DP Barcode : D182797
PC Code No : 121601
EEB Out :

JAN 13 1993

To: JOANNE MILLER
Product Manager
Registration Division (H7505C)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 10182-EUP-54
Chemical Name : ACETOCHOLR
Type Product : HERBICIDE
Product Name :
Company Name : ICI AMERICAS
Purpose : REVIEW REQUEST FOR EUP EXTENSION

Action Code : 716 Date Due : 12-10-92
Reviewer : MIKE DAVY Date In EEB: 09-22-92

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

Y

DP BARCODE: D182797

CASE: 194562 DATA PACKAGE RECORD DATE: 09/21/92
SUBMISSION: S425704 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EUP (SECT 5) ACTION: 716 EUP NC F/F EXT/RENW REQ
CHEMICALS: 121601 Acetochlor (ANSI) 70.8700%

ID#: 010182-EUP-054
COMPANY: ICI AMERICAS INC.
PRODUCT MANAGER: 23 JOANNE MILLER 703-305-7830 ROOM: CM2 237
PM TEAM REVIEWER: JESSE MAYES 703-305-5218 ROOM: CM2 235
RECEIVED DATE: 08/28/92 DUE OUT DATE: 12/26/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 182797 EXPEDITE: N DATE SENT: 09/21/92 DATE RET.: / /
CHEMICAL: 121601 Acetochlor (ANSI)
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 12/10/92 CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	09/21/92	/ /
BRAN: EEB	09/22/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review this extension request for acetochlor. Attached is information relative to your reviews for the original EUP.

Thanks.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
182799	EFGB	09/21/92	12/10/92	Y	N	Y
182801	TB-2	09/21/92	12/10/92	Y	N	Y
182802	TSCB	09/21/92	12/10/92	Y	N	Y

Ecological Effects Branch Review

Chemical: Acetochlor (ICIA5676 6.4EC)

100 **Submission and Purpose and Label Information**

100.1 **Submission Purpose and Pesticide Use**

The registrant (ICI Agricultural Products) is requesting an extension to Experimental Use Permit (EUP) to conduct field testing on popcorn and field corn for 1993 season with ICIA5676 6.4EC herbicide (acetochlor). This review will address two rebuttals and an EUP extension request made by ICI. The rebuttals are on the previous EUP review and on a DER of 123-1 Seed Germination, Seedling Emergence and Vegetative Vigor study (MRID #415651-40). These are submitted under D182797.

100.2 **Formulation Information**

Active Ingredient:
Acetochlor.....70.87%
Inert Ingredients.....29.13%

Contains 6.4 pounds active ingredient per gallon.

100.3 **Application Methods, Directions, Rates**

1. States, amounts, acreage

The listing of the states, amounts and acreage are attached. This testing will be located at 43 states in 1993 involving a total of 3368 acres and 6736 pounds of active ingredients.

2. Directions for application

ICIA5676 6.4EC will be applied with liquid or dry fertilizer and/or in water and may be tank mixed with atrazine, bladex, or gramoxone extra (with a surfactant nonionic active ingredient) according to the labeled rates. The application rate ranges from 1 pint/A (0.8 lbs. ai) to 3 pints/A (2.4 lbs. ai) for field corn or popcorn. Application is to be done as preemergence, pre-plant incorporation, or postplant-preemergence in conventional or no-tillage systems. The application is to be done only once before the corn plant emerges from the surface.

100.4 **Target Organisms**

Target pests will include barnyardgrass, broadleaf signalgrass, ragweed, crabgrass, fall panicum, field sandbur, giant foxtail, goosegrass, green foxtail, lambquarters, red rice, pigweed, seedling johnsongrass, shattercane, Texas panicum, wild proso millet, witchgrass, yellow foxtail and yellow nutsedge.

100.5 **Precautionary Labeling**

Environmental Hazards

"This product is toxic to fish. Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters."

101 **Hazard Assessment**

101.1 **Discussion**

The maximum labeled rate of this product is 3 pint/A (2.4 lbs. ai) applied to conventional, reduced tillage, or no-tillage systems. Only one treatment of this product is to be applied to corn. The EUP does indicate that aerial application as well as ground application will be used.

Data from EFGWB suggest that acetochlor is stable in aquatic systems with a hydrolytic half life greater than 24 months and is moderately to highly mobile in soil adsorption and column leaching studies. Microbial metabolism is a major pathway of degradation for acetochlor. This product dissipates in <3 days when applied to California sandy soil. However, it may be stable on foliage since photodegradation and volatilization are negligible. The solubility of acetochlor 0.0223 ppm. Acetochlor does not bioaccumulate. The mode of action for acetochlor is adsorption through the coleoptile of germinating seedlings and secondarily via the root system.

Terrestrial exposure

Below are the maximum expected residues (ppm) on vegetation immediately after one application of 2.4 lb. ai/A (based on Hoerger and Kenaga, 1972).

range grass	grass	leaves & leafy crop	forage crop & insect	pods with seeds	grain	fruits
576	264	300	139	28	24	16

Aquatic exposure

Aquatic exposure will occur via runoff from ground application and via both runoff and spray drift from aerial applications. The following represents a scenario of runoff into a 1 acre pond from a 10 acre drainage basin.

A. Ground Application

Assuming the product is applied to a 10 acre field by ground equipment and 5% runoff occurs, the water concentration in an adjacent 1 acre field 6 feet deep could be **73.2 ppb (0.073 ppm)** (10A x 2.4 lb. ai/A x 5% x 61 ppb). In 6 inches of water, the concentration could be **881 ppb (0.881 ppm)**.

B. Aerial Application

Assuming this product is applied aerially to a 10 acre field and 5% runoff occurs, the water concentration in an adjacent 1 acre field 6 feet deep could be **51 ppb or 0.05 ppm** (([10A x 2.4 lb. ai/A x 60% application efficiency x 5% runoff] + [2.4 lb. ai/A x 5% drift]) x 61 ppb) In 6 inches of water, the concentration could be **616 ppb (0.616 ppm)**.

101.2 **Likelihood of Adverse Effects to Nontarget Organisms**

Terrestrial Organisms

Data from avian single-dose oral and dietary studies indicate that acetochlor is slightly toxic to birds (mallard duck LD_{50}= 1788 mg/kg; bobwhite and mallard dietary LC_{50}'s >4610 and >4171 ppm, respectively).

Acetochlor is slightly toxic to mammals with a lowest oral LD_{50} of 1550 mg/kg rats. The systemic and reproductive NOEL for rats was 500 ppm, respectively, in a two-generation reproduction test. The reproduction study concluded in a decreased weight gain in pups. HED has identified that acetochlor is a carcinogenic risk to mammals, affecting the liver and sinus areas.

EEB has chronic avian concerns primarily because acetochlor is persistence. Avian reproduction studies have been submitted and are currently in review.

The daily maximum expected residues on a full foliage field do not exceed the avian acute LC_{50} (>4171 ppm). However, these residues do exceed the mammalian reproductive NOEL (500 ppm). In a worst case scenario, no-tillage corn may have a large amount of weeds with seed heads at the time of application, but the amount of foliage in the field will be considerably less than a field full of foliage. Due to contact herbicide used in no-tillage systems, the leaves of the weeds will be shriveled or fallen a less than a week. The acetochlor that will be available to mammals and birds will come from seeds that are eaten and the chemical that will adhere to feathers or fur from the foliage that remains due to the effects of the contact herbicide as well as foliage before leaf drop from the contact herbicide. The daily maximum expected residue does not appear to be as much as the table cited above since acetochlor is

5

applied only at pre-emergence when there is little vegetation available. Under the conditions of the EUP, with minimal acreage and one time spraying, chronic effects are further lessened.

Beneficial Insects

Application to corn will not result in exposure of bees to acetochlor since the application is made at a time when the chemical will not be present on the pollen grains. No hazard is expected since this pesticide tested practically nontoxic to honey bees in an acute study and will not be available to the bees.

Aquatic Organisms

It seems that acetochlor would have moderately acute effects on daphnids (Daphnia LC_{50}= 8.2 ppm) and bluegill (LC_{50}= 1.6 ppm) and is highly toxic to trout (LC_{50}= 0.38 ppm). Aquatic EEC= 0.073 ppm. Minimal adverse acute effects are expected for aquatic organisms at the labeled rate of acetochlor on corn.

Plants

The Ecological Effects Branch has reviewed the Selenastrum capricornutum nontarget aquatic plant (123-2) study submitted by ICI.

The EC_{50} value for the Selenastrum capricornutum aquatic plant is 1.43 ppb. Aquatic EEC= 0.073 ppm (73 ppb). It could be assumed that acetochlor would have an **adverse impact on aquatic plants** from ground runoff or aerial drift at the labeled rate of application in corn fields.

101.3 Endangered Species Considerations

The endangered species triggers are as follows:

Birds:	417 ppm	(LC_{50} 4171/10)
Mammals:*.....	1500 ppm	(LC_{50} 15000 ppm/10)
Fish:	0.02 ppm	(LC_{50} 0.38 ppm/20)
Aquatic Invertebrates:	0.41 ppm	(LC_{50} 8.2 ppm/20)
Plants:	1.43 ppb	(EC_{50} 1.43 ppb)

*,Based on the LD_{50} of 1500 mg/kg for the female rat.

A summary of the affect levels for acetochlor is as follows:
Acute oral LD_{50} for mallard duck.....1788 mg/kg
Dietary LC_{50} for bobwhite quail.....4610 ppm
for mallard duck.....4171 ppm
Acute oral LD_{50} for female rat.....1500 mg/kg
Acute static toxicity for Daphnia magna.....8.2 ppm
for bluegill sunfish.....1.6 ppm
for rainbow trout.....0.38 ppm
Acute toxicity- aquatic plants Selenastrum capricornutum...1.43 ppb

The maximum estimated residues on terrestrial food items (576 ppm for range grass or short grass) do not exceed 1/10th the lowest mammalian LC_{50}'s. The estimated residues on short grass items do exceed the chronic systemic and reproductive NOEL for rats of 500 ppm. However, due to lack of full foliage at time of application, minimal adverse chronic effects for endangered mammals are anticipated.

Although the maximum estimated residues on terrestrial food items (576 ppm on short grass) do exceed the triggers for endangered avians on an acute basis, minimal adverse effects are expected due to lack of full foliage at time of application. The EEB is unable to address chronic risk to birds at this time.

The aquatic EEC (0.073 ppm) in water adjacent to treated areas does not exceed that for endangered aquatic invertebrates, but **adverse effects are expected for endangered fish and aquatic plants.**

101.4 **Adequacy of Data**

Seventeen studies with acetochlor were submitted by ICI for review under the current EPA guidelines. The following table indicates the status of each:

Study type		MRID#	Category
71-1	Oral Toxicity to Bobwhite	419633-03	In Review
71-1	Oral Toxicity to Bobwhite	419633-02	In Review
71-1	Oral Toxicity to Mallard	415651-29	Core
71-2	Dietary toxicity to Mallard	415651-30	Core
71-2	Dietary Toxicity to Bobwhite	415651-31	Core
71-4	Reproduction in Mallard	415920-09	In Review
71-4	Reproduction in Bobwhite (Vol. 1 & 2)	415920-10	In Review
71-4	Reproduction in Bobwhite	419633-05	In Review
72-1	Acute Toxicity to Rainbow Trout	415651-32	Core
72-1	Acute Toxicity to Rainbow Trout	419633-06	In Review
72-1	Acute Toxicity to Bluegill Sunfish	415651-33	Core
72-2	Toxicity to Daphnia magna	415651-34	Core
72-4	Daphnia magna life cycle	415651-38	In Review
72-4	Chronic Tox. to Fathead Embryo/Larv	415920-11	In Review
72-3	Acute Toxicity to Mysid Shrimp	415651-35	Core
72-3	Acute Toxicity to Pacific Oyster	415651-36	Core
72-3	Acute Toxicity to Sheepshead Minnow	415651-37	Core

123-1	Seed Emerge & Vegetat Vigor-Plants	415651-40	Invalid
123-2	Growth & Reprod. of Aquatic Plant (Selenastrum capricornutum)	415651-41	Core
141-1	Acute Toxicity to Honey Bee	415651-41	Core
-----	Histopathological Report on LD_{50} of Bobwhite	419633-04	In Review

The available data were sufficient to assess acute hazards to nontarget organisms for this EUP.

For registration under section 3, the following studies are requirements that are currently in review:

71-4 Avian reproduction studies for mallard and bobwhite

72-4 Chronic toxicity to fathead embryo and larvae and Daphnia magna life cycle.

For registration under section 3, the following studies are requirements that have been satisfied:

71-1 Oral toxicity to mallard

71-2 Dietary toxicity to mallard and bobwhite

72-1 Acute toxicity to trout, bluegill

72-2 Acute toxicity to Daphnia magna

72-3 Acute toxicity to mysid shrimp, pacific oyster and sheepshead minnow

123-2 Acute toxicity to aquatic plant- Selenastrum capricornutum

For registration under section 3, the following studies are currently outstanding:

123-2 Aquatic plant studies for freshwater diatoms, Lemna gibba, Skeletonema costatum and Anabaena flos-aquae because acetochlor is a herbicide with aerial application.

123-1 Germination and seedling emergence studies and vegetative vigor studies for non-target plants because acetochlor is a herbicide with aerial application.

Aerial droplet size (201-1) and Aerial field drift (201-2) studies because EEB has concerns for drift to non-target organisms.

In addition to the above, further data for registration under section 3 may be required depending on the results of the above and their impact on non-target organism: e.g. 72-5 Life Cycle of Fish, 124-1 Terrestrial Plant Field, and 124-2 Aquatic Plant Field studies.

Response to Previous EUP Rebuttal and DER

The Ecological Effects Branch has reviewed the ICI rebuttal for Acetochlor EUP and the 123-1 Seed Germination, Seedling Emergence and Vegetative Vigor study (MRID # 4156651-40). This action is under D182797.

Response to EUP

1. Registrant has indicated that EEB has chronic avian concerns primarily because acetochlor is carcinogenic to mammals.

Avian reproduction tests are a requirement because acetochlor is persistent in the environment and chronic exposure is expected. Avian reproduction studies are currently in review.

2. Registrant has expressed that EEB's scenario of acetochlor exceeding the grazing or herbivore mammalian NOEL's on tall grass may not be accurate since the chemical is applied when little foliage is available to which acetochlor may adhere.

EEB agrees with ICI. In a worst case situation, a no-tillage system may have numerous weeds with seed heads. After a contact herbicide burndown, there will still be some plant material left-whether stems, seed heads or wilted leaves. The acetochlor residue may stick to these plant materials. The small mammal will eat the seeds, the fur may pick up some residues and the mammal may clean itself with the tongue thereby licking residues from the fur. EEB still has some concerns but recognizes that the adverse effects due to the amount of residue may be minimal. EEB will adjust its risk assessment to reflect this.

3. Registrant believes that it is inappropriate to utilize the chronic NOEL with the maximum estimated residues on the foliage for determining of risk to mammals.

EEB maintains that it is appropriate to utilize the chronic mammalian NOEL for risk assessment. However, as outlined in number 2 above, EEB recognizes that the adverse effects due to the amount of residue may be minimal.

4. Registrant has indicated that EEB's aquatic assessment using 6 inches of water may be inappropriate and that EEB should use the 6 foot water scenario. Therefore, the endangered species risk criteria was not exceeded and adverse effects would not be expected on aquatic invertebrates and fish, given the proposed use pattern.

EEB agrees with ICI. EEB policy now is to use 6 feet of water unless there is a specific situation that warrants the use of 6 inches of water. The EEC value of 0.073 ppm will pose minimal risk to aquatic invertebrates.

EEB has made the acute trout study, MRID# 41565132, core per 1/23/92 review. In this study, the study temperature ranges from 14.6-15.8°C. The SEP says that the temperature should be 12°C. The second study on trout, MRID# 41963306, was done with temperature in compliance of the SEP. However the results were 1.2 ppm. It appears that the trout's higher respiration at the higher temperature may have caused the fish to take up the chemical at a faster rate. However, it is also known that many streams that have temperatures similar to the first study also have trout. When two valid values are given for a species, EEB would use the more sensitive value. Therefore, EEB recognizes that the EC_{50}=0.038 ppm as a valid value for risk assessments. It appears that endangered fish species may be at risk to acetochlor that has been applied at labeled rates from runoff.

EEB agrees with ICI that there is still risk to endangered plants from runoff that may be near the use sites.

Response to ICI's Rebuttal on DER (123-1) MRID #415651-40

1. Registrant agrees with EEB that Pale persicaria (Polygonum lapathifolium) had poor germination and therefore should not be considered. Registrant says that another species will be used. Species that are used should be from a healthy and germinable lot of seed. Yet, this deviation alone would not make this an invalid study.

2. EEB accepts the ICI's raw data for solution or spray calculations. The lack of this data does not make the study invalid.

3. Registrant provided raw data that consisted of averages within a replicate. EEB would like data that refers to individual plants within the replicate for determination of such summaries. These data would not be acceptable. The lack of these data alone does not make this study invalid.

4. Registrant indicates that EEB uses inappropriate statistical analysis for the determination of NOEC. Registrant feels that a more accurate NOEC would be an EC_{10} which would be regarded as a reasonable worst case of NOEC.

In the determination of NOEC, EEB uses the analysis of variance to determine the significant differences with concentrations. The lowest concentration that shows a significant difference would be the subtoxic concentration which is called the LOEC (lowest observable effect concentration). The NOEC is the test level in which observations do not significantly differ statistically from the control. This difference in determination of NOEC or LOEC does not make a study invalid or supplemental.

5. EEB agrees with ICI in that three-fold or five fold dilution progression can be used more efficiently considering the ranges of response. This deviation from SEP and the reasons should have been communicated to EEB. However, there was no consistent gradient in the three-, four- and five-fold concentrations. There were three- and five-fold concentrations within a test. **This deviation contributes to this study being invalid.**

6. EEB agrees with ICI that this division of the plant species into "cool season" and "warm season" was unnecessary but may reflect the climate of Britain. This would not make a study invalid.

7. The registrant has indicated that the introduction of fungicides and insecticides into the test should not impact the study since these chemicals are not phytotoxic and there was a need to control disease and insect infestations.

The introduction of other chemicals into a pesticide dose response study is unacceptable regardless of the disease or insect infestation. The greenhouse should have been prepared prior to the test for such threats by proper horticulture practices. The introduction of these other chemicals brings serious questions about the interactions of chemicals or the masking of susceptibility of plants to acetochlor. **This alone would make the "cool climate" species test invalid.**

8. Registrant indicated that although top-watering may move the acetochlor down through the soil (being mobile in soil), they do not believe that any of the acetochlor leached out. Registrant further states that when the acetochlor was below the seeds, the roots would later come into contact with the chemical and over time would thereby be exposed to the chemical throughout the soil profile.

EEB agrees with ICI in that acetochlor may have moved down the soil profile. However, the mode of action for acetochlor is that the primary uptake is through the coleoptile and secondary uptake is through the roots. When the chemical leaches down to the roots or beyond due to top-watering, the roots may take up some of the chemical. However, the primary means of uptake by the coleoptile is avoided. In a good study, EEB assumes that the chemical will be accessible to the plants all of the time and exposure is not delayed until the roots reach the chemical. EEB further assumes that the primary means of uptake, i.e. through the coleoptiles, should occur. Top-watering does not allow EEB to be certain that this occurred. **This is a significant factor to making this study invalid.**

9. EEB accepts the data on specific plants within the replicates from ICI.

11

10. Registrant indicated that it is possible that growing of multiple plants in the same container led to competition. Registrant further states that if there has been competition, any treatment-related effects may be accentuated and the results more severe than may be expected in the absence of competition. Registrant believes that there is no evidence to suggest that competition has adversely affected the interpretation of the results.

In the seedling emergence study, there appeared to be a crowding or competition in the seed trays as the plants got larger. The results could accentuated the results in a positive or negative way depending on the species. Different species may show different responses due to the overcrowding of the growing plants. It could be difficult to judge which plants are more sensitive to acetochlor by guessing the competition factors. Dose-response studies are suppose to be free from such variables. This is a contributing factor towards making this study invalid.

11. EEB has considered ICI's request to make the studies core. EEB maintains that the preponderance of serious deviations such as competition among plants, adding other chemicals into "cool climate" species, the possible leaching of acetochlor beyond the primary means of uptake of the plant (coleoptile) and the inconsistent gradient of the three and five fold concentrations, together made this study invalid. EEB maintains that this study (MRID# 415651-40) is invalid and another study must be done on seedling emergence and vegetative vigor using 10 species as set forth in the guidelines.

101.5 Adequacy of Labeling

Labeling is adequate.

As a warning to the user concerning the hazard of drift to plants, EEB suggests the following statement that may be inserted with the Environmental Hazard Statement in a section 3 registration:

> "This herbicide is phytotoxic at low concentrations. Non-target plants may be adversely affected from drift."

103 Conclusion

EUP Extension

EEB has completed a risk assessment of acetochlor (ICIA5676 6.4EC) and has determined that birds and mammals should not be adversely affected from the use of this chemical under the conditions of the EUP. Risk to aquatic plants may be substantial but the limited acreage involved in the EUP and one time application are mitigating factors.

EEB **can not** fully evaluate the potential risk to endangered species of fish and plants because of

71-4 Avian Reproduction and 72-4 Early Life Stage of Fish and Aquatic Invertebrate Life Cycle data that are in review and

123-2 Aquatic plant studies for freshwater diatoms, Lemna gibba, Skeletonema costatum and Anabaena flos-aquae and 123-1 Germination, Seedling Emergence and Vegetative Vigor data that are outstanding and

Outstanding Aerial droplet size (201-1) and Aerial field drift (201-2) data which is deferred to EFGWB.

We do have sufficient information to conclude that if acetochlor is used adjacent to a location of an endangered species habitat, **endangered species of plants and fish may be adversely affected.** We are unable to determine what risk are involved without **specific** locations of the sites of the proposed EUP.

Prior to application of this product, ICI must submit to this agency a list of locations where this pesticide will be used experimentally and identify any sites within counties where endangered fish or aquatic plant species occur. The agency must agree that the locations do not present a hazard to any endangered species.

Response to ICI's Rebuttal on Previous EUP Review

EEB has taken comments from the registrants into consideration and modify the risk assessments on this EUP review accordingly.

Response to ICI's Rebuttal on DER (123-1) MRID #415651-40

EEB maintains that this study (MRID# 415651-40) is invalid and another study must be done on seedling emergence and vegetative vigor using 10 species as set forth in the guidelines.

Michael Davy, Agronomist Michael Davy 1/11/93
Ecological Effects Branch
Environmental Fate and Effects Division

Daniel Rieder, Head Section 3 1-11-93
Ecological Effects Branch
Environmental Fate and Effects Division

Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division