2-27-91

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

Thiobencarb
108401, 2665

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

February 27, 1991

SUBJECT: List B - Phase IV, Bolero

FROM: James Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: Linda Deluise
Reregistration Branch
Special Review and Reregistration Branch H7508C

Attached please find:

1. Data Requirements Summary List; and

2. List B Phase IV Response on Existing Studies Sheets

If you have questions, please contact Dan Rieder (557-1451).

(1)

3.12.91

Thiobencarb
108401, 2665

ECOLOGICAL EFFECTS BRANCH
DATA REQUIREMENTS FOR PESTICIDE REGISTRATION

~~Reviewers Name:~~ ~~Daniel Rieder~~
Telephone No.: 557-1451

DATE: 2-27-91

Required studies for (chemical name): Bolero (thiobencarb)
Chemical No: 108401
Case No.: 2665

DATA REQUIREMENT		FULFILLED Y/N	MRID	DATE	
71-1(a)	Acute Avian Oral, Quail/Duck	N	57222	(7-14-80) IBT	Y (1992)
71-1(b)	Acute Avian Oral, (TEP)	RESERVED[1]			
71-2(a)	Acute Avian Diet/Quail	Y	57224	(7-15-80)	N IBT
71-2(b)	Acute Avian Diet/Duck	Y	57225	(7-15-80)	N IBT
71-3	Wild Mammal Toxicity	N/A			
71-4(a)	Avian Reproduction/Quail	N	25774 WI	(1-13-80)	Y
71-4(b)	Avian Reproduction/Duck	Y	25778 ?	(12-3-80)	N 095106 - IB 241483 - Supp
71-5(a)	Simulated Terrestrial Field	RESERVED[2]			
71-5(b)	Actual Terrestrial Field	RESERVED[2]			
72-1(a)	Acute Fish Toxicity/Bluegill	Y	50665 ABC	(12-2-80)[3]	OK TEP, can be used for TGA

[1] Reserved pending results of acceptable 71-1(a) avian oral study with technical grade ai.

[2] Reserved pending results of an acceptable acute oral LD50, and an acceptable bobwhite quail avian reproduction study.

[3] Test material was 10G; however, test material concentration was measured, allowing this study to suffice for a test with the technical grade ai.

2nd page is missing

72-6	Aquatic Org. Accumulation	RESERVED[6]		
72-7(a)	Simulated Aquatic Field Study	N/A		
72-7(b)	Actual Aquatic Field Study	N	256967, 252022 ~~92182086~~, ~~92182089~~ (145835) - summarized (one study, 8-6-85) ~~92182088~~ 3-4-91	Not in PDMS " CA
122-1(a)	Seed Germ./Seedling Emerg.	N	41690902 in review	N (Supp I)
122-1(b)	Vegetative Vigor	N	41690902 in review	Y (core)
122-2	Aquatic Plant Growth	N	41690901 in review	Y (core)
123-1(a)	Seed Germ./Seedling Emerg.	N	41690902 in review	N
123-1(b)	Vegetative Vigor	N	41690902 in review	Y
123-2	Aquatic Growth	N	41690901 in review	Y (core)
124-1	Terrestrial Field	RESERVED[7]		
124-2	Aquatic Plant Growth	RESERVED[7]		
141-1	Honey Bee Acute Contact	N		
141-2	Honey Bee Residue on Foliage	N		
141-5	Field Test for Pollinators	RESERVED[8]		

---

[6] In the case of Bolero, an acceptable EFGB fish bioaccumulation study will suffice for this data requirement. The registrant referenced an MRID number (44508) for 165-4 Bioaccumulation in Fish. If this study is determined to be acceptable by EFGB, then EEB will waive this data requirement.

[7] Reserved pending results of TIER II phytotoxicity testing.

[8] Reserved pending results of lower tier testing.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food, Indoor Food

Guideline No: 71-1(a)
Title: Acute Avian Oral/Mallard

MRIDs and Dates of Unacceptable Studies Reviewed:
57222 7-14-80

MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:

57222: Test was categorized as supplemental because testing procedure description was incomplete.

An avian acute oral LD50 is required.

IBT Replaced with MRID 42600201

4

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food, Indoor Food

Guideline No: 71-2(a)
Title: Acute Avian Dietary/Quail

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
57224 7-15-80

Comments:

IBT

5

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 71-2(b)
Title: Acute Avian Dietary/Mallard

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
57225 7-15-80

Comments:

IBT

6

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 71-4(a)
Title: Acute Reproduction/Quail

MRIDs and Dates of Unacceptable Studies Reviewed:
25774 1-13-80

MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:
25774: Study was categorized as invalid because test birds were in poor health.

A Bobwhite Quail avian reproduction study is required.

Replaced with MRID 43075401

7

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 71-4(b)
Title: Avian Reproduction/Mallard

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
25778 12-3-90

Comments:

If Acc. No. 095106, then invalid (IBT)

8

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-1(a)
Title: Acute Fish Toxicity/Bluegill

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
50665 12-2-80

Comments: 50665 Test was conducted with a 10G formulation. When test concentrations are measured, a granular formulation can be used to suffice for a test with a technical grade.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-1(b)
Title: Acute Fish Toxicity/Bluegill (TEP)

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
50665 12-2-80 (10G)

Comments: 50665 Test was conducted with a 10G formulation.

Normally, testing would be required for all TEP's applied to rice including the 8EC. Since testing with the 8EC was performed with an estuarine fish and mollusc , and the 8EC is about 85% ai (very close to a technical grade ai), no additional testing is required.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food, Indoor Food

Guideline No: 72-1(c)
Title: Acute Fish Toxicity/Rainbow Trout

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
50664 12-2-80

Comments: 50664 Test was conducted with a 10G formulation. When test concentrations are measured, a granular formulation can be used to suffice for a test with a technical grade.

11

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-1(d)
Title: Acute Fish Toxicity/Rainbow Trout (TEP)

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
50664 12-2-80

Comments: 50664 Test was conducted with a 10G formulation.

Normally, testing would be required for all TEP's applied to rice including the 8EC. Since testing with the 8EC was performed with an estuarine fish and mollusc , and the 8EC is about 85% ai (very close to a technical grade ai), no additional testing is required.

12

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food, Indoor Food

Guideline No: 72-2(a)
Title: Acute Aquatic Invertebrate Toxicity/Daphnia magna

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
25778 6-9-80

Comments:
The data requirement is fulfilled with 25778, no additional data are required.

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Aquatic Food

Guideline No: 72-2(b)
Title: Acute Aquatic Invertebrate Toxicity (TEP)/Daphnia magna

MRIDs and Dates of Unacceptable Studies Reviewed:
50666 12-2-80 (10G)
40031001 5-22-87 (8EC)
MRIDs and Dates of Fully Acceptable Studies Reviewed:
79118 6-9-80

Comments:

50666: Test was categorized as supplemental because it failed to produce a test level where ≥50% mortality occurred.
40031001: Test organism was inappropriate to fulfill guideline requirement. Test was conducted for purposes other than fulfilling guideline requirement; it did fulfill this specific requirement.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-3(a)
Title: Acute Estu/Mari Tox Fish

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
79110 1-16-80
79112 1-17-80
Comments:

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-3(b)
Title: Acute Estu/Mari Tox Mollusk

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
79114 2-6-80

Comments:

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-3(c)
Title: Acute Estu/Mari Tox Shrimp

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:

50667	12-2-80	Core
79117	6-10-80	Suppl.

Comments:

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Aquatic Food

Guideline No: 72-3(d)
Title: Acute Estu/Mari Tox Fish (TEP)

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
79111 1-17-80 (8EC)

Comments:

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Aquatic Food

Guideline No: 72-3(e)
Title: Acute Estu/Mari Tox Mollusk (TEP)

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:
79115 2-7-80 (8EC)

Comments:

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Aquatic Food

Guideline No: 72-3(f)
Title: Acute Estu/Mari Invertebrate (TEP)

MRIDs and Dates of Unacceptable Studies Reviewed:
79113 2-6-80 (8EC)

MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:
79113: Study was conducted with inappropriate test species.

Normally, testing would be required for all TEP's applied to rice including the 8EC. Since testing with the 8EC was performed with an estuarine fish and mollusc , and the 8EC is about 85% ai (very close to a technical grade ai), no additional testing is required.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-4(a)
Title: Early Life Stage Fish

MRIDs and Dates of Unacceptable Studies Reviewed:
79112 1-17-80

MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:
79112: Study did not fulfill guideline requirement because raw data on "time to hatch" were not provided.

The required raw data should be provided. If the raw data are unavailable, the fish early life stage test must be repeated. Note that the 72-5 fish full life cycle test may also be required, pending results of an acceptable fish early life stage test. If the registrant conducts and submits an acceptable fish full life cycle test with technical grade Bolero, the early life stage test would not be required.

Also, the NOEC was not determined. Not upgradable

21

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-4(b)
Title: Life-Cycle Aquatic Invertebrate

MRIDs and Dates of Unacceptable Studies Reviewed:
41636101 12-3-90
79117 6-10-80 Rejected
MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:
41636101: Study failed to produce a NOEL. Significant adverse effects occurred at lowest test level. Raw data were not provided.
79117: Study did not fulfill requirements because raw data were not provided.

Guideline fulfilled by Acc. No. 241483

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-5
Title: Fish Full Life Cycle Test

MRIDs and Dates of Unacceptable Studies Reviewed:

MRIDs and Dates of Fully Acceptable Studies Reviewed:

Comments:

No studies were provided, however, the registrant requested a waiver from conducting this study. The registrant contends that the following points support such a request.

1. A large scale field study has demonstrated no long-term or chronic effects to fish.

2. The California Department of Fish and Game, which has extensively monitored the effects of Bolero on fish populations in California, states that "Bolero" has not been responsible for any adverse effects on aquatic organisms in California.

3. The use of Bolero in Arkansas for several years has not impacted the intermediate fish host of the fat pocketbook pearly mussel.

4. No adverse effects to fish have been reported from Japan.

5. Reproductive studies in mammals indicate no unusual reproduction effects from exposure to Bolero.

EEB Response:

The Texas field study resulted in a fish kill attributed to Bolero. Further, there were reductions in populations of certain species of fish during the treatment years compared to the reference (no treatment) year. But more importantly, the test was

designed such that it would have been difficult to detect long-term or chronic effects to fish such as the ones measured during a fish full life cycle test. First, there was no replication (one treatment site), so that changes suggested by the sample analysis could not be interpreted with regard to natural variation or treatment effect. Second, the open "estuarine" system would have allowed unaffected fish to enter the study area and affected fish to leave the area.

The California rice growing area is far different than the Southern rice growing region. Rice floodwater in California may be held by the farmer until the applied pesticides have had a chance to degrade, thus reducing their potential for hazard to natural aquatic organisms. This is because there is little rain, and most of the water in the paddies is irrigation water drawn from the rivers. Therefore, it is possible that the concentrations of Bolero in the surface waters of California are not high enough to be causing adverse effects to fish. In the South the potential for heavy rainfalls in a short period makes holding floodwater on rice fields is virtually impossible. Even during the time the Texas field study was being conducted, heavy rainfall had caused unscheduled discharge of rice floodwater throughout the area.

The statement concerning the impact of Bolero on fish in Arkansas is unfounded. It may have been based on results of extensive searches for the fat pocketbook pearly mussel. These surveys have discovered new populations of the mussel in areas where they were previously unknown. There was no information on the effects of Bolero on the unknown fish species which serves as host to the mussel. The inference that increased findings of the mussel reflect an actual increase in the numbers of the species may be incorrect. The new discoveries could be the result of increased effort and improved detection methods. In any case, the Texas field study resulted in a fish kill. If the fish that serves as host to the mussel is as sensitive as the fish killed by Bolero in Texas, they may also be killed, thus impacting the endangered species. In light of the survey results, perhaps the area where Bolero is excluded should be increased to protect these new populations.

Little information from Japan has been provided. If the Japanese have not observed adverse effects it could be the result of a number of reasons including:

- The fish cultured in Japan may not be as sensitive as some species in the United States;

- The Japanese were not looking for, or could not detect with their monitoring methods, the long-term or chronic effects with which EEB is concerned; or

- The farming practices in Japan precluded the adverse effects observed in the Texas field study.

It would be incredible that, if the Japanese fish producers observed dead fish or noticed a marked decline in the number of their cultured populations, they would not report this as an undesirable adverse effect. So clearly, the effects reported during the Texas field study have not been occurring in Japan.

While reproductive effects in mammals may clue EEB to the potential effects of a pesticide in other organisms, such as fish, a lack of these effects does not preclude the concern or the data requirement.

The need for the fish full life cycle study is dependent on the results of a valid fish early life stage test. If the EEC is greater than 0.1 the NOEL of the fish ELS, the life study test is required. The registrant may perform the Fish Full Life Cycle test instead. An acceptable fish full life cycle test would suffice for the 72-4 Fish Early Life Stage Test.

Thiobencarb
108401, 2665

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH

List B Phase 4 - Response on Existing Studies Reviewed

Chemical ai Name: Bolero Case No: 2665
Chemical Number: 108401

Reviewer Name: Dan Rieder
Phone No: 557-1451
Date: 12-5-90

Use Pattern(s): Terrestrial Food, Aquatic Food

Guideline No: 72-7(b)
Title: Actual Aquatic Field Study

MRIDs and Dates of Unacceptable Studies Reviewed:
92182088 3-4-91

MRIDs and Dates of Fully Acceptable Studies Reviewed:
256967, 252022, 92182086, 92182089,
145835 (5 MRID's, 1 study) 8-6-85
Comments: 92182088 is scientifically sound, but does not fulfill any requirement.

The MRID numbers (256967, 252022, 92182086, 92182089) refer to an acceptable study. However, additional testing in the form of field residue monitoring is required. This monitoring is necessary for EEB to complete their evaluation of the hazards of using Bolero on rice.

The registrant has requested a waiver for this data requirement. Their contention revolves around three basic points:

1. Laboratory data indicate a large margin of safety exists for the fat pocketbook pearly mussel, thus negating the concern for toxicity to this endangered species dwelling in waterways receiving runoff from rice growing areas in Arkansas.

2. A large scale field study indicated no chronic or long-term effects to fish.

3. Historical use in California and Japan have not resulted in observed chronic effects to fish.

In summary, the issues raised do not support the requested waiver. The laboratory data to which the registrant refers was a study which specifically addressed the toxicity of bolero to adult apple snails. The study does not indicate the toxicity of bolero to bivalve embryo-larvae development or shell growth, the endpoints

of greater concern for endangered species. Acceptable testing indicates that bolero has an EC50 of 320 ppb for oysters. This is more indicative of the potential toxicity to endangered mollusks. The main concern, however, is for hazard to fish, the intermediate host of larval mollusks.

The point that the field study negated hazard to fish is incorrect. First, a fish kill occurred during the study. This mortality was attributed to Bolero, indicating that concentrations of Bolero resulting from actual use are acutely hazardous to certain fish species. If the intermediate host of the fat pocketbook pearly mussel happened to be a species sensitive to Bolero, the endangered mussel may be impacted indirectly by a reduction of fish serving as host and/or loss of individual larvae attached to the individual that died. Second, with regard to chronic and long-term effects, the study was not designed to detect such effects, so failure to detect them does not mean they were not occurring. Finally, there were reductions in number of certain species of fish. Whether these represented actual populations declines because of Bolero is impossible to tell, but they preclude a conclusion that no effects occurred.

The conditions in California, such as tighter control over floodwater, allows rice growers to hold floodwater until levels of Bolero have declined. Such control is impossible in the Southern rice growing region, where heavy rain falls result in unscheduled flushing, as occurred during the time the Texas field study was being conducted.

Reports from Japan that Bolero has had no adverse effect on fish in rice paddies may reflect differences in fish sensitivities. The field study conducted in Texas resulted in a fish kill, and it is unlikely that the Japanese would interpret a fish kill as "no adverse effects."

While the residue monitoring was not required specifically because of risk to the endangered mussel, the results would be provided to the USFWS to see if it changes their biological opinion of the potential effects of Bolero to this species. The use of Bolero is currently prohibited from certain areas to avoid exposure to the Fat Pocketbook Pearly Mussel.

The residue monitoring is necessary so EEB can determine to what extent Bolero is reaching waterways from treated rice fields. The results would be compared to laboratory toxicity data and the previous field study to see if concentrations which caused adverse effects in these tests are exceeded and, if so, how often. This monitoring requirement was reiterated in a memorandum from James Akerman to Richard Mountfort dated November 23, 1988.