.TAMMANY	D
SAN DIEGO	6				

TOTAL CA ACRES	TOTAL HI ACRES	TOTAL LA ACRES
547	33	0

ö	POTATOES	ö

STATE> COUNTY		COUNTY		NJ COUNTY	NJ ACRES
CUMBERLAND	321	BEAUFORT	282	ATLANTIC	349
HANCOCK	11	BRUNSWICK	D	BURLINGTON	362
KNOX	9	CAMDEN	2143	CAPE MAY	12
SAGADAHOE	D	CARTERET	968	CUMBERLAND	1959
WALDO	290	NEWHANOVER	D	GLOUCESTER	D
WASHINGTON	16	PAMLICO	2321	MIDDLESEX	1265
YORK	D	PASQUOTANK	4138	MONMOUTH	638
		TYRRELL	3187	SALEM	1705

TOTAL ME ACRES	TOTAL NC ACRES	TOTAL NJ ACRES
647	13039	6290

ö	POTATOES	ö

STATE> COUNTY	NY ACRES	OR COUNTY	OR ACRES	SC COUNTY	SC ACRES
SUFFOLK	10358	LANE	15	CHARLESTON	5
				HORRY	11

TOTAL NY ACRES	TOTAL OR ACRES	TOTAL SC ACRES
10358	15	16

ö	POTATOES	ö

STATE> COUNTY	TX ACRES	WA COUNTY	WA ACRES	VA COUNTY	VA ACRES
BRAZORIA	220	GRAY HARBOR	D	ACCOMACK	6813
		KING	1	JAMES CITY	3
		PIERCE	26	KING AND QUEEN	D
		SKAGIT	3095	KING GEORGE	2
		THURSTON	13	NORTHHAMPTON	4475
		WALLA WALLA	9094	PRINCE GEORGE	D
				WESTMORELAND	3
				YORK	3

TOTAL TX ACRES	TOTAL WA ACRES	TOTAL VA ACRES

220 12229 11299

POTATOES

STATE>	UT ACRES
COUNTY	
BOXELDER	D
DAVIS	279
SALT LAKE	10
TOOELE	4
WEBER	34

TOTAL POTATOES
ACRES

55020

TOTAL UT ACRES
327

TABLE 1

SUGARBEETS

STATE>	CA ACRES
COUNTY	
CONTRA COSTA	550
MONTEREY	4378
SANTA BARBARA	220
SANTA CLARA	882
SOLANO	16764

TOTAL CA ACRES
AND US TOTAL
22794

PECANS, POTATOES SUGARBEETS

CROPS	TOTALS:
PECANS	27571
POTATOES	55020
SUGARBEETS	22794
	105385

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POTATOES

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