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May 4, 2001

TO: Governor's Office, Todd O'Hair, Room 204, State Capitol, P.O. 200801, Helena, MT 59620-0801
Environmental Quality Council, Capitol Building, Room 106, P.O. Box 201704, Helena, MT 59620
Dept. Environmental Quality, Metcalf Building, P.O. Box 200901, Helena, MT 59620-0901
Montana Fish, Wildlife & Parks

Director's Office
Wildlife Division
Legal Unit

FWP Commissioners
Dennis Flath
Fisheries Division

MT Historical Society, State Historic Preservation Office, POB 201202 Helena, MT 59620-1202
MT State Parks Association, P.O. Box 699, Billings, MT 59103
MT State Library, 1515 E. Sixth Ave., POB 201800, Helena, MT 59620
James Jensen, Montana Environmental Information Center, POB 1184, Helena, MT 59624
Janet Ellis, Montana Audubon Council, POB 595, Helena, MT 59624
George Ochenski, POB 689, Helena, MT 59624
Gallatin County Commissioners, Gallatin County Courthouse, 311 West Main, Bozeman, MT 59715
Jerry DiMarco, P.O. Box 1571, Bozeman, MT 59771
Wildlife Federation, P.O. Box 1175, Helena, MT 59624
Wayne Hurst, P.O. Box 728, Libby, MT 59923
Glen Hockett, 745 Doane Road, Bozeman, MT 59715
Jack Atcheson, State Land Coalition, 3210 Ottawa St., Butte, MT 59701
John Bloomquist, Montana Stock Growers Assoc., 44 W. 6th Ave. P.O. Box 1185, Helena, MT 59624
Bob Gilbert, Montana Woolgrowers Assoc., P.O. Box 1693, Helena, MT 59624
Tom Sather, Headwaters Fish & Game Assoc., P.O. Box 1941, Bozeman, MT 59771-1941
Perry Backus, 65 Redtail, Dillon, MT 59725

Ladies and Gentlemen:

Enclosed are two separate Environmental Assessments (EA's) addressing the presence of New Zealand Mud Snails in the Darlington Ditch, at and adjacent to the Cobblestone Fishing Access Site on the Madison River. They are the Darlington Ditch New Zealand Mud Snail Control Project EA and the Cobblestone Fishing Access Site Footbridge EA. The comment period for Both EA's will run from May 4, 2001 through June 4, 2001. Public involvement for this proposal consisted of production and advertisement of this EA. Public meetings will be held in Three Forks on May 21, 2001 at the Three Forks Methodist Church Annex, 112 Cedar St. at 7:00 p.m. and at the Bozeman Public Library, 220 East Lamme at 7:00 p.m., May 24, 2001. Comments should be sent to: Montana Fish, Wildlife & Parks, Patrick J. Flowers, 1400 So. 19th, Bozeman, MT 59718-5496, e-mail: pflowers@montana.edu

Sincerely,

Patrick J. Flowers by E. W.

Patrick J. Flowers
Regional Supervisor

DRAFT

MEPA/NEPA/HB495 CHECKLIST

PART I. PROPOSED ACTION DESCRIPTION

1. Type of Proposed State Action Construction of footbridge across the Darlinton Ditch at Cobblestone Fishing Access Site (FAS).
2. Agency Authority for the Proposed Action 87-1-209 M.C.A. authorizes Montana Fish, Wildlife & Parks to acquire and develop properties for fishing access and outdoor recreation purposes.
3. Name of Project Cobblestone FAS footbridge.
4. Name, Address and Phone Number of Project Sponsor (if other than the agency)
Agency sponsored.
5. If Applicable:
Estimated Construction/Commencement Date Summer, 2001
Estimated Completion Date Summer, 2001
Current Status of Project Design (% complete) 90%
6. Location Affected by Proposed Action (county, range and township)
Cobblestone FAS, along lower Madison River, Gallatin County, Township 01 North, Range 02 East.
7. Project Size: Estimate the number of acres that would be directly affected that are currently:
 - (a) Developed:
residential.....__ acres
industrial.....__ acres
 - (b) Open Space/Woodlands/
Recreation.....__ acres
 - (c) Wetlands/Riparian
Areas.....__ acres
 - (d) Floodplain.....__ acres
 - (e) Productive:
irrigated cropland.....__ acres
dry cropland.....__ acres
forestry.....__ acres
rangeland.....__ acres
other.....__ acres
8. Map/site plan: attach an original 8 1/2" x 11" or larger section of the most recent USGS 7.5' series topographic map showing the location and boundaries of the area that would be affected by the proposed action. A different map scale may be substituted if more appropriate or if required by agency rule. If available, a site plan should also be attached.

See attached vicinity map, FAS site map, master site plan and footbridge plan sketch.

Revised 5/1/2001

9. **Narrative Summary of the Proposed Action or Project including the Benefits and Purpose of the Proposed Action.**

The proposed action is to construct a footbridge (see attached sketch detailing footbridge design) over the Darlington Ditch (DD) near the public parking area within Cobblestone FAS. With the recent (June, 2000) discovery of the New Zealand Mud Snail (NZMS) within this section of DD, Cobblestone FAS was closed to public entry while FWP conducted additional research and evaluated a course of action to deal with the introduced mollusk. When the site was open to public use all recreationists are forced to wade through Darlington Ditch to access the Madison River within Cobblestone FAS. FWP is proposing to construct a footbridge over DD as a stop-gap measure to reduce the possibility that recreationists wading DD will spread the NZMS into the adjacent Madison River. This proposed action could permit FWP to re-open the site for public recreation use and access to the Madison River. The proposal includes utilizing fencing to channel all river bound foot traffic to the footbridge to prevent people from wading in DD in the vicinity of the parking lot. Fencing would restrict access to DD throughout the FAS parking area, both along the east side of the ditch and the Madison River side (west) of the ditch. Approximately 400 yards of 4-strand smooth wire fencing, attached to wood fence posts, would be utilized to fence the shoreline of DD. Jack-leg fencing will be utilized across DD to restrict wading (see attached master site plan). Other types of fencing materials were considered for this project but were rejected because of potential impacts to mammals and birds, user safety and because of the aesthetic concerns. Signing will be used to inform site users of the presence of NZMS and to encourage them to take a variety of precautions to prevent spread of the NZMS into the Madison River.

In June, 2000 New Zealand Mud Snails were discovered in an approximately 2000 foot section of the Darlington Ditch within Cobblestone FAS and an adjacent downstream neighbors property. The NZMS is native to New Zealand as their name implies. How they arrived in North America is undocumented, but the evidence suggests they arrived in shipments of trout or trout eggs sent from New Zealand to private commercial aquaculture facilities in Idaho. NZMS were first detected in springs along the Snake River near Hagerman, Idaho. The first documentation of NZMS in Montana waters was in 1994, when they were found in the Yellowstone National Park section of the Madison River above Hebgen Reservoir. Since that time they have spread downstream as far as Quake Lake and are continuing to spread down-river. We do not know how the snails arrived in Darlington Ditch at the Cobblestone FAS, but researchers feel they have been there for only two or three years. While the NZMS has been confirmed in Darlington Ditch their densities are as yet unknown.

Impacts of NZMS on fish populations or even individual fish is yet unknown. The NZMS has not invaded any section of a Montana river that has long-term fish population data available. Studies in New Zealand suggest that brown trout (non-native to New Zealand) derive as little as 2% of the nutritive value available from ingested NZMS. The NZMS are very small, and have an opercle that they close over the shell orifice to protect themselves. High percentages of the NZMS pass unharmed through the digestive system of fish. FWP is concerned that if NZMS attain high enough densities to displace a large portion of the existing aquatic invertebrate fauna, and fish get little nutritive value from NZMS, the diets of fish could be negatively impacted.

Another concern with NZMS is that they reproduce asexually – they clone themselves. A single snail can start a whole new population. Genetic analyses of NZMS in the Madison River reveals that they are almost entirely of a single genetic profile, which is the same as the Snake River NZMS.

The proposal to construct a footbridge over DD, if implemented, would allow FWP to re-open Cobblestone FAS which has been closed to public use since May 25, 2000. The proposed footbridge would be constructed as a temporary facility whose longevity would be dependent on efforts to eradicate the NZMS. Total eradication of the NZMS would likely be necessary to remove the footbridge and return the FAS to post NZMS discovery status.

It must be noted that the proposed footbridge would not be constructed to facilitate easy access to the Madison River. Past proposals to provide a vehicle bridge over Darlinton Ditch to facilitate river craft launching has been met with wide-scale public criticism. The footbridge proposal would consist of three approximately 30-foot long untreated pole stringers placed on simple timber or concrete abutments to span the spring creek/ditch. The stringers would be decked with planks. The bridge would be approximately 6 inches to one foot above the high water level of Darlinton Ditch. The water in the ditch/spring creek is approximately one foot deep at the proposed footbridge location.

10. Listing of any other Local, State or Federal agency that has overlapping or additional jurisdiction.

(a) Permits:

<u>Agency Name</u>	<u>Permit</u>	<u>Date Filed/#</u>
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FWP	Montana Stream Protection Act Permit	
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(b) Funding:

<u>Agency Name</u>	<u>Funding Amount</u>
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FWP	\$1,500
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(c) Other Overlapping or Additional Jurisdictional Responsibilities:

<u>Agency Name</u>	<u>Type of Responsibility</u>
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State Historic Preservation Office	Cultural Clearance
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11. List of Agencies Consulted during Preparation of the EA:

None

PART II. ENVIRONMENTAL REVIEW

PHYSICAL ENVIRONMENT

1. LAND RESOURCES Will the proposed action result in:	IMPACT*				Can Impact Be Mitigated*	Comment Index
	Unknown*	None	Minor*	Potentially Significant		
a. Soil instability or changes in geologic substructure?		X				
b. Disruption, displacement, erosion, compaction, moisture loss, or over-covering of soil which would reduce productivity or fertility?		X				
c. Destruction, covering or modification of any unique geologic or physical features?		X				
d. Changes in siltation, deposition or erosion patterns that may modify the channel of a river or stream or the bed or shore of a lake?			X		Yes	See 1d. below
e. Exposure of people or property to earthquakes, landslides, ground failure, or other natural hazard?		X				
f. Other <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

The bridge will be designed to pass normal high flows of the ditch/spring creek. Although flooding is unlikely in a regulated spring creek (Darlinton Ditch), in a large flood event, the bridge may be displaced and cause some erosion or channel modification.

- * Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- * Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- * Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

PHYSICAL ENVIRONMENT

2. <u>APR</u> Will the proposed action result in:	IMPACT [☆]				Can Impact Be Mitigated [☆]	Comment Index
	Unknown [☆]	None	Minor [☆]	Potentially Significant		
a. Emission of air pollutants or deterioration of ambient air quality? (also see 13 (c))		X				
b. Creation of objectionable odors?		X				
c. Alteration of air movement, moisture, or temperature patterns or any change in climate, either locally or regionally?		X				
d. Adverse effects on vegetation, including crops, due to increased emissions of pollutants?		X				
♦e. For P-R/D-I projects, will the project result in any discharge, which will conflict with federal or state air quality regs? (Also see 2a)						
f. Other <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Air Resources (Attach additional pages of narrative if needed):

- ☆ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- » Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ♦ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ♦♦ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

PHYSICAL ENVIRONMENT

3. <u>WATER</u>	IMPACT*				Can Impact Be Mitigated*	Comment Index
	Unknown*	None	Minor*	Potentially Significant		
Will the proposed action result in:						
a. Discharge into surface water or any alteration of surface water quality including but not limited to temperature, dissolved oxygen or turbidity?		X				
b. Changes in drainage patterns or the rate and amount of surface runoff?		X				
c. Alteration of the course or magnitude of floodwater or other flows?		X				
d. Changes in the amount of surface water in any water body or creation of a new water body?		X				
e. Exposure of people or property to water related hazards such as flooding?		X				
f. Changes in the quality of groundwater?		X				
g. Changes in the quantity of groundwater?		X				
h. Increase in risk of contamination of surface or groundwater?		X				
i. Effects on any existing water right or reservation?		X				
j. Effects on other water users as a result of any alteration in surface or groundwater quality?		X				
k. Effects on other users as a result of any alteration in surface or groundwater quantity?		X				
♦♦l. For P-R/D-I, will the project affect a designated floodplain? (Also see 3c)						
♦m. For P-R/D-I, will the project result in any discharge that will affect federal or state water quality regulations? (Also see 3a)						
n. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Water Resources (Attach additional pages of narrative if needed):

- * Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- > Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ♦ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ♦♦ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

PHYSICAL ENVIRONMENT

4. VEGETATION	IMPACT				Can Impact Be Mitigated	Comment Index
	Unknown	None	Minor	Potentially Significant		
Will the proposed action result in:						
a. Changes in the diversity, productivity or abundance of plant species (including trees, shrubs, grass, crops, and aquatic plants)?		X				
b. Alteration of a plant community?		X				
c. Adverse effects on any unique, rare, threatened, or endangered species?		X				
d. Reduction in acreage or productivity of any agricultural land?		X				
e. Establishment or spread of noxious weeds?		X				
♦♦f For P-R/D-L, will the project affect wetlands, or prime and unique farmland?						
g. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ☆ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- ▶ Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ♦ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ♦♦ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

PHYSICAL ENVIRONMENT

<p>► 5. FISH/WILDLIFE</p>	IMPACT [♦]				Can Impact Be Mitigated [♦]	Comment Index
	Unknown [♦]	None	Minor [♦]	Potentially Significant		
Will the proposed action result in:						
a. Deterioration of critical fish or wildlife habitat?		X				
b. Changes in the diversity or abundance of game animals or bird species?		X				
c. Changes in the diversity or abundance of nongame species?		X				
d. Introduction of new species into an area?		X				
e. Creation of a barrier to the migration or movement of animals?		X				
f. Adverse effects on any unique, rare, threatened, or endangered species?		X				
g. Increase in conditions that stress wildlife populations or limit abundance (including harassment, legal or illegal harvest or other human activity)?		X				
♦♦h. For P-R/D-J, will the project be performed in any area in which T&E species are present, and will the project affect any T&E species or their habitat? (Also see 5f)						
♦i. For P-R/D-J, will the project introduce or export any species not presently or historically occurring in the receiving location? (Also see 5d)						
j. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ♦ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ♦ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ♦♦ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

NOISE/ELECTRICAL EFFECTS	IMPACT [Ⓞ]				Can Impact Be Mitigated [Ⓞ]	Comment Index
	Unknown [Ⓞ]	None	Minor [Ⓞ]	Potentially Significant		
Will the proposed action result in:						
a. Increases in existing noise levels?		X				
b. Exposure of people to severe or nuisance noise levels?		X				
c. Creation of electrostatic or electromagnetic effects that could be detrimental to human health or property?		X				
d. Interference with radio or television reception and operation?		X				
e. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ☆ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- ◆ Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ◆ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ◆◆ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

7. LAND USE	IMPACT [⊕]				Can Impact Be Mitigated [⊕]	Comment Index
	Unknown [⊕]	None	Minor [⊕]	Potentially Significant		
Will the proposed action result in:						
a. Alteration of or interference with the productivity or profitability of the existing land use of an area?		X				
b. Conflicted with a designated natural area or area of unusual scientific or educational importance?		X				
c. Conflict with any existing land use whose presence would constrain or potentially prohibit the proposed action?		X				
d. Adverse effects on or relocation of residences?		X				
e. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ⊕ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- ▶ Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ◆ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ◆◆ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

RISK/HEALTH HAZARDS	IMPACT ^o				Can Impact Be Mitigated ^o	Comment Index
	Unknown ^o	None	Minor ^o	Potentially Significant		
Will the proposed action result in:						
a. Risk of an explosion or release of hazardous substances (including, but not limited to oil, pesticides, chemicals, or radiation) in the event of an accident or other forms of disruption?		X				
b. Affect an existing emergency response or emergency evacuation plan or create a need for a new plan?		X				
c. Creation of any human health hazard or potential hazard?		X				
d. For P-R/D-L, will any chemical toxicants be used? (Also see 8a)						
e. Other: N/A						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ◆ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- ◆ Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ◆ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ◆ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

9. COMMUNITY IMPACT	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Alteration of the location, distribution, density, or growth rate of the human population of an area?		X				
b. Alteration of the social structure of a community?		X				
c. Alteration of the level or distribution of employment or community or personal income?		X				
d. Changes in industrial or commercial activity?		X				
e. Increased traffic hazards or effects on existing transportation facilities or patterns of movement of people and goods?		X				
f. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- * Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- > Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ◆ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ◆◆ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

10. PUBLIC SERVICES/TAXES/UTILITIES	IMPACT ^o				Can Impact Be Mitigated ^o	Comment Index
	Unknown ^o	None	Minor ^o	Potentially Significant		
Will the proposed action result in:						
a. Will the proposed action have an effect upon or result in a need for new or altered governmental services in any of the following areas: fire or police protection, schools, parks/recreational facilities, roads or other public maintenance, water supply, sewer or septic systems, solid waste disposal, health, or other governmental services? If any, specify: _____			X			See 10a. below
b. Will the proposed action have an effect upon the local or state tax base and revenues?		X				
c. Will the proposed action result in a need for new facilities or substantial alterations of any of the following utilities: electric power, natural gas, other fuel supply or distribution systems, or communications?		X				
d. Will the proposed action result in increased used of any energy source?		X				
e. Define projected revenue sources			X			See 10e. below
f. Define projected maintenance costs.			X			See 10 f. below
g. Other: _____						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

10a. The construction of a footbridge across Darlington Ditch will necessitate a certain level of on-going maintenance to keep the structure sound and safe.

10e. The projected revenue source for this proposed project is Fishing License dollars.

10f. It is projected that annual maintenance costs for this proposed structure would run between \$100 and \$500.

- o Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- o Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- o Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- o Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

11. AESTHETICS/RECREATION	IMPACT [⊕]				Can Impact Be Mitigated [⊕]	Comment Index
	Unknown [⊕]	None	Minor [⊕]	Potentially Significant		
Will the proposed action result in:						
a. Alteration of any scenic vista or creation of an aesthetically offensive site or effect that is open to public view?		X				
b. Alteration of the aesthetic character of a community or neighborhood?		X				
c. Alteration of the quality or quantity of recreational/tourism opportunities and settings? (Attach Tourism Report)		X				
d. For P-R/D-L, will any designated or proposed wild or scenic rivers, trails or wilderness areas be impacted? (Also see 11a, 11c)						
e. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

- ⊕ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ◆ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ◆◆ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

12. CULTURAL/HISTORICAL RESOURCES	IMPACT ^o				Can Impact Be Mitigated ^o	Comment Index
	Unknown ^o	None	Minor ^o	Potentially Significant		
Will the proposed action result in:						
a. Destruction or alteration of any site, structure or object of prehistoric historic, or paleontological importance?		X				See 12a. below
b. Physical change that would affect unique cultural values?		X				See 12b. below
c. Effects on existing religious or sacred uses of a site or area?		X				See 12c. below
♦♦d. For P-R/D-1, will the project affect historic or cultural resources? Attach SHPO letter of clearance. (Also see 12.a)						
e. Other: <u>N/A</u>						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

12a,b & c. No impacts will occur to historic or cultural resources or values. (See attached State Historic Preservation Office letter of clearance.)

- ☆ Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- ♦ Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- ♦♦ Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

HUMAN ENVIRONMENT

13. SUMMARY EVALUATION OF SIGNIFICANCE	IMPACT ^o				Can Impact Be Mitigated ^o	Comment Index
	Unknown ^o	None	Minor ^o	Potentially Significant		
Will the proposed action, considered as a whole:						
a. Have impacts that are individually limited, but cumulatively considerable? (A project or program may result in impacts on two or more separate resources, which create a significant effect when considered together or in total.)		X				
b. Involve potential risks or adverse effects which are uncertain but extremely hazardous if they were to occur?		X				
c. Potentially conflict with the substantive requirements of any local, state, or federal law, regulation, standard or formal plan?		X				
d. Establish a precedent or likelihood that future actions with significant environmental impacts will be proposed?		X				
e. Generate substantial debate or controversy about the nature of the impacts that would be created?			X			See 13e. below
♦f. For P-R/D-I, is the project expected to have organized opposition or generate substantial public controversy? (Also see 13e)						
♦♦g. For P-R/D-I, list any federal or state permits required.						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

13e. Neighboring landowners have contacted Regional FWP staff and expressed opposition to the construction of a footbridge as a solution to potentially controlling the spread of NZMS into the Madison River. The construction of a footbridge is being proposed as a stop-gap measure to reduce the potential of NZMS spread into this portion of the Madison River and permit FWP to reopen the site for public use.

- o Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.
- o Include a narrative description addressing the items identified in 12.8.604-1a (ARM)
- o Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.
- o Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

2. Description and analysis of reasonable alternatives (including the no action alternative) to the proposed action whenever alternatives are reasonably available and prudent to consider and a discussion of how the alternatives would be implemented:

Alternative A – Proposed action and preferred alternative. Described and analyzed in this EA. Proposal includes construction of footbridge and erection of fencing to channel site users to and across the footbridge to access the Madison River. Signing will be used to inform users of the presence of NZMS in DD and delineate precautions to take in order to prevent the spread of NZMS into the Madison River. This proposed approach is a reasonable compromise between continuing to keep the site closed and taking precautionary measures to slow or prevent the introduction of NZMS into the Madison River by recreationists.

Alternative B – Reopen Cobblestone FAS with no footbridge. This alternative does nothing to mitigate the presence of NZMS in Darlinton Ditch and would likely result in increased possibilities that NZMS would be more rapidly spread to the Madison River by wading recreationists. FWP does not feel this is a prudent alternative.

Alternative C (No Action) – Keep Cobblestone FAS closed indefinitely (or perhaps permanently). This action would result in the loss of a valuable public access site to the Madison River. FWP has a responsibility to sportsmen to manage properties purchased with fishing license dollars and to have them available for public use. In addition, federal Land and Water Conservation Fund dollars have been used to both acquire this property and to develop it with facilities. Use of this federal funding source requires that the property be used for outdoor recreation purposes. Closure of this site would also mean that a long stretch of the lower Madison River would become more difficult to access and potentially lead to crowding on other segments of the Madison River. Significant numbers of Madison River users would likely be upset with the loss of this access site.

3. Evaluation and listing of mitigation, stipulation, or other control measures enforceable by the agency or another government agency:

FWP has the authority to continue the existing closure of Cobblestone FAS to public entry.

4. Based on the significance criteria evaluated in this EA, is an EIS required? YES / NO If an EIS is not required, explain why the EA is the appropriate level of analysis for this proposed action:

An EA is the appropriate level of analysis for this proposal as impacts to the human and natural environment would be minimal.

5. Describe the level of public involvement for this project if any and, given the complexity and the seriousness of the environmental issues associated with the proposed action, is the level of public involvement appropriate under the circumstances?

This EA will be distributed for a 30-day public comment period commencing on May 4, 2001. All individuals who have previously contacted FWP and left mailing addresses will be sent copies of the EA as will all agencies and individuals on the Region Three EA distribution list. Legal notices announcing the release of this EA will be published in the Bozeman Daily Chronicle and Helena Independent Record newspapers. Public involvement for this proposal consisted of production and advertisement of this EA. Public meetings will be held in Three Forks May 21, 2001 at the Three Forks Methodist Church Annex, 112 Cedar St. at 7:00 p.m. and at the Bozeman Public Library, 220 East Lamme at 7:00 p.m., May 24, 2001.

6. Duration of comment period if any:

The comment period will be 30 days commencing on May 4, 2001 and closing at 5 p.m. on April 4, 2001.

Montana Fish, Wildlife, & Parks
Patrick J. Flowers
1400 South 19th
Bozeman, Mt 59718-5496
e-mail: pflowers@montana.edu

7. Name, title, address and phone number of the Person(s) Responsible for Preparing the EA:

Jerry Walker
Regional Parks Manager
1400 S. 19th Ave.
Bozeman, MT 59718
406-994-4042
gwalker@montana.edu

PART III. NARRATIVE EVALUATION AND COMMENT

It has been determined that this project is exempt from the provisions of HB 495. See attached HB 495 Exemption form.

VICINITY MAP

**COBBLESTONE FAS
SITE MAP**

Cobblestone FAS

Lands File Number: 3365
T1N/R2E

190.278 acres

Fee Simple
FAS Parcel

0 acres

Leased
FAS Parcel

Scale in feet
Scale 1:18000

Fishing Access Sites (FAS) are digitized and maintained by the Information Services Unit of the Montana Fish, Wildlife and Parks. FAS's were digitized at 1:24,000 using the COGO module of Arc/Info. The background image is a USGS 7.5-minute quadrangle digital raster graphic.

Montana Fish,
Wildlife & Parks

Map produced by NRIS,
request# 00FWP6 - September 21, 1999

**COBBLESTONE
MASTER SITE PLAN**

MADISON

RIVER

Four Stan
Smooth wire
Fence
X X X Jack-leg
Fence

access area

Bar Scale..... In Feet

STATE OF MONTANA
FISH AND GAME COMMISSION
RECREATION AND PARKS DIVISION

master site plan
Cobblestone
Fishing Access Site

APPROVED BY

DATE

**DARLINTON SPRING
CREEK BRIDGE
SKETCH**

DARLINGTON SPRING CREEK BRIDGE SKETCH

* NOT TO
SCALE

LEVEE

← TO
MADISON RIVER

Fill as
needed

7'

Approx.
30'

Fill as
needed

→ TO COBBLESTONE
FAS PARKING
AREA

DARLINGTON SPRING CREEK

END DETAIL

2x8" 0-10"
PLANKING

Log
Stringers

BURIED WOOD FOOTER

**HB 495 EXEMPTION
FORM**

DRAFT

HB 495 EXEMPTION FORM

Use this form when a park improvement or development project meets the criteria identified in 12.8.602 (1) ARM, but determined to NOT significantly change park features or use patterns.

State Park or Fishing Access Site Project Description:

Cobblestone Fishing Access Site Footbridge Proposal

This improvement or development project does not significantly change park or fishing access site features or use patterns. Provide the reason for exemption across from the appropriate item.

12.8.602 (ARM) (1)	Reason for Exemption
(a) Roads/trails	Bridge will be placed on existing trail
(b) Buildings	
(c) Excavation	Minimal (> 5 cubic yards) for bridge footings
(d) Parking	
(e) Shoreline alterations	Two minor footings for bridge
(f) Construction into water bodies	Footbridge will span spring creek/ditch
(g) Construction w/impacts on cultural artifacts	
(h) Underground utilities	
(i) Campground expansion	

Some activities considered that do not significantly impact site features or use patterns are:

Signing, fencing, barriers, road grading, garbage collection, routine latrine and facility maintenance.

Signature

Jerry Walker

Date 4/11/01

c: Helena HB 495 Coordinator
Regional Park Manager

**STATE HISTORIC
PRESERVATION OFFICE
CLEARANCE LETTER**

Steve Ag
file in 40.2

K-5 HQ

State Historic Preservation Office

Montana Historical Society

Mailing Address: 225 North Roberts • Helena, MT 59620-9990

Office Address: 102 Broadway • Helena, MT • (406) 444-7715

RECEIVED
JAN 03 1992
DESIGN AND CONSTRUCTION
BUREAU

December 31, 1991

Paul Valle
Fish, Wildlife and Parks
Capitol Complex
Helena, MT 59620

RE: Cobblestone FAS

Dear Paul:

As requested we have conducted a cultural resource file search and review for the project area cited above. We concur that prior survey on the Cobblestone FAS failed to locate evidence of cultural resources. Based on the previous findings and the scope of proposed work we believe it is unlikely that significant cultural resources will be impacted by the project.

Thank you for consulting with us.

Sincerely,

David Schwab
State Archaeologist

File:Cobblestone FAS

1420 East Sixth Avenue
Helena, Montana 59620

December 9, 1991

Marcella Sherfy
State Historic Preservation Officer
State Historic Preservation Program
Montana Historical Society
225 North Roberts
Helena, Montana 59620

Dear Marcella:

The Department of Fish, Wildlife and Parks is proposing to do improvements on our Cobblestone FAS in Gallatin County, T1S, R2E, Section 5. The scope of the proposed project is to regrade and gravel existing road and parking areas, install a handicapped latrine, hard surface parking pad and trail and a footbridge across the existing ditch to allow pedestrian access to the river. This site was previously surveyed for cultural resources on March 27, 1978 with no cultural sites found. Based on a past cultural study and the proposed scope of this project, we believe that there is little likelihood of this project impacting cultural resources.

Please provide your comments regarding this project.

Thank you.

Sincerely,

PAUL VALLE
Cultural Resources Coordinator
Field Services Division

cd

NEPA/NEPA/HB495 CHECKLIST

PART I. PROPOSED ACTION DESCRIPTION

1. Type of Proposed State Action:
Removal of an invasive non-native snail from a section of Darlington Ditch using the molluscicide Bayluscide (niclosamide)
2. Agency Authority for the Proposed Action:
87-1-201 (Temporary) Powers and duties:
 - (1) The department (Department of Fish, Wildlife, & Parks) shall supervise all the wildlife, fish, game, game and nongame birds, waterfowl, and the game and fur-bearing animals of the state and may implement voluntary programs that encourage hunting access on private lands and that promote harmonious relations between landowners and the hunting public. It possesses all powers necessary to fulfill the duties prescribed by law and to bring actions in the proper courts of this state for the enforcement of the fish and game laws and the rules adopted by the department.
 - (2) The department shall enforce all the laws of the state respecting the protection, preservation, and propagation of fish, game, fur-bearing animals, and game and nongame birds within the state.
 - (3) The department has the exclusive power to spend for the protection, preservation, and propagation of fish, game, fur-bearing animals, and game and nongame birds all state funds collected or acquired for that purpose, whether arising from state appropriation, licenses, fines, gifts, or otherwise. Money collected or received from the sale of hunting and fishing licenses or permits, from the sale of seized game or hides, from fines or damages collected for violations of the fish and game laws, or from appropriations or received by the department from any other sources is appropriated to and under control of the department.
3. Name of Project:
Darlington Ditch New Zealand Mud Snail Control Project
4. Name, Address and Phone Number of Project Sponsor (if other than the agency)
5. If Applicable:
Estimated Construction/Commencement Date July 5, 2001

Estimated Completion Date July 27, 2001

Current Status of Project Design (% complete) 10

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

6. Location Affected by Proposed Action (county, range and township):
Gallatin County, Darlinton Ditch, T1N, R2E, Sections 29 and 32

7. Project Size: Estimate the number of acres that would be directly affected that are currently:

	<u>Acres</u>		<u>Acres</u>
(a) Developed:		(d) Floodplain	<u>0</u>
Residential	<u>0</u>		
Industrial	<u>0</u>	(e) Productive:	
	3.63	irrigated cropland	<u>0</u>
(b) Open Space/Woodlands/Recreation	<u>3.63</u>	dry cropland	<u>0</u>
		forestry	<u>0</u>
(c) Wetlands/Riparian Areas	<u>0</u>	rangeland	<u>0</u>
		other	<u>0</u>

8. Map/site plan: attach an original 8 1/2" x 11" or larger section of the most recent USGS 7.5' series topographic map showing the location and boundaries of the area that would be affected by the proposed action. A different map scale may be substituted if more appropriate or if required by agency rule. If available, a site plan should also be attached.

See page 3:

9. Listing of any other Local, State or Federal agency that has overlapping or additional jurisdiction.

- (a) Permits:

<u>Agency Name</u>	<u>Permit</u>	<u>Date Filed/#</u>
Montana Department of Environmental Quality	308 (water quality exemption)	to be filed
Gallatin County	Floodplain permit	will be filed if this permit is necessary
Fish, Wildlife, & Parks	124 permit	will be filed if this permit is necessary

- (b) Funding: \$ 44,155.28
see page 23 for itemized budget

<u>Agency Name</u>	<u>Funding Amount</u>
Upper Midwest Environmental Services Center	\$ 33,270.00 (travel, lodging, and meals)
If this project is undertaken, grants and in-kind services will be sought to pay costs of UMESC.	

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Figure 1. Darlington Ditch anticipated treatment area.

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Montana Fish, Wildlife, & Parks

\$ 10,885.28

MFWP costs would be paid from existing budgets (federal aid money will not be used in this project)

- (c) Other Overlapping or Additional Jurisdictional Responsibilities:

Agency Name _____ Type of Responsibility _____

Montana Department of Agriculture - Special Local Need pesticide registration

10. Narrative summary of the proposed action or project including the benefits and purpose of the proposed action:

Background:

The New Zealand Mud Snail (*Potamopyrgus antipodarum*) has recently invaded North American waters (Kerans et al 2000, Langenstein and Bowler 1989, Zaranko et al 1997, MFWP 1996-2000, Bowler and Frest, pers.comm., Becker pers.comm.). Impacts of the New Zealand Mud Snail (NZMS) to native aquatic invertebrates and other fish food organisms are presently being monitored, but the NZMS is known to attain densities as high as 300,000 per square meter in the Madison River in Yellowstone National Park (Kerans 2000), and 1,000,000 per square meter in springs adjacent to the Snake River near Hagerman Idaho (Richards pers.comm. 2000). Preliminary analyses of samples from Darlinton Ditch show periphyton density in the infested portion of the stream is approximately half that outside the infested area (Kerans 2001). In the Madison River Drainage, NZMS have been documented in the Firehole and Gibbon Rivers, headwaters of the Madison River in Yellowstone National Park, and all mainstem Madison waters as far downstream as Reynolds Pass Bridge, and in Darlinton Ditch Spring Creek along the lower Madison River (Figure 1). In the Madison River at Highway 191, near West Yellowstone, they comprised 70 percent of all aquatic invertebrates collected during sampling in August 1998. Extensive surveys in the Madison River in June, 2000, revealed no other sources of NZMS. A report of NZMS in the West Gallatin River above the Gallatin Forks has been investigated, but remains unconfirmed. NZMS are not known to exist in any other Montana waters. They have been documented in the headwaters of the Yellowstone and Snake rivers in Yellowstone National Park.

Fish generally receive little nutritive value from NZMS because of the small size of the snails, the hardness of their shell, and the fact that NZMS have a calcified operculum that closes over the shell orifice, protecting them from digestive fluids of the fish. Studies in New Zealand determined that brown trout extracted less than 2 % of the energy available from ingested NZMS with unbroken shells, and rainbow trout extracted almost 20 %, while other molluscs with unbroken shells yielded 38-67% of the energy available (McCarter 1986). A significant proportion of NZMS pass through trout unharmed, so are available to be introduced into new waters with cleaning of the fish, or by passage through the fish's gut during migration. The high density attained by

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NZMS raises concern for their potential impacts on the density and dynamics of native aquatic invertebrates that serve as food items for trout and other fish. Kerans et al. (2000) preliminarily found NZMS density to be negatively correlated to the density of several families of aquatic insects, including pteronarcid stoneflies and ephemereid mayflies, and positively correlated to heliocopsychid and limnephilid caddisflies, flatworms, and nematodes. Efforts are underway to secure funding for additional studies to further determine the impacts of NZMS density on fish food availability and diet.

NZMS are extremely effective colonizers. They can reproduce by parthenogenesis (cloning), therefore, only one NZMS can start a new population and all offspring will be genetically identical to the parent. To date, North American populations have been found to be over 99% female, which reproduce by parthenogenesis. In the Snake River, Idaho, the average annual fecundity of NZMS is 230, and they begin reproducing early in their life cycle (Bowler pers.comm.1998). NZMS have been characterized as "born pregnant" – young NZMS emerge from the adult female with immature larvae developing in their ovaries. NZMS utilize a variety of substrate materials, including vegetation that may break free and drift downstream, transporting snails to new locations. NZMS also may capture or produce an air-bubble, using it to transport themselves downstream. The small size of young NZMS can lead recreationists and other water users to inadvertently transport them from one waterbody to another, and they can be transported in the guts of animals that ingest them.

The proposed action is intended to eliminate NZMS from an approximately one-mile section of the Darlington Ditch Spring Creek along the lower Madison River. The most severe infestation is at the Cobblestone FAS, where densities range from 100/m² to 100,000/m² in mid summer 2000 (Richards pers.comm. 2000). A single NZMS has been sampled approximately one mile downstream of the Cobblestone FAS. Elimination of NZMS from Darlington Ditch will remove the threat they pose to the fish food web, and eliminate a source for potential downstream invasion to the nearby rivers.

The molluscicide:

Bayluscide (active ingredient niclosamide) is an EPA registered pesticide for use in control of sea lamprey in tributaries to the Great Lakes, Finger Lakes, and Lake Champlain, and as a molluscicide to control freshwater snails that carry vectors for diseases that affect humans and fish. Typically, Bayluscide is used in combination with 3-trifluoromethyl-4-nitrophenol (TFM) to treat sea lamprey larvae in tributaries of the Great Lakes. Less than 400 pounds of active ingredient (a.i.) niclosamide is used each year in lamprey and freshwater snail treatments in the U.S. Niclosamide has also been used as a veterinary and human drug for treatment of parasites (EPA 1999a). Several formulations are available, including a 70% wettable powder (EPA registration number 6704-87, Appendix A1) that we propose to use in Darlington Ditch. This formulation has been used in Puerto Rico to control freshwater snails which serve as vectors for schistosomiasis, however this use of the Bayluscide 70% wettable powder formulation (WP) for human health purposes is presently not eligible for EPA reregistration due to a lack of use

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information, an application methods summary, and a 21-28 day dermal toxicity study (EPA 1999b). See Appendices B1 and B2 for the complete text of EPA 1999a and EPA 1999b-information on niclosamides regulatory history, human health assessment, environmental assessment, risk mitigation, additional data requirements, product labeling, and regulatory conclusion.

Bayluscide is registered in Florida for control of freshwater snails in commercially operated ponds used for the production of ornamental fish (Appendix A2), and in Arkansas for control of snails in commercially operated freshwater ponds used for baitfish and ornamental fish production (Appendix A3).

The chemical formula of Bayluscide is $C_{15}H_9Cl_2N_3O_5$. It is the ethanolamine salt of niclosamide ($C_{13}H_9Cl_2N_3O_4$). To conduct treatments for mollusc control, the 70% wettable powder formulation of Bayluscide generally is applied at 0.5 – 1.0 ppm a.i. (niclosamide) for 6-24 hours (Chemagro Corporation, undated information, Appendix C). For example, in laboratory tests, 100% mortality of freshwater snails was obtained after one hour exposure to 5 ppm Bayluscide, and in a flowing stream, 1 ppm applied for 12 hours controlled freshwater snails for one month over a distance of 3 stream miles. Generally, lower concentrations applied over a longer duration of time result in the most effective treatment. For the Darlinton Ditch project, bioassays will be conducted prior to the project to determine the susceptibility of NZMS to Bayluscide, and to determine the concentration and duration of the application necessary to cause 100% mortality of sentinel NZMS.

Health and environmental information:

Human health information for niclosamide is in Appendix B1, pages 2-3, and Appendix B2, pages 14-21. Appendix B1 addresses toxicity, dietary exposure, occupational and residential exposure, and human risk assessment, Appendix B2 addresses acute toxicity, subchronic toxicity, chronic toxicity/carcinogenicity, developmental toxicity, and mutagenicity. Niclosamide showed no evidence of causing developmental toxicity, carcinogenicity, or mutagenicity. During acute toxicity tests, niclosamide was administered to test rats in a single oral dose of 1000 ppm (mg/kg). No mortality or clinical signs were seen (Appendix B2, page 15, Table 5). Additionally, other test animals showed no evidence of dermal irritation, but did exhibit dermal sensitization and evidence of eye irritation. During chronic toxicity tests, dogs were orally administered the 70% wettable powder formulation at rates of 0, 1.56, 6.25, or 25 mg/kg/day for 180 days. No animals died or exhibited any signs of toxicity. Body weights and daily food consumption of both treated and control dogs were similar (Appendix B2, page 16). However, in chronic toxicity tests on hamsters, all dose groups except low dose females showed significantly lower body weights compared to the control group. However, niclosamide is categorized as practically nontoxic to small mammals on an acute oral basis. The U.S. Fish & Wildlife Service holds the nationwide registration for Bayluscide, and has placed restrictions against irrigation (for mitigation measures, see Section 3, item i, page 13, and Section 7, item c, page 19) and drinking water removal (see

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Section 8, item c, page 20) during treatment. Bayluscide and its residues exhibit rapid dissipation in water and in fish.

As currently used in the tributaries of the Great Lakes to control larval sea lamprey, the initial application site of the TFM/Bayluscide mixture is typically one mile above the upstream-most distribution of the sea lamprey larvae to provide adequate time for mixing. The concentration is maintained by booster stations downstream of the initial application site. The frequency of booster stations is determined on a case-by-case basis, depending on water chemistry parameters and on-site analytical analysis. Treatments are conducted from the initial application point to the mouth of the stream or river, where it enters the Great Lakes. Rivers as large as 20,000 cubic feet per second (cfs) are treated (T. Bills pers.comm. 2001). There is no effort to neutralize the TFM/niclosamide mixture upon entering the Great Lakes, other than dilution.

The Environmental Assessment for niclosamide is in Appendix B2, pages 28-34. Niclosamide is highly toxic to freshwater fish (Appendix B1, page 3 and Appendix B2, page 29; Appendix C, page 65). The toxic action of niclosamide on fish is reversible if the fish are placed in fresh water before disequilibrium occurs (Appendix C, page 65).

The following toxicity information summary is listed in Appendix B2, page 29:

- Avian acute – moderately toxic (LD_{50} ¹ 60 mg/kg)
- Avian subacute dietary - practically nontoxic (LC_{50} > 5419 mg/kg diet)
- Mammalian acute – practically nontoxic (LD_{50} > 1000 mg/kg)
- Fish (freshwater acute) – highly toxic to very highly toxic (LC_{50} 0.03 – 0.23 mg/L)
- Invertebrates (freshwater) acute – slightly to very highly toxic (EC_{50} 0.034 - >50 mg/L)
- Invertebrates (freshwater) chronic – NOAEC 0.03 mg/L; LOEC 0.05 mg/L)
- Aquatic plants – toxic (0.04 – 1450 mg/L)

¹ see Appendix B2, page iii for definitions

Discussion of the environmental fate (degradation, break-down, dilution, etc.) of niclosamide is in Appendix B2, page 31. Overall, there is insufficient data available to assess the environmental fate of niclosamide. In an on-going study, half-life (the amount of time necessary for a given quantity of a substance to decay to half that quantity) of niclosamide has been measured as follows: 30 hours at pH 9.0, 11 hours at pH 7.0, and 7 hours at pH 5.0 (Terry Bills, pers.comm. 2000). The pH of Darlington Ditch water has consistently been measured at 8.4 - 8.5 from summer 2000 through spring 2001. Major routes of dissipation of niclosamide are dilution, dispersion, adsorption to sediments and suspended particulates and possibly photodegradation in clear shallow water. The adsorption of niclosamide to sediments and suspended particulates is reversible, so nontarget species, especially benthic organisms, may be exposed to niclosamide for extended periods of time. Bioconcentration in fish is not expected to occur. In a study to determine the photodegradation rate of niclosamide, the degradates were not identified and the output of the light source may not have been comparable with natural sunlight (Appendix

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B2, page 31-32). Niclosamide mobility increases with pH (Appendix B2, page 32), ranging from moderately mobile at 8.0 to very mobile at 9.0. Sediment type also factors into the mobility of niclosamide. At pH less than 6.5, niclosamide reportedly precipitates out of solution.

The Material Safety Data Sheet for niclosamide is in Appendix D.

Application of the molluscicide:

To legally permit the use of a pesticide in Montana, it must be registered with the Montana Department of Agriculture. Bayluscide currently is not registered. Registration can be achieved through a process known as a Special Local Need (SLN) permit (Appendix E).

Based on water chemistry and baseflow stream discharge of Darlington Ditch, the minimum quantity of Bayluscide wettable powder that would be necessary to treat the affected area is 55 pounds a.i. (approximately 79 pounds of Bayluscide). It is likely more than this would be necessary due to degradation over the stream course being treated, variations in water chemistry or stream discharge, and potentially treating more stream length due to expansion of the NZMS population beyond the distribution documented in 2000. Any additional quantity of Bayluscide necessary to complete an effective treatment will be determined by conditions present at the time of treatment, as determined by personnel of the U.S. Geological Survey Upper Midwest Environmental Services Office in La Crosse Wisconsin, who will be on-site with the necessary equipment to mix the wettable powder formulation and apply it to the stream.

The recommended rate for control of snails is a concentration of 0.5-1.0 ppm (mg/l) a.i. for 24 hours. As previously stated, bioassays will be conducted prior to the treatment to determine more precisely the necessary concentration and duration, to determine if the NZMS exhibits similar susceptibility as other freshwater snails, and to test neutralization techniques. The equipment is the same that is used to apply the TFM/niclosamide solution to tributaries of the Great Lakes for control of sea lamprey larvae. If this project is conducted, specific water chemistry parameters will be monitored to fill the data gaps necessary for determining the reregistration eligibility of Bayluscide for use as a molluscicide.

Application of the Bayluscide at the concentration and duration necessary to eradicate the NZMS would also affect other molluscs, fish, and possibly other aquatic invertebrates. To mitigate these impacts, Bayluscide treatments would be conducted only in the segment of stream occupied by NZMS, which would allow recolonization of the treated segment by organisms from untreated sections of the stream. There would be no attempt to salvage fish in the treated section due to the likelihood they have ingested NZMS. In fact, the fish in the treatment area will intentionally be sacrificed. Electrofishing will be used to capture as many fish as possible within the treatment area prior to the application of the Bayluscide. These fish will be disposed of in a manner that will prevent the release of any ingested NZMS into water. Block nets will be set at the upstream and downstream limits of the known NZMS distribution to prevent fish from entering or escaping the treatment area once treatment has begun. Fish within the treatment area that are killed by the Bayluscide will be collected after the treatment to prevent the release

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of ingested NZMS into the stream as the fish decay and disposed of. There is a possibility that fish will have ingested NZMS then moved outside the treatment area, which would be a potential reintroduction source if the NZMS survive passage through the fish's gut.

11. List of agencies consulted during preparation of the EA:

- U.S. Geological Survey, Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin
- Montana Department of Agriculture – Helena, Montana
- Montana Department of Environmental Quality – Helena, Montana
- U.S. Environmental Protection Agency – Helena, Montana and Washington, D.C.
- Arkansas Department of Environmental Quality, NPDES Branch, Little Rock, Arkansas
- U.S. Fish & Wildlife Service, Fish Farming Experimental Station, Stuttgart, Arkansas
- Florida Department of Environmental Protection, Tallahassee, Florida

12. Alternatives considered in the Environmental Assessment

Alternative 1: Eradication of New Zealand Mud Snails in Darlinton Ditch using the molluscicide Bayluscide. This is the proposed action and preferred alternative.

Under this alternative, fish in the treatment area will intentionally be sacrificed either through capture by electrofishing or by collection after application of the Bayluscide. All fish would be disposed of in a manner that prevents the release of NZMS into surface water.

Bioassays will be conducted prior to treatment to determine the susceptibility of NZMS to Bayluscide and to test Bayluscide neutralization measures.

Alternative 2: no action

Under this alternative, the New Zealand Mud Snail population will continue to expand in Darlinton Ditch spring creek and potentially spread into the lower Madison River.

13. Alternatives considered but not given detailed study

Alternative 3: Eradication of New Zealand Mud Snail in Darlinton Ditch using rotenone

Rotenone concentrations as high as 4.5 ppm applied for 48 hours resulted in only a 25 % kill of test snails (Zischke 1952 in Schnick 1974a)

Alternative 4: Eradication of New Zealand Mud Snail in Darlinton Ditch using antimycin

Antimycin concentrations of 10 – 40 ppb applied for an undefined period of time resulted in a greater abundance of test snails after treatment (Degan 1973 in

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

Schnick 1974b), or test snails showed no effect to antimycin at 15 ppb (Berger 1965c in Schnick 1974b).

Alternative 5: Eradication of New Zealand Mud Snail in Darlinton Ditch by heating the stream water to a lethal level.

It is unlikely that the volume of stream water in Darlinton Ditch can be heated to the necessary temperature (122°F) and that temperature maintained over the necessary distance of stream (up to 1 mile) to be fatal to all NZMS. This method would likely be less specific than use of the molluscicide, therefore causing negative impacts to all non-target organisms.

Alternative 6: Eradication of New Zealand Mud Snail in Darlinton Ditch by dewatering the stream.

It is unlikely this alternative would be viable due to the unlikelihood of completely dewatering the stream without significant alteration of the stream channel to pool the water for diversion with pumps or other means. Base flow appears to be about 6 cubic feet per second, and it is unknown where groundwater springs surface along the course of the stream that would prevent complete dewatering. This method would likely be less specific than use of the molluscicide, therefore causing negative impacts to all non-target organisms.

Alternative 7. Eradication of all fish from Darlinton Ditch using rotenone followed by eradication of New Zealand Mud Snails in Darlinton Ditch using the molluscicide Bayluscide.

Due to the potential that fish in Darlinton Ditch have ingested NZMS and moved into uninfested sections of the stream, electrofishing would be conducted to capture as many fish as possible of all species present in Darlinton Ditch. These fish would be held in isolation until ingested NZMS are purged.

All fish throughout the length of Darlinton Ditch not captured by electrofishing would then be eradicated using the fish toxicant rotenone. As many of these fish as possible would be collected and disposed of to prevent the release of NZMS as the fish decay. A minimum of several days would be necessary between eradicating the remaining fish with rotenone and treating the stream with the molluscicide to allow uncollected fish to decay and release the ingested NZMS.

In one pond treatment, apparent synergism occurred when Bayluscide was applied to a pond that had previously been treated with a product containing rotenone (Appendix C, page 66). The pond remained toxic to fish for six weeks.

Due to the potential for synergistic action of rotenone and Bayluscide, this alternative was dismissed.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

Alternative 8. Eradication of all fish from Darlington Ditch using antimycin followed by eradication of New Zealand Mud Snails in Darlington Ditch using the molluscicide Bayluscide.

For reasoning, see Alternative 7. The sole difference between alternatives 7 and 8 is the selection of the piscicide. Antimycin affects fewer non-target species, but is effective over a narrower range of water chemistry parameters, such as pH. There are no known instances of synergism between Bayluscide and antimycin.

This alternative was dismissed for concerns similar to those in Alternative 7, despite the lack of information regarding synergistic effects of antimycin and Bayluscide.

PART II. ENVIRONMENTAL REVIEW

1. Evaluation of the impacts of the Proposed Action including secondary and cumulative impacts on the Physical and Human Environment.

A. PHYSICAL ENVIRONMENT

1. <u>LAND RESOURCES</u> Will the proposed action result in:	IMPACT *				Can Impact Be Mitigated*	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
• ••Soil instability or changes in geologic substructure?		X				
b. Disruption, displacement, erosion, compaction, moisture loss, or over-covering of soil which would reduce productivity or fertility?		X				
c. ••Destruction, covering or modification of any unique geologic or physical features?		X				
d. Changes in siltation, deposition or erosion patterns that may modify the channel of a river or stream or the bed or shore of a lake?		X				
e. Exposure of people or property to earthquakes, landslides, ground failure, or other natural hazard?		X				
f. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

• Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

•• Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

••• Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

•••• Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

2. <u>AIR</u>	IMPACT *				Can Impact Be Mitigated*	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. **Emission of air pollutants or deterioration of ambient air quality? (also see 13 (c))			X		NO	2a
b. Creation of objectionable odors?		X				
c. Alteration of air movement, moisture, or temperature patterns or any change in climate, either locally or regionally?		X				
d. Adverse effects on vegetation, including crops, due to increased emissions of pollutants?		X				
e. ***For P-R/D-J projects, will the project result in any discharge, which will conflict with federal or state air quality regs? (Also see 2a)		NA				2e
f. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Air Resources (Attach additional pages of narrative if needed):

Comment 2a. Emission of pollutants.

Alternative 1: Proposed action.

Minor amounts of air pollutants will be released due to motor vehicle operation and use of equipment to mix the powdered molluscicide with water for application to the stream.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 2e. P-R/D-J Projects.

The proposed action will not be funded with P-R/D-J dollars.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

10. WATER	IMPACT *				Can Impact Be Mitigated*	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. *Discharge into surface water or any alteration of surface water quality including but not limited to temperature, dissolved oxygen or turbidity?			X		NO	3a
b. Changes in drainage patterns or the rate and amount of surface runoff?		X				
c. Alteration of the course or magnitude of floodwater or other flows?		X				
d. Changes in the amount of surface water in any water body or creation of a new water body?		X				
e. Exposure of people or property to water related hazards such as flooding?		X				
f. Changes in the quality of groundwater?			X		NO	3f
g. Changes in the quantity of groundwater?		X				
h. Increase in risk of contamination of surface or groundwater?			X		NO	3h
i. Effects on any existing water right or reservation?			X		YES	3i
j. Effects on other water users as a result of any alteration in surface or groundwater quality?		X				
k. Effects on other users as a result of any alteration in surface or groundwater quantity?		X				
l. ****For P-R/D-J, will the project affect a designated floodplain? (Also see 3c)		NA				
m. ***For P-R/D-J, will the project result in any discharge that will affect federal or state water quality regulations? (Also see 3a)		NA				
n. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Water Resources (Attach additional pages of narrative if needed):

Comment 3a. surface water discharge

Alternative 1: Proposed action.

Bayluscide dissipates through dilution, dispersion, sorption to sediments and suspended particles, and possibly photodegradation. Neither hydrolysis or volatilization are known to affect its fate. [¹⁴C]niclosamide (niclosamide tagged with radio-active Carbon) does not degrade in solutions at pH 5.0, 6.9, or 8.7. However, under photolytic conditions, niclosamide degrades with a half-life of 3.3 days at pH 6.9.

Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

If the proposed action is implemented, Bayluscide will be applied to the waters of Darlinton Ditch after the irrigation water is shut off between cuttings or for the season, or irrigators will be asked to temporarily cease operation until the pesticide has dissipated and degraded. The water in Darlinton Ditch is not used for human consumption, therefore mitigation for this use is not required. See the 3rd and 4th paragraphs on page v of the Executive Summary of the Reregistration Eligibility Decision (Appendix B2).

Alternative 2: No action.

There would be no impact under this alternative.

Comment 3f. groundwater quality

Alternative 1: Proposed action.

If surface waters within the project area infiltrate into groundwater, the groundwater could be affected. However, Bayluscide is known to adsorb to sediments which will reduce or prevent its infiltration into groundwater.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 3h. Increase in risk of contamination of surface or groundwater

Alternative 1. Proposed action

Bayluscide dissipates through dilution, dispersion, sorption to sediments and suspended particles, and possibly photodegradation. Neither hydrolysis or volatilization are known to affect its fate. [¹⁴C]niclosamide did not degrade in solutions at pH 5.0, 6.9, or 8.7. However, under photolytic conditions, niclosamide degraded with a half-life of 3.3 days at pH 6.9.

If surface waters within the project area infiltrate into groundwater, the groundwater could be affected. However, Bayluscide is known to adsorb to sediments which will reduce or prevent its infiltration into groundwater.

Alternative 2. No action

There would be no impact under this alternative.

Comment 3i. Effect on existing water rights or reservations

Alternative 1: Proposed action.

If the proposed treatment is conducted during the irrigation season, irrigation could be interrupted due to the requirement that irrigation water not be withdrawn during treatments.

Mitigation: The target date for conducting the treatment will be during the non-irrigating season or during a cutting of hay when irrigation is not occurring.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 3l.

The proposed action will not be funded with P-R/D-J dollars.

Comment 3m.

The proposed action will not be funded with P-R/D-J dollars.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

12. VEGETATION	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Changes in the diversity, productivity or abundance of plant species (including trees, shrubs, grass, crops, and aquatic plants)?		X				
b. Alteration of a plant community?		X				
c. Adverse effects on any unique, rare, threatened, or endangered species?			X		Yes	4c
d. Reduction in acreage or productivity of any agricultural land?		X				
e. Establishment or spread of noxious weeds?			X		Yes	4e
f. ****For P-R/D-J, will the project affect wetlands, or prime and unique farmland?		NA				
g. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 4c. adverse effects on unique, rare, threatened, or endangered species.

Alternative 1: Proposed Action

date, surveys have revealed no unique, rare, threatened, or endangered plants present in the area.

Mitigation: If any unique, rare, threatened, or endangered plants are identified in the area, measures will be implemented to protect to them.

Alternative 2. No action.

Left unchecked, the NZMS population may affect abundance of aquatic plants upon which they graze, including undetected unique, rare, threatened, or endangered aquatic plants.

Comment 4e. establishment or spread of noxious weeds.

Alternative 1: Proposed Action

Project vehicles and equipment could be vectors for the spread of noxious weeds.

Mitigation: Project vehicles and equipment not normally associated with the project area will be thoroughly cleaned, including the undercarriage, prior to accessing the site.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 4f.

The proposed action will not be funded with P-R/D-J dollars.

Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

** 5. <u>FISH/WILDLIFE</u>	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Deterioration of critical fish or wildlife habitat?	X					5a
b. Changes in the diversity or abundance of game animals or bird species?			X		YES	5b
c. Changes in the diversity or abundance of nongame species?				X	NO	5c
d. Introduction of new species into an area?		X				
e. Creation of a barrier to the migration or movement of animals?		X				
f. Adverse effects on any unique, rare, threatened, or endangered species?			X		YES	5f
g. Increase in conditions that stress wildlife populations or limit abundance (including harassment, legal or illegal harvest or other human activity)?			X		YES	5g
h. ****For P-R/D-J, will the project be performed in any area in which T&E species are present, and will the project affect any T&E species or their habitat? (Also see 5f)		NA				
i. ***For P-R/D-J, will the project introduce or export any species not presently or historically occurring in the receiving location? (Also see 5d)		NA				
j. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 5a. Deterioration of critical fish or wildlife habitat

Alternative 1. Proposed action

With the proposed action, the abundance and distribution of aquatic invertebrates that serve as fish food items will return to the "natural" condition. Physical habitat will be unaffected by the proposed action.

Alternative 2. No action

Left unchecked, the NZMS population may reduce abundance of other aquatic invertebrate species that serve as fish food. It is unknown what impacts such an affect would have on populations of game and non-game fish.

Comment 5b. change the diversity or abundance of game animals or bird species

Alternative 1. Proposed action

Mortality of game fish could occur due to the application of Bayluscide, and in fact is desired as described under Alternative 1 (Part I, section 12). More extensive impacts on the local fish population were considered in alternatives 7 and 8, but were dismissed (Part I, section 13).

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

Mitigation: Fish outside the treatment area will repopulate the area after treatment and after removal of the block nets.

Alternative 2. No action

Left unchecked, the NZMS population may affect abundance of other aquatic invertebrate species that serve as fish food. It is unknown what impacts such an affect would have on populations of game and non-game fish.

Comment 5c. change in the diversity or abundance of nongame species.

Alternative 1. Proposed action

The intent of the project is to eradicate a non-native mollusc, therefore, a significant change in the relative abundance of non-game species is desired. Other non-game species may also be affected, but would recolonize the project area from upstream. The relative abundance of these organisms would likely be different than prior to treatment. However, after the NZMS removal, the original non-game species will exist without the impacts brought by the NZMS.

Alternative 2. No action

Left unchecked, the NZMS population may affect abundance of other aquatic invertebrate species that serve as fish food. It is unknown what impacts such an affect would have on populations of game and non-game fish.

Comment 5f. adverse effects on unique, rare, threatened, or endangered species.

Alternative 1. Proposed action.

To date, surveys have revealed no unique, rare, threatened, or endangered species present in the area.

Mitigation: If any unique, rare, threatened, or endangered species are identified in the area, measures will be implemented to protect to them.

Alternative 2. No action.

Left unchecked, the NZMS population may affect abundance of other aquatic invertebrate species that serve as food for unique, rare, threatened, or endangered species in the area, and may also affect the abundance of any undetected unique, rare, threatened, or endangered aquatic invertebrates.

Comment 5g. conditions that stress wildlife or limit abundance.

Alternative 1. Proposed action.

Project activities such as vehicle traffic and equipment operation may temporarily displace or disturb wildlife.

Mitigation: Project activities will remain localized at the project site.

Alternative 2. No action.

There would be no impact under this alternative.

Comment 5h.

The proposed action will not be funded with P-R/D-J dollars.

Comment 5i.

The proposed action will not be funded with P-R/D-J dollars.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

B. HUMAN ENVIRONMENT

6. <u>NOISE/ELECTRICAL EFFECTS</u> Will the proposed action result in:	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
a. Increases in existing noise levels?			X		NO	6a
b. Exposure of people to severe or nuisance noise levels?			X		YES	6b
c. Creation of electrostatic or electromagnetic effects that could be detrimental to human health or property?		X				
d. Interference with radio or television reception and operation?		X				
e. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 6a. increase in existing noise level.

Alternative 1. Proposed action.

Operation of equipment and vehicles may result in a temporary increase in noise levels in the vicinity of the project area.

Alternative 2. No action.

There would be no impact under this alternative.

Comment 6b. exposure of people to severe or nuisance noise levels.

Alternative 1. Proposed action.

Project personnel may be exposed to loud noises during operation of application equipment.

Mitigation: Project personnel working in the vicinity of loud noises will be provided hearing protection for their use.

Alternative 2. No action.

There would be no impact under this alternative.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

LAND USE	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Alteration of or interference with the productivity or profitability of the existing land use of an area?		X				
b. Conflicted with a designated natural area or area of unusual scientific or educational importance?		X				
c. Conflict with any existing land use whose presence would constrain or potentially prohibit the proposed action?	X				YES	7c
d. Adverse effects on or relocation of residences?		X				
e. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 7c. conflict with existing land use.

Alternative 1. Proposed action.

If the proposed treatment is conducted during the irrigation season, irrigation could be interrupted due to the requirement that irrigation water not be withdrawn during treatments.

Mitigation: The target date for conducting the treatment will be during the non-irrigation season or during a break in irrigation, when the stream channel is at base flow and not used to transport irrigation water.

Alternative 2: No action.

It is possible that the presence of the NZMS could extend the present closure of the Cobblestone Fishing Access Site, or result in permanent closure.

Mitigation: A separate Environmental Assessment addresses a proposal to construct a footbridge and fencing around a portion of Darlington Ditch to prevent access to the infested portion of the stream and reduce the likelihood of inadvertent spread of NZMS after the site re-opens.

Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

8. <u>RISK/HEALTH HAZARDS</u>	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Risk of an explosion or release of hazardous substances (including, but not limited to oil, pesticides, chemicals, or radiation) in the event of an accident or other forms of disruption?		X				
b. Affect an existing emergency response or emergency evacuation plan or create a need for a new plan?		X				
c. Creation of any human health hazard or potential hazard?			X		YES	8c
d. ***For P-R/D-J, will any chemical toxicants be used? (Also see 8a)		NA				
e. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 8c. creation of human health hazard.

Alternative 1. Proposed action.

Bayluscide is a moderate skin sensitizer, can produce slight skin irritation, and has caused eye irritation. There is no known domestic use of water from Darlinton Ditch.

Mitigation: Only project personnel will be exposed to Bayluscide. These individuals will wear Personnel Protective Equipment, including goggles and protective clothing.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 8d.

The proposed action will not be funded with P-R/D-J dollars.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

COMMUNITY IMPACT	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Alteration of the location, distribution, density, or growth rate of the human population of an area?		X				
b. Alteration of the social structure of a community?		X				
c. Alteration of the level or distribution of employment or community or personal income?		X				
d. Changes in industrial or commercial activity?			X		NO	9d
e. Increased traffic hazards or effects on existing transportation facilities or patterns of movement of people and goods?		X				
f. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 9d. changes in industrial or commercial activity.

Alternative 1. Proposed action.

There is a potential for temporary interruption of irrigation at certain times of the year (see comment 7c). The project site is currently closed to public access to prevent the spread of NZMS. Completion of the treatment will result in re-opening of the site for recreation, including guided angling and wildlife viewing. Angling regulations for trout at Darlington Ditch require catch and release, therefore, there are no human consumption risks after the project is completed.

Mitigation: The target date for conducting the treatment will be during the non-irrigating season.

Alternative 2: No action.

There would be no impact under this alternative.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

10. PUBLIC SERVICES/TAXES/UTILITIES	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Will the proposed action have an effect upon or result in a need for new or altered governmental services in any of the following areas: fire or police protection, schools, parks/recreational facilities, roads or other public maintenance, water supply, sewer or septic systems, solid waste disposal, health, or other governmental services? If any, specify:		X				
b. Will the proposed action have an effect upon the local or state tax base and revenues?		X				
c. Will the proposed action result in a need for new facilities or substantial alterations of any of the following utilities: electric power, natural gas, other fuel supply or distribution systems, or communications?		X				
d. Will the proposed action result in increased used of any energy source?		X				
e. **Define projected revenue sources						10e
f. **Define projected maintenance costs.						10f
g. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative needed):

Comment 10e. Projected revenue sources.

See page 23 for the estimated costs of the project. Grants and in-kind services will be applied for or contributed to pay the costs of the UMESC. Costs of MFWP will be paid from existing budgets, however, federal aid dollars will not be spent on this project.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

Darlington Ditch New Zealand Mud Snail Control Project Estimated Budget

Montana Fish, Wildlife, & Parks

Salary and Benefits	5,715		
Travel/lodging	1,485		
Equipment & supplies	500		
Bayluscide	79 lbs x \$40.32/lb		3,185.28
Total MFWP Cost			10,885.28

Upper Midwest Environmental Services Center:

US Fish & Wildlife Service

Salary and Benefits	10,400		
Office Support	1,700		
Travel	2,600		
Vehicle	1,600		
Other Equipment	1,000		
Miscellaneous Supplies	1,000		
Total Direct Costs		18,300	
Overhead (20%)		3,700	
Total USFWS Cost			22,000

US Geological Survey

Salary and Benefits	4,800		
Travel	1,700		
Equipment & Supplies	1,500		
Total Direct Costs		8,000	
USGS Overhead (22%)		1,800	
UMESC Overhead (15%)			1,470
Total USGS Cost			11,270

TOTAL COST

\$ 44,155.28

These costs are minimum and could change upward if the treatment is more complex or takes more time than anticipated.

• Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

** 11. AESTHETICS/RECREATION	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. Alteration of any scenic vista or creation of an aesthetically offensive site or effect that is open to public view?			X		NO	11a
b. Alteration of the aesthetic character of a community or neighborhood?			X		NO	11b
c. **Alteration of the quality or quantity of recreational/tourism opportunities and settings? (Attach Tourism Report)			X		NO	11c
d. ***For P-R/D-J, will any designated or proposed wild or scenic rivers, trails or wilderness areas be impacted? (Also see 11a, 11c)		NA				
e. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 11a. creation of an aesthetically offensive site or effect that is open to public view.

Alternative 1. Proposed action.

Due to the location of the NZMS in Darlington Ditch, project activities will necessarily be conducted in a state Fishing Access Site. The site is currently closed to public access, but project personnel and activities will be visible from outside the site, including nearby residences. Additionally, some members of the public may be offended that pesticides are being applied. These activities will be temporary.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 11b. alteration of the aesthetic character of a community or neighborhood.

Alternative 1. Proposed action.

See comment 11a.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 11c. alteration of the quality or quantity of recreational opportunities.

Alternative 1. Proposed action.

Completion of the treatment will result in re-opening of the site for recreational access and activities. Angling regulations for trout at Darlington Ditch require catch and release, therefore, there are no human consumption risks. There is a potential temporary reduction in the number and size of trout and other fish species as a result of the proposed action.

Alternative 2: No action.

Left unchecked, the NZMS population may affect abundance of other aquatic invertebrate species that serve as fish food. It is unknown what impacts such an affect would have on populations of game and non-game fish.

Comment 11d.

The proposed action will not be funded with P-R/D-J dollars.

* Include a narrative explanation under Part III describing the scope and level of impact. If the impact is unknown, explain why the unknown impact has not or can not be evaluated.

** Include a narrative description addressing the items identified in 12.8.604-1a (ARM)

*** Determine whether the described impact may result and respond on the checklist. Describe any minor or potentially significant impacts.

**** Include a discussion about the issue in the EA narrative and include documentation if it will be useful.

2. CULTURAL/HISTORICAL RESOURCES	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
Will the proposed action result in:						
a. **Destruction or alteration of any site, structure or object of prehistoric historic, or paleontological importance?		X				
b. Physical change that would affect unique cultural values?		X				
c. Effects on existing religious or sacred uses of a site or area?		X				
d. ****For P-R/D-J, will the project affect historic or cultural resources? Attach SHPO letter of clearance. (Also see 12.a)		NA				12d
e. Other:						

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Land Resources (Attach additional pages of narrative if needed):

Comment 12d.

The proposed action will not be funded with P-R/D-J dollars.

SIGNIFICANCE CRITERIA

13. SUMMARY EVALUATION OF SIGNIFICANCE Will the proposed action, considered as a whole:	IMPACT *				Can Impact Be Mitigated *	Comment Index
	Unknown *	None	Minor *	Potentially Significant		
a. Have impacts that are individually limited, but cumulatively considerable? (A project or program may result in impacts on two or more separate resources that create a significant effect when considered together or in total.)		X				
b. Involve potential risks or adverse effects which are uncertain but extremely hazardous if they were to occur?		X				
c. Potentially conflict with the substantive requirements of any local, state, or federal law, regulation, standard or formal plan?		X				
d. Establish a precedent or likelihood that future actions with significant environmental impacts will be proposed?			X		NO	13d
e. Generate substantial debate or controversy about the nature of the impacts that would be created?			X		NO	13e
f. ***For P-R/D-J, is the project expected to have organized opposition or generate substantial public controversy? (Also see 13e)		NA				
g. ****For P-R/D-J, list any federal or state permits required.		NA				

Narrative Description and Evaluation of the Cumulative and Secondary Effects on Water Resources (Attach additional pages of narrative if needed):

Comment 13d. establish a precedent or likelihood of future significant actions.

Alternative 1. Proposed action.

Use of a molluscicide for treating other sites for NZMS or other invasive molluscs may be proposed in the future, but given the present data set and state of knowledge of Bayluscide characteristics, environmental impacts would not be significant.

Alternative 2: No action.

There would be no impact under this alternative.

Comment 13e. generation of substantial debate or controversy.

Alternative 1. Proposed action.

When conducted following label instruction and with proper safety procedures in place, pesticide use is generally an accepted method of control for unwanted or invasive organisms. However, proposals to use EPA registered pesticides in native trout restoration programs have resulted in appeals and litigation.

Alternative 2: No action.

Failure to address invasive species problems has generated debate and dissatisfaction among some groups and individuals. There have not yet been appeals or litigation filed seeking solutions to these issues, but such actions have been considered.

Comment 13f.

The proposed action will not be funded with P-R/D-J dollars.

Comment 13g.

The proposed action will not be funded with P-R/D-J dollars.

PART II. ENVIRONMENTAL REVIEW, CONTINUED

2. Description and analysis of reasonable alternatives (including the no action alternative) to the proposed action whenever alternatives are reasonably available and prudent to consider and a discussion of how the alternatives would be implemented:

see Section 10, Narrative summary of the proposed action, beginning on page 4 and Sections 12 and 13, list of alternatives, beginning on page 8.

3. Evaluation and listing of mitigation, stipulation, or other control measures enforceable by the agency or another government agency:

Presently the site is closed to the public to prevent the spread of the NZMS. The closure will remain in effect during and for a short period after treatment to assure that the public is not exposed to the pesticide.

PART III. NARRATIVE EVALUATION AND COMMENT

N/A

PART IV. EA CONCLUSION SECTION

1. Based on the significance criteria evaluated in this EA, is an EIS required (YES/NO)? If an EIS is not required, explain why the EA is the appropriate level of analysis for this proposed action.

No, an EIS is not required under the Montana Environmental Policy Act (MEPA) because the project lacks significant effects to the physical and human environment. Therefore, the impacts are appropriately addressed through an Environmental Assessment. The primary impact expected to result from this project is the eradication of NZMS from Darlington Ditch, which is the intended consequence of the action.

2. Describe the level of public involvement for this project if any and, given the complexity and the seriousness of the environmental issues associated with the proposed action, is the level of public involvement appropriate under the circumstances?

Public involvement for this proposal consisted of production and advertisement of this EA. Public meetings will be held in Three Forks on May 21, 2001 at the Three Forks Methodist Church Annex, 112 Cedar St. at 7:00 p.m. and at the Bozeman Public Library, 220 East Lamme at 7:00 p.m., May 24, 2001.

3. Duration of comment period, if any.

The public comment period for this proposal is from **May 4, 2001 until 5:00 p.m. June 4, 2001.**

Montana Fish, Wildlife, & Parks
 Patrick J. Flowers
 1400 South 19th
 Bozeman, Mt 59718-5496
 e-mail: pflowers@montana.edu

4. Name, title, address and phone number of the person(s) responsible for preparing the EA:

Pat Clancey
MFWP
Box 1336
Ennis, MT 59729
406-682-7807
e-mail: pcensfw@3rivers.net

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- Montana Fish, Wildlife, & Parks. 2000. Madison River/Ennis Reservoir Fisheries and Madison River Drainage Westslope Cutthroat Trout Conservation and Restoration Program. 1999 Annual Report to PPL Montana (formerly Montana Power Company), Environmental Division, Butte and Turner Enterprises, Inc., Gallatin Gateway. 23 pages.
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APPENDIX A1

U.S. ENVIRONMENTAL PROTECTION AGENCY
Bayluscide (70% wettable powder) label

U.S. LABEL-(S)

Reason to Issue: To show changes made per
A's request 8/10/92

Date of Draft: 8/27/92
Supersedes draft dated 7/31/92

Reg. No. 6704-87

TOTAL NET WEIGHT - POUNDS

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons
under their direct supervision and only for those users covered by
the Certified Applicator's certification.

BAYLUSC
IDE

(Formerly BAY 73)
70% WETTABLE POWDER

LAMPRICIDE

MOLLUSCIDICIDE

FOR CONTROL OF SEA LAMPREY
LARVAE

FOR CONTROL OF FRESH-WATER
SNAILS

KEEP OUT OF REACH OF CHILDREN

Puerto Rico Only

DANGER

(See Below for Statements of
Practical Treatment and of
Precautionary Statements)

ACTIVE INGREDIENT:

5-Chloro-N-(2-chloro-4-nitrophenyl)-
2-hydroxybenzamide compound with 2-
aminoethanol (1:1).....70%

INERT INGREDIENTS:.....30%
100%

EPA Reg. No. 6704-87
EPA Est. No. 33967-NJ-1

STOP - READ THE LABEL BEFORE USE

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT
WITH ITS LABELING.

General Use Restrictions:

Local, State, and Provincial Fish and Game Agencies must be contacted before product is
applied. Municipalities that use streams requiring treatment as potable water sources
must be notified of the impending treatment at least 24 hours prior to application.
Agricultural irrigators that use streams requiring treatment as a source of irrigation
water must be notified of the impending treatment at least 24 hours prior to application.
Agricultural irrigators must turn off their irrigation system for a 24-hour period during
and after treatment.

Aerial applications of Bayluscide are prohibited.

IMPORTANT: READ THESE ENTIRE DIRECTIONS AND CONDITIONS OF SALE BEFORE USING BAYLUSCIDE 70% WETTABLE POWDER.

CONDITIONS OF SALE: THE DIRECTIONS ON THIS LABEL WERE DETERMINED THROUGH RESEARCH TO BE THE DIRECTIONS FOR CORRECT USE OF THIS PRODUCT. THIS PRODUCT HAS BEEN TESTED FOR A RANGE OF WEATHER CONDITIONS SIMILAR TO THOSE WEATHER CONDITIONS THAT ARE ORDINARY AND CUSTOMARY TO THE GEOGRAPHIC AREA WHERE THE PRODUCT IS USED. INSUFFICIENT CONTROL OF PESTS AND/OR INJURY TO THE CROP TO WHICH THE PRODUCT IS APPLIED MAY RESULT FROM THE OCCURRENCE OF EXTRAORDINARY OR UNUSUAL WEATHER, OR FROM FAILURE TO FOLLOW LABEL DIRECTIONS. IN ADDITION, FAILURE TO FOLLOW LABEL DIRECTIONS MAY CAUSE INJURY TO OTHER CROPS, ANIMALS, MAN, OR THE ENVIRONMENT. U.S. FISH AND WILDLIFE SERVICE OFFERS, AND THE BUYER ACCEPTS AND USES, THIS PRODUCT SUBJECT TO THE CONDITIONS THAT EXTRAORDINARY OR UNUSUAL WEATHER, OR FAILURE TO FOLLOW LABEL DIRECTIONS ARE BEYOND THE CONTROL OF U.S. FISH AND WILDLIFE SERVICE AND ARE, THEREFORE, THE RESPONSIBILITY OF THE BUYER.

FOR CONTROL OF SEA LAMPREY LARVAE

USE RESTRICTIONS:

ONLY FOR RETAIL SALE TO AND APPLICATION BY CERTIFIED APPLICATORS OF THE U.S. FISH AND WILDLIFE SERVICE, FISHERIES AND OCEANS CANADA, AND PROVINCIAL AND STATE FISH AND GAME EMPLOYEES OR PERSONS UNDER THEIR DIRECT SUPERVISION.

State and Provincial Fish and Game Agencies must first be contacted before product is applied.

BAYLUSCIDE 70% Wettable Powder may be used as a synergist in combination with TFM (EPA Reg. No. 6704-45) for control of sea lamprey larvae (*Petromyzon marinus*) in waters in the Great Lakes basin and the Lake Champlain system.

Application of BAYLUSCIDE 70% Wettable Powder may be made as a simultaneous addition with TFM on larger rivers to reduce the amount of TFM required or as a subsequent addition downstream to enhance TFM larvicidal activity.

Prior to using BAYLUSCIDE-TFM, pretreatment surveys must be made to determine larvae populations.

All waters selected for treatment must first be analyzed on site to determine both the minimum concentration of material required to kill lamprey larvae and the maximum concentration that can be applied without causing undue fish mortality. "Analysis:" constitutes live animal bioassay or the use of a regression established by past bioassays and total alkalinity and conductivity of water.

Lethal concentrations may vary depending upon water chemistry and temperature. Carefully calculate stream flow-rate and add the amount of material necessary to kill lamprey larvae with minimal fish mortality. Metering devices will be used that accurately deliver application rates as calculated. Chemicals will be monitored calorimetrically or by gas chromatography to insure that minimum lethal concentrations for sea lampreys are maintained and maximum allowable concentrations are not exceeded.

Mixing and Application Directions:

When using BAYLUSCIDE 70% Wettable Powder as a synergist in combination with TFM, mix in proportions so as to result in a final concentration of BAYLUSCIDE 70% Wettable Powder of not more than 2% of TFM by weight. BAYLUSCIDE 70% Wettable Powder may be added to TFM in 2 ways:

1. One method of application is a slurry of BAYLUSCIDE 70% Wettable Powder pumped into the water through a pump while the TFM is fed separately through a conventional fuel pump feeder in amounts calculated to deliver the desired rate of TFM to BAYLUSCIDE. BAYLUSCIDE is more easily mixed as a slurry than with TFM and more uniform feed rates result.
2. A second application method is used on the large river systems with multiple tributaries. The number of application sites on these large rivers precludes the use of the first method because of the number of feeders involved, the need for a 110-volt power source at each site to run a pump, and the often difficult access to these sites. BAYLUSCIDE is introduced into the chemical bank in amounts calculated to produce the desired TFM to BAYLUSCIDE ratio. The TFM applications in tributaries are timed so that the individual chemical banks meet and form a chemical bank in the main stream that approximates the chemical concentrations in the tributaries. Since the banks are diluted by ground water, swamp seepage, untreated tributaries, occasionally rain, or other conditions that cannot be included when the application rates for the tributaries are calculated, the toxicity of the bank in the main stream must be raised by the addition of TFM or BAYLUSCIDE. The latter can be used in place of TFM because of the increased toxicity of the TFM-BAYLUSCIDE because of the increased toxicity of the TFM-BAYLUSCIDE mixture over TFM alone to sea lamprey larvae.

FOR CONTROL OF FRESH-WATER SNAILS - PUERTO RICO ONLY

Use Restrictions:

FOR USE ONLY BY PUBLIC HEALTH OFFICIALS AND OTHER TRAINED PERSONNEL OF PUBLIC HEALTH PROGRAMS.

Mixing and Application Directions:

BAYLUSCIDE 70% Wettable Powder MOLLUSCICIDE gives effective control of freshwater snail species that act as intermediate hosts of organisms causing schistosomiasis. This compound kills snails and snail eggs. The Wettable powder wets readily when added to water and suspensions are easily applied to moving or impounding waters. Mix suspension thoroughly and maintain continuous agitation.

Flowing Streams: Sufficient quantities of BAYLUSCIDE should be metered into flowing water to obtain a final concentration of 0.5 to 1.0 part per million active ingredient of the toxicant. For maximum kill of snails, the 0.5-ppm concentration should be maintained for a 24-hour period. Repeat treatments as required.

Impounded Water: Apply sufficient quantities of BAYLUSCIDE to obtain a final concentration of 0.5 ppm of actual toxicant in the water (1.92 pounds BAYLUSCIDE 70% Wettable Powder per acre-foot of water). Repeat treatment as required.

STORAGE AND DISPOSAL

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal.

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rancid is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not use container in connection with food, feed, or drinking water. Completely empty container into application equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed above. In spill leak incidents, keep unauthorized people away. You may contact Chemtrec for decontaminating procedures or any other assistance that may be necessary. The Chemtrec telephone number is 800-424-9300.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes eye damage. May be harmful if swallowed or inhaled. Do not get in eyes. Do not breathe dust. Wash thoroughly with soap and water after handling. Wear goggles or face shield when handling. Wear a mask or respirator jointly approved by the Mining Enforcement and Safety Administration (formerly in U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

Do not contaminate feed or food. Keep out of reach of children.

STATEMENTS OF PRACTICAL TREATMENT

If in eyes: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention. If on skin: Wash immediately with soap and warm water. If irritation occurs, get medical attention. If swallowed: Drink promptly a large quantity of milk, or if milk is not available, large quantities of water. Avoid alcohol. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. If inhaled: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

ENVIRONMENTAL HAZARDS

Directions for use must be strictly followed to minimize hazards to non-target organisms. Do not contaminate water by cleaning of equipment or disposal of wastes.

This product is toxic to fish. Shrimp and crab may be killed at application rates recommended on this label. Do not apply where these are important resources.

Manufactured by

BAYER CORPORATION
SPECIALTY PRODUCTS
Box 4913
Kansas City, MO 64120-0013

Packaged by

BARTLO PACKAGING INC.
61 Willett St.
Passaic, NJ 07055

for

Fish and Wildlife Service
United States Department of the Interior
18th and C Streets, N.W.
Washington, D.C. 20240

BAYLUSCIDE is a Reg. TM of the ultimate parent company of Bayer Corp

APPENDIX A2

STATE OF FLORIDA BAYLUSCIDE LABEL

KEEP OUT OF REACH OF CHILDREN

RESTRICTED USE PESTICIDE

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS
OR PERSONS UNDER THEIR DIRECT SUPERVISION,
AND ONLY FOR THOSE USES COVERED BY THE
CERTIFIED APPLICATOR'S CERTIFICATION.

FOR DISTRIBUTION AND USE ONLY WITHIN FLORIDA

BAYLUSCIDE[®]
(Formerly Bay 73)
70% WETTABLE POWDER
MOLLUSCICIDE
(EPA REG. NO. 6704-87)

ACTIVE INGREDIENT:

5-Chloro-N-(2-chloro-4-nitrophenyl)-2-hydroxybenzamide compound with 2-aminoethanol (1:1)	70%
INERT INGREDIENTS:	30%
TOTAL	100%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes eye damage. May be harmful if swallowed or inhaled. Do not get in eyes. Do not breath dust. Wash thoroughly with soap and water after handling. Wear goggles or face shield when handling. Wear a mask or respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and by the national Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11.

Do not contaminate feed or food. keep out of reach of children.

STATEMENTS OF PRACTICAL TREATMENT

If in eyes: Hold eyelids open and flush with steady, gently stream of water for 15 minutes. Get medical attention. If on skin: Wash immediately with soap and warm water. If irritation occurs, get medical attention. If swallowed: Drink promptly a large quantity of milk, or if milk is not available, large quantities of water. Avoid alcohol. Note to Physician: Probable mucosal damage may contraindicate to use of gastric lavage. If inhaled: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Category of Applicator:	Certified Applicator
Crop/Site:	Commercially operated fresh-water ponds used for production of ornamental fish
Target Pest/Problem:	Fresh-water snails
Dosage:	1 lb. of 70% wettable powder/surface acre of pond
Dilution or Application Rate:	1 lb/surface acre of pond
Method of Application:	Commercially available sprayer
Frequency/Timing of Application:	Single application to drained pond
Field Reentry Safety Interval:	None
Other requirements:	If ponds discharge to surface waters, within 48 hours of chemical application, a National Pollutant Discharge Elimination System (NPDES) permit for the active ingredient must be obtained from EPA prior to the treatment of ponds which discharge to surface waters.

Aerial applications of Bayluscide are prohibited.

This labeling must be in the possession of the user at the time of pesticide application.

ENVIRONMENTAL HAZARDS

Directions for use must be strictly followed to minimize hazards to non-target organisms. Do not contaminate water by cleaning of equipment or disposal of wastes.

This product is toxic to fish. Shrimp and crab may be killed at application rates recommended on this label. Do not apply where these are important resources.

STORAGE AND DISPOSAL

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal.

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of according to label instruction, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

Container Disposal: Do not use container in connection with food, feed, or drinking water. Completely empty container into application equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed above. In spill or leak incidents, keep unauthorized people away. You may contact Chemtrec for decontamination procedures or any other assistance that may be necessary. The Chemtrec telephone number is 800-424-9300.

CONDITIONS OF SALE: THE DIRECTIONS ON THIS LABEL WERE DETERMINED THROUGH RESEARCH TO BE THE DIRECTIONS FOR CORRECT USE OF THIS PRODUCT. THIS PRODUCT HAS BEEN TESTED FOR A RANGE OF WEATHER CONDITIONS SIMILAR TO THOSE WEATHER CONDITIONS THAT ARE ORDINARY AND CUSTOMARY IN THE GEOGRAPHIC AREA WHERE THE PRODUCT IS USED. INSUFFICIENT CONTROL OF PESTS AND/OR INJURY TO THE CROP TO WHICH THE PRODUCT IS APPLIED MAY RESULT FROM THE OCCURRENCE OF EXTRAORDINARY OR UNUSUAL WEATHER, OR FROM FAILURE TO FOLLOW LABEL DIRECTIONS. IN ADDITION, FAILURE TO FOLLOW LABEL DIRECTIONS MAY CAUSE INJURY TO OTHER CROPS, ANIMALS, MAN, OR THE ENVIRONMENT. U.S. FISH AND WILDLIFE SERVICE OFFERS, AND THE BUYER ACCEPTS AND USES, THIS PRODUCT SUBJECT TO THE CONDITIONS THAT EXTRAORDINARY OR UNUSUAL WEATHER, OR FAILURE TO FOLLOW LABEL DIRECTIONS ARE BEYOND THE CONTROL OF U.S. FISH AND WILDLIFE SERVICE AND ARE, THEREFORE, THE RESPONSIBILITY OF THE BUYER.

Manufactured by

MILES INC.
SPECIALTY PRODUCTS
Box 4913
Kansas City, MO 64120-0013

for

Florida Tropical Fish Farms Association
PO Box Drawer 1519
Winter Haven, FL 33882-1519

NET CONTENTS: _____

EPA SLN NO. FL. _____

BAYLUSCIDE is a Reg. TM of the ultimate parent company of Miles Inc.

APPENDIX A3

STATE OF ARKANSAS BAYLUSCIDE LABEL

SUPPLEMENTAL LABELING
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF ARKANSAS

RESTRICTED USE PESTICIDE

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION. CERTIFIED APPLICATORS MUST ALSO ENSURE THAT ALL PERSONS INVOLVED IN THESE ACTIVITIES ARE INFORMED OF THE PRECAUTIONARY STATEMENTS.

Bayluscide™ 70% Wettable Powder
(EPA REG. NO. 6704-87)

COMPOSITION

ACTIVE INGREDIENT:

5-Chloro-N-(2-chloro-4-nitrophenyl)-2-hydroxybenzamide compound with 2-amonoethanol (1:1) 70%

INERT INGREDIENTS: 30%

100 %

THIS LABEL IN ADDITION TO THE STANDARD FEDERAL LABEL PRINTED ON THE CONTAINER

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FOR THE CONTROL OF SNAILS IN COMMERCIALY OPERATED, FRESHWATER PONDS, USED ONLY FOR BAIT FISH AND ORNAMENTAL FISH PRODUCTION. CONSULT WITH ALL LABEL DIRECTIONS BEFORE APPLYING THIS PRODUCT.

Bayluscide can be used to control snails in commercially operated freshwater ponds prior to stocking ornamental fish such as koi carp, goldfish, comets, shubunkins, fantails, and baitfish such as shiners and minnows.

Use rate: Apply Bayluscide to ponds at least 4 days prior to stocking fish. For empty ponds, use 1 lb of 70% wettable powder per surface acre of pond bottom then fill 2-4 days later. For water-filled ponds, use 0.25 lb/acre foot of water then stock fish no sooner than 4 days after the application. Mix the required amount of Bayluscide in sufficient water to enable uniform application to the pond.

Other requirements/restrictions: Waters treated under this SLN shall be for ornamental or baitfish production only. No fish intended for human consumption may be present in treated water. No discharge from treated ponds within 7 days of application. If ponds discharge to surface waters of the state, a National Pollution Discharge Elimination System (NPDES) permit or equivalent state permit for fish ponds is required prior to treatment of ponds.

24c (SLN) Registrant: Arkansas Bait and Ornamental Fish Growers Association, Inc. Address: 331 Northeast Rd., P.O. Box 412, Lonoke, AR 72086

EPA SLN NO. AR99-****

APPENDIX B1

R.E.D. FACTS
NICLOSAMIDE

R.E.D. FACTS

Niclosamide

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. The decisions for Niclosamide and TFM were combined into one publication because the use patterns are very similar and the compounds are often used together. This fact sheet summarizes the information in the RED document for reregistration case 2455, 2-amino ethanol salt of 2',5'-dichloro-4'-nitro salicylanilide (Niclosamide).

Use Profile

Niclosamide is used as (1) a lampricide to control sea lamprey larvae in tributaries to the Great Lakes, the Finger Lakes and Lake Champlain and (2) a molluscicide to control freshwater snails which carry the vectors for diseases which affect fish and humans. Less than 400 pounds of active ingredient niclosamide is used each year in lamprey and freshwater snail treatments. Niclosamide has been used as a human and veterinary drug for treatment of parasites.

Formulations include a 70% wettable powder (WP) and two granular formulations. The WP is applied by metered pump from the back of a boat or by backpack sprayer. The 3.2% granular product is applied with a backpack blower device that spreads the granules over a wide surface area.

Regulatory History

Niclosamide was first registered as a pesticide in the U.S. in 1964 by the U.S. Department of Agriculture (USDA), the Agency's predecessor for pesticide regulation under FIFRA. Currently, five niclosamide products are registered with EPA: a 70% WP for sea lamprey control, two Special Local Needs labels with the 70% WP, one 3.2% granular formulation, and one 5% granular formulation. The registrant has requested voluntary cancellation of the 5% granular product.

Human Health Assessment

Toxicity

Niclosamide has acute oral LD₅₀ values of >1000 mg/kg (Toxicity Category III). The acute dermal toxicity is minimal, as indicated by a LD₅₀ > 2000 mg/kg (Toxicity Category III). It produced slight skin irritation (Toxicity Category IV) and caused eye irritation (unclassified Toxicity Category based on short time interval of eye examination). It was a moderate skin sensitizer. The acute inhalation data are not available.

Niclosamide showed no evidence of causing developmental toxicity, mutagenicity or carcinogenicity.

Dietary Exposure

People are unlikely to be exposed to residues of niclosamide through the diet due to: the low amount of compound used, the United States Fish and Wildlife Service restrictions against removing irrigation and drinking water from streams during treatment, and the rapid dissipation of residues in fish and water. The Special Local Needs Labels for the use in ornamental fish ponds are also not likely to result in any dietary exposure. Tolerances have not been established and are not required for niclosamide.

Occupational and Residential Exposure

Occupational and residential risk assessments were not conducted for niclosamide based on the low volume used. Protective measures currently on niclosamide labels were considered adequate for the products being reregistered. All products are Restricted Use Pesticides and all labels require double layers of clothing and respirators. Industrial hygiene and medical monitoring programs are required routinely for all handlers of products containing niclosamide.

Human Risk Assessment

Risk assessments were not conducted for niclosamide based on the extremely low volume and infrequency of use. Niclosamide use is closely regulated by the US Fish and Wildlife Service and by the states which issued Special Local Need labels.

Environmental Assessment

Niclosamide is applied to freshwater tributaries and is therefore expected to have little impact on terrestrial plants and animals. Applications are designed to have minimal effects on fish, but other aquatic animals are expected to be impacted.

Environmental Fate

- In addition to dilution and dispersion, sorption to sediments and suspended particulates and possibly photodegradation (in clear shallow waters), are the major routes of dissipation of niclosamide. Neither hydrolysis nor volatilization from soil or water surfaces should be major fate processes for this compound.
- In most aquatic environments, niclosamide will adsorb to suspended solids and sediment and this binding is reversible.
- It is unclear what role, if any, aerobic and anaerobic microbial degradation plays in the dissipation of niclosamide in the aquatic environment.
- Accumulation in fish is not expected.

Ecological Effects

- Avian acute- **moderately toxic** (LD_{50} 60 mg/kg)
- Avian subacute dietary- practically **nontoxic** (LC_{50} > 5,419 mg/kg diet)
- Mammalian acute- practically **nontoxic** (LD_{50} > 1,000 mg/kg)
- Fish (freshwater acute)- highly toxic to **very highly toxic** (LC_{50} 0.03 - 0.23 mg/L)
- Invertebrates acute- slightly to **very highly toxic** (EC_{50} 0.034-50 mg/L)
- Invertebrates chronic- (NOAEC 0.03 mg/L; LOEC 0.05 mg/L)
- Aquatic plants- toxic (0.04 to > 1,450 mg/L)

Environmental Risk Characterization

The effects of niclosamide at the treatment site are likely to be mitigated by photodegradation and the flushing action of the stream/river.

At the predicted treatment levels, acute high risk, acute restricted use, and endangered species levels of concern are exceeded for aquatic animals. Although niclosamide is likely to have an immediate effect on the aquatic community, the data suggest that most organisms recover quickly and the treatment area community structure returns to pre-treatment conditions within weeks or months. This recovery is site specific and may take much longer in certain environments. Certain species

may be significantly impacted, most notably the indigenous lamprey species. In general, however, native lamprey species have tended to populate the upper reaches of tributary streams, whereas the sea lamprey is more likely to inhabit lower reaches of the stream. Thus, nontarget species that may have been affected in the treatment area are repopulated through downstream migration from untreated areas. Furthermore, retreatment of the stream will not occur for at least 3 to 5 years. Additionally, a genuine effort is made to document where sensitive populations reside, and steps are undertaken to avoid treatments at concentrations known to be toxic to these organisms. The long-term effects remain uncertain to more sensitive species, such as indigenous lampreys, and to aquatic communities downstream from the treatment sites where chronic effects may be more likely.

Risk Mitigation

The use practices of niclosamide have been refined over the past several years in order to lower the impacts of these applications on non-target organisms and to lower occupational and non-occupational exposure to people. Niclosamide is a Restricted Use Pesticide and the labels refer users to the US Fish and Wildlife Service's Manual for Pesticide Applications. Additional mitigation required by the Agency includes minor clarifications of label language. Aerial applications were prohibited on some of the current labels and will be prohibited on all new labels in order to lessen chances of nontarget human and other terrestrial animal exposures to these restricted use compounds.

Additional Data Required

EPA is requiring the following additional generic studies for niclosamide to confirm its regulatory assessments and conclusions:

Photodegradation in Water	Guideline # 835-2240 (161-2)
Aerobic Aquatic Metabolism	Guideline # 835-4300 (162-4)
Anaerobic Aquatic Metabolism	Guideline #835-4400 (162-3)

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All niclosamide end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see attached labeling table from the Niclosamide RED document.

Regulatory Conclusion

The use of currently registered products containing niclosamide in accordance with approved labeling for sea lamprey control or in ornamental fish aquaculture will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, uses of several niclosamide products are eligible for reregistration.

The registrant has requested cancellation of the 5% granular product used to kill snails which carry the vector for Swimmer's Itch.

The use of the 70% WP as a molluscicide in Puerto Rico against snails which carry the vector for Schistosomiasis is considered to be ineligible pending additional use information and exposure data.

Niclosamide products will be reregistered for all other uses once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for niclosamide during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. The document is entitled Reregistration Eligibility Decision: 3-Trifluoro-Methyl-4-Nitro-Phenol CASE 3082 and Niclosamide CASE 2455. To obtain a copy of this RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See <http://www.epa.gov/REDs>.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the niclosamide RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the niclosamide RED, or reregistration of individual products containing niclosamide, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. *Carol Stewart*

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is ace.orst.edu/info/nptn.

Table 15: Summary of Required Labeling Changes for Niclosamide

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Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into a lampricide for use in tributaries to the Great Lakes, Lake Champlain or the Finger Lakes or into a molluscicide for use against fresh water snails.	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This chemical is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
End Use Products Intended for Occupational Use (Non-WPS)		
Restricted Use Pesticide is Triggered by Active Ingredient	"RESTRICTED USE PESTICIDE due to:"	Top of Front Panel and enclosed in a box.
	<i>For Bayluscide 70% WP insert: "acute inhalation toxicity, aquatic organism toxicity and to the need for highly specialized applicator training."</i>	
	<i>For Bayluscide 3.2% Granular: "to acute hazards to the eye, nontarget aquatic organisms, and to the need for highly specialized applicator training."</i>	
	"RESTRICTED USE PESTICIDE"	Immediately under the heading Directions for Use.

Table 15: Summary of Required Labeling Changes for Niclosamide

Description	Required Labeling	Placement on Label
PPE Requirements Established by the RED Based on the Active Ingredient. ¹	<p>"Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart."</p> <p>"Mixers, loaders, applicators and other handlers must wear:</p> <p>Long sleeved shirt and long pants</p> <p>Rubber boots & socks</p> <p>Chemical resistant gloves such as (registrant inserts correct glove type)</p> <p>Chemical resistant aprons or coveralls</p> <p>Face shield</p> <p>NIOSH approved respirator with:</p> <ul style="list-style-type: none"> - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or - a canister with any N,R,P or HE prefilter NIOSH approved organic vapor resistant respirator." 	<p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
User Safety Requirements	<p>"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry."</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

Table 15: Summary of Required Labeling Changes for Niclosamide

Description	Required Labeling	Placement on Label
User Safety Recommendations	<p>"User Safety Recommendations"</p> <p>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."</p> <p>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."</p> <p>"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards	<p>"Environmental Hazards"</p> <p>"This chemical is toxic to fish and aquatic invertebrates. Nontarget aquatic organisms may be killed at rates recommended on this label."</p> <p>"Directions for use must be strictly followed to minimize hazards to non-target organisms. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."</p> <p>"Local, State, and Provincial Fish and Game Agencies must be contacted before product is applied. Municipalities that use streams requiring treatment as potable water sources must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators that use streams requiring treatment as a source of irrigation water must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators must turn off their irrigation systems for a 24-hour period during and after treatment."</p> <p>"May not be used by unauthorized personnel."</p>	<p>Precautionary Statements under Environmental Hazards</p>
Application Restrictions	<p>"Do not apply this product in a way that will contact workers or other persons, either directly or through drift"</p>	<p>Directions for Use</p>

Table 15: Summary of Required Labeling Changes for Niclosamide

Description	Required Labeling	Placement on Label
Other Use/Application Restrictions	"Applicators must follow the instructions provided in the "Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey (<i>Petromyzon marinus</i>) Control Program" for correct rates of application. Prior to and during the application of this chemical, take all appropriate actions to notify public water users including notification actions specified in this manual."	Directions for Use under Application Instructions and/or General Precautions and Restrictions
Other Use/Application Restrictions	"Aerial applications of this product are prohibited."	Directions for Use under Application Instructions and/or General Precautions and Restrictions

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

APPENDIX C
CHEMAGRO CORPORATION DATA

CHEMAGRO CORPORATION

KANSAS CITY • MISSOURI • 64120

P. O. BOX 4913 • TELEPHONE AREA CODE 816 HUMBOLDT 3-4250

BAYLUSCIDE*

Molluscicide

ORIGIN

BAYLUSCIDE is a molluscicide being developed by Chemagro Corporation and will be manufactured in the United States by Chemagro Corporation under license. BAYLUSCIDE is protected by U.S. Patent No. 3,079,297; 3,113,067 and Canadian Patent No. 686,211.

CHEMISTRY

The chemical name of BAYLUSCIDE is:
Aminoethanol salt of 2',5-dichloro-4'-nitrosalicylanilide.

Its structural formula is:

PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Bright yellow crystalline powder.	Melting Point:	216° C.
Molecular Weight:	388.1		
Solubility:	Solubility in water (distilled) 230 ppm. $\pm$ 50 at room temperature; reduced solubility in hard waters.		
Stability:	Good thermal stability. The anilide has good stability to acids and alkali. The aminoethanol salt is probably converted to the anilide in acid or alkali.		

FORMULATIONS AVAILABLE FOR TESTING

BAYLUSCIDE is available for testing in the formulations listed below. It is requested that the nature of a contemplated project be specified when requesting samples.

BAYLUSCIDE 70% Wetttable Powder
BAYLUSCIDE Granulars
BAYLUSCIDE Technical (Available only for special purposes)
BAYLUSCIDE Analytical Standards available on request

*Reg. U.S. Pat. Off. by Farbenfabriken Bayer A.G., Chemagro Corporation licensee. Trademark in Canada.

MAMMALIAN TOXICITY

A. Acute Toxicity

<u>SPECIES</u>	<u>SEX</u>	<u>LD₅₀ mg./kg.</u>	<u>METHOD OF ADMINISTRATION</u>
Rats	Male	> 1,500*	Oral
Rats	Male	110	Intraperitoneal
Mice	-	15	Intravenous
Rabbits	-	4,000*	Oral
Cats	-	250*	Oral

*No mortality occurred at this level.

B. Subacute Toxicity

<u>SPECIES</u>	<u>SEX</u>	<u>ROUTE</u>	<u>DOSE</u>	<u>DURATION OF TEST</u>	<u>OBSERVATIONS</u>
Rats	Male	Oral	5 ppm. ration	90 days	No symptoms.
Rats	Female	Oral	5 ppm. ration	90 days	No symptoms.
Rats	Male	Oral	15 ppm. ration	90 days	No symptoms.
Rats	Female	Oral	15 ppm. ration	90 days	No symptoms.
Rats	Male	Dermal	200 mg./kg./day	21 days	No symptoms.
Rats	Female	Dermal	200 mg./kg./day	21 days	No symptoms.

RESIDUE ANALYSIS

A method for the determination of BAYLUSCIDE in water supplies has been published (R. Strufe, *Pflanzenschutz Nachrichten* 15:1962/1, pages 42-49). Copies of the method are available for distribution and will be furnished by Chemagro Corporation upon request.

BIOLOGICAL EFFECTIVENESS

BAYLUSCIDE is especially toxic to fresh water snails, such as those which serve as intermediate hosts of organisms causing schistosomiasis and fascioliasis in man. It has also shown excellent promise in laboratory and field trials as a fish toxicant for use in streams or impounded water. Toxic levels for all species of fish tested are well below 0.5 ppm. of active ingredient in the water. Other aquatic organisms such as crayfish, frogs, and clams may also be affected. BAYLUSCIDE has only a relatively slight effect on plankton and aquatic vegetation.

REGISTERED COMMERCIAL USES

This registration information may not be up to date and, for this reason, must not be used in connection with label recommendations.

70% Wettable Powder Formulation:

PEST	REMARKS
Fresh-water Snails Snail Eggs	FLOWING STREAMS: Sufficient quantities of BAYLUSCIDE 70% W.P. should be metered into the water to obtain a final concentration of 0.5 to 1 part per million active ingredient. For maximum kill of snails, the 0.5-ppm. concentration should be maintained for a 24-hour period; the 1-ppm. rate should be applied continuously over a 6-hour period. Repeat treatment as necessary.
Fresh-water Snails Snail Eggs	IMPOUNDED WATER: Apply sufficient quantities of BAYLUSCIDE 70% W.P. to obtain a final concentration of 0.5 ppm. actual toxicant in the water (1.92 pounds of 70% W.P. per acre-foot of water). Repeat treatment as required.
Restrictions: For use in Puerto Rico only. For use only by public health officials and other trained personnel of public health programs. Toxicity to fish and certain amphibians may occur at concentrations above 0.5 ppm.	

5% Heavy Granular Formulation:

PEST	REMARKS
Fresh-water Snails (vectors of swimmer's itch) (Michigan, Minnesota, Wisconsin only)	Apply 100 pounds of BAYLUSCIDE 5% Granular evenly over each surface acre of water. Use equipment that can be accurately calibrated to distribute the required amount of granules evenly over the area to be treated. Treat only those areas where surveys have shown snail beds to be present. To minimize the hazard to fish, apply to only 1/3 of a selected treatment area at a time. Allow 24 hours between applications at each site. One application of these specially prepared granules will effectively control snail populations in lakes and ponds.
Restrictions: For use only by specially trained state and federal employees in the areas of public health, water resources or conservation or under their direct supervision. Consult State and/or Federal Fish and Game Agencies before applying this product. When applied as directed, BAYLUSCIDE will not harm game fish populations that may be present in treated waters. BAYLUSCIDE applications will be toxic to freshwater clams and mussels and may be toxic to fish species unable to maintain a position above the lake bottom.	

ANTICIPATED REGISTRATIONS

Registration is anticipated within the next year for the following uses:

As a total fish toxicant.

Control of lamprey eel larvae in combination with TFM.

FOR EXPERIMENTAL USE ONLY

The rates and uses mentioned in the following Sections, "Summary of Experimental Performance Data" and "Recommendations for Further Evaluation," are not registered for commercial use and are provided only for the information of and use by qualified persons engaged in research or experimental activities.

SUMMARY OF EXPERIMENTAL PERFORMANCE DATA

FISH

At the concentrations tested, BAYLUSCIDE acts rapidly against fish. Within a few minutes after application the fish become hyperactive, darting at high speeds and gasping for air. This is followed by a loss of equilibrium after which the fish can be observed swimming on their backs or sides. The fish gradually become less active until finally entering a state of paralysis, then death. The mode of action of BAYLUSCIDE involves, in part, blockage of oxygen uptake from the water. Preliminary data indicate that the toxic action of BAYLUSCIDE is reversible if fish are placed in fresh water before loss of equilibrium occurs.

Tabulated below are LC₅₀ concentrations in parts-per-million of active ingredient in the water for several common species of fish as determined in a laboratory test.

<u>SPECIES</u>	<u>WATER TEMPERATURE</u>	<u>LC₅₀ (PPM.) AT 24 HOURS</u>	<u>LC₅₀ (PPM.) AT 96 HOURS</u>
Largemouth Bass	17° C.	0.111	0.062
Smallmouth Bass	17° C.	0.089	0.060
Bluegills	12° C.	0.105	0.094
Bluegills	17° C.	0.082	0.068
Bigmouth Buffalo fish	17° C.	0.080	
Black Bullhead	12° C.	0.104	0.088
Brown Bullhead	17° C.	0.071	0.056
Carp	12° C.	0.143	0.139
Carp	17° C.	0.148	0.148
Carp	17° C.	0.245	0.225
Channel Catfish	17° C.	0.084	0.082
Fathead Catfish	17° C.	0.043	0.043
Goldfish	17° C.	0.279	0.230
Fathead Minnow	17° C.	0.106	0.102
Yellow Perch	17° C.	0.082	0.081
White Sucker	12° C.	0.084	0.081
Green Sunfish	17° C.	0.158	0.100
Redear Sunfish	17° C.	0.157	0.088
Tilapia	17° C.	0.180	0.109
Brook Trout	12° C.	0.061	0.061
Rainbow Trout	12° C.	0.052	0.050

The data above support the conclusion that carp and goldfish are somewhat more resistant to the effects of BAYLUSCIDE than other species and that fathead catfish are the least resistant. Additional data are needed to delineate the specificity of BAYLUSCIDE against different fish species. Also of interest is the fact that LC₅₀ levels at 24 and 96 hours after application are nearly identical for many of the species tested.

In another laboratory test, BAYLUSCIDE was found to be less toxic to rainbow trout than the data above would indicate. Concentrations of 0.12 ppm. or less caused no mortality within 22 hours. Concentrations of 0.13 to 0.20 ppm. caused mortalities ranging from 10 to 90 percent within 22 hours. Mature brown trout were found to be more sensitive to BAYLUSCIDE than rainbow trout. Complete mortality of brown trout occurred within 90 minutes at concentrations of 0.16 ppm. and higher.

In either flowing streams or impounded waters BAYLUSCIDE is not subject to removal by suspended organic matter nor to degradation by sunlight. In alkaline waters, somewhat higher dosages of BAYLUSCIDE are required for effective fish removal. Data indicate that variations in water hardness between 44 and 376 ppm. do not alter the toxicity of BAYLUSCIDE. There is some preliminary evidence of microbial degradation of BAYLUSCIDE. One recent paper reports that a bacterium, tentatively identified as a pseudomonad is capable of utilizing BAYLUSCIDE as its sole nitrogen source. This bacterium was frequently isolated from the intestinal tracts of fish and fresh water snails.

Field trials with BAYLUSCIDE have been conducted in rivers, ponds, lakes, and reservoirs using concentrations of 0.1 to 1 ppm. active ingredient in the water with much success. These concentrations have eliminated such species as yellow perch, pumpkin seeds, spottail shiners, bullheads, green sunfish, carp, log perch, smallmouth bass, and species in the genera *Tilapia*, *Protopterus*, *Clarias*, *Barbus*, and *Astatoreochromis*. On the basis of results obtained to date, BAYLUSCIDE appears toxic to all species of fresh water fish. Other aquatic organisms such as crayfish, frogs, and clams are also affected by applications of BAYLUSCIDE at these concentrations. However, planktonic organisms are only slightly affected and populations return to pre-treatment levels about two weeks after treatment.

SUMMARY OF EXPERIMENTAL PERFORMANCE DATA (Continued)

The data indicate that BAYLUSCIDE remains at toxic levels in ponds for relatively short periods of time. In one test, 0.5 ppm. of BAYLUSCIDE was completely detoxified within ten days at water temperatures ranging from 9° to 27° C. Results from another test are tabulated below.

Concentration of BAYLUSCIDE in ppm. in Water

	Pond A	Pond B	Pond C	Pond D
Applied (calculated)	1.0	0.5	0.3	0.3
Immediately after treatment	1.3	0.4	1.5	0.3
24 hours later	0.2	0.4	0.4	trace*
48 hours later	trace	0.25	trace	trace
1 week later	trace	0.2	trace	0.3

*Less than 0.2 ppm.

Apparent synergism occurred on one test where BAYLUSCIDE was applied to a pond which had been previously treated with a product containing rotenone. This pond remained toxic to fish for six weeks.

SNAILS

BAYLUSCIDE at concentrations of 0.5 to 1 ppm. active in water will effectively control all stages of several species of snails.

Concentrations as low as 0.2 ppm. have given control of young snails after exposure to BAYLUSCIDE for a 24-hour period. Good kill of newly laid eggs was also obtained at this concentration after an exposure period of 6 hours. In laboratory tests, 100% mortality of snails was obtained after an exposure of 1 hour to 5 ppm. At 2, 3, and 4 ppm., the range of mortality was 97 to 100%.

In a flowing stream, 1 ppm. introduced continuously for a 12-hour period gave control of snails for one month over a distance of three miles downstream. BAYLUSCIDE is basically stable in water and is only slightly affected by sunlight or contamination by organic matter.

Free-living larval stages of certain trematodes are very susceptible to BAYLUSCIDE. Tests have shown that miracidia and cercariae of *Schistosoma* spp. are killed after a few minutes exposure to BAYLUSCIDE at a concentration of 0.3 ppm. A concentration of 0.1 ppm. gave effective kill when miracidia and cercariae were exposed for longer periods.

The 5% heavy granular applied at the rate of 100 pounds per surface acre has given excellent kill of snails (*Stagnicola emarginata*, *Compaloma*, *Helisoma*, and *Lymnaea stagnicolus*) which serve as intermediate hosts for organisms causing swimmer's itch. The use of BAYLUSCIDE heavy granular formulation has been successful in depositing the required concentration of toxicant on the bottom of lakes. These treatments for snail control have killed darters and clams, but did not affect bluegills, perch, or shiners.

Concentrations of 0.5, 0.7, and 1 ppm. gave excellent control of snails (*Physa* sp. and *Helisoma* sp.) in laboratory tests. These two snail species were effectively controlled on water cress with sprays of BAYLUSCIDE applied at concentrations of 1, 5, 10, and 20 ppm. Phytotoxicity was observed at the 5-, 10-, and 20-ppm. levels.

Phytotoxicity was reported in a test in which a solution containing 2 ppm. of BAYLUSCIDE was sprayed on beds of watercress. Excellent control of snails was reported when the plants were treated at a concentration of 1 ppm. No phytotoxicity was observed at the 1 ppm. level.

No phytotoxicity has been observed on rice, oats, sugarcane, or aquatic vegetation when treated at concentrations needed for snail control.

SEA LAMPREYS (*Petromyzon marinus*)

A combination of 0.5% to 2% BAYLUSCIDE plus 98% to 99.5% TFM (3-trifluoro-methyl-4-nitrophenol) has proved to be very effective for control of the sea lamprey. Applications were made to streams flowing into the Great Lakes. A concentration of 2 ppm. of the mixture gave good kill of lampreys and was not toxic to rainbow, brook, or brown trout. Higher concentrations were required to give effective kill in alkaline waters.

The 5% heavy granular has given control of sea lampreys in situations where normal stream treatment has not been effective such as in estuaries or unusually deep portions of streams. This same formulation has been extremely useful as a survey tool to determine populations of sea lampreys present before treatment.

RECOMMENDATIONS FOR FURTHER EVALUATION

Additional data are needed to fully delineate the biological activity of BAYLUSCIDE in fish management programs. The following suggestions are offered as a guide for future research:

1. Data have been presented in the Biological Effectiveness Section of this data sheet to show that BAYLUSCIDE may be selective in its toxicity to certain species of fish. Additional data are needed to determine if selective control can be obtained in field tests.
2. Additional data are needed to determine how soon after treatment restocking of fish may be undertaken. On the basis of present data, this period is estimated at three weeks, but it may be considerably shorter.
3. Additional data are needed to determine the conditions necessary for reversing the toxic action of BAYLUSCIDE in affected fish.
4. Another question of importance is whether BAYLUSCIDE exerts an ovicidal effect on fish eggs. This effect, if present, would be of practical value in complete restocking programs.
5. BAYLUSCIDE may be very useful as a fish harvesting tool in view of its low order of mammalian toxicity and probable reversibility of fish toxicity. Additional data are required to fully determine the potential of BAYLUSCIDE for this purpose.

The selection of rates for proposed tests should be made after thoroughly reviewing current registered uses for BAYLUSCIDE as well as the information presented in this data sheet.

In view of the toxicity of BAYLUSCIDE to various species of aquatic snails, it is recommended that additional testing be carried out for control of snails that serve as intermediate hosts for organisms causing diseases of man and animals. In addition, BAYLUSCIDE should be evaluated for the control of aquatic snails that attack aquatic vegetation of economic importance. Concentrations for evaluation should be in the range of 0.2 to 2 ppm. active in water.

In order to facilitate a more complete interpretation of data, we request that the batch number of each formulation be included in all reports of test results. This number is prominently displayed on the label of each container.

RESTRICTIONS

Crops upon which non-registered applications of BAYLUSCIDE are made should not be used for animal or human food.

CAUTION

May be harmful if excessive amounts are swallowed or inhaled. Wash thoroughly with soap and warm water after handling. Do not contaminate feed or food. Keep out of reach of children.

NOTICE

Material which may be furnished in connection with this Technical Data Sheet is for experimental use. While known information is included, experimentation may develop information which will change the hazards of use. Use of such material is at the risk of user.

APPENDIX D

Niclosamide Material Safety Data Sheet

THE WORLD'S FOREMOST MANUFACTURER OF RESEARCH
BIOCHEMICALS AND DIAGNOSTIC REAGENTSTELEPHONE: USA/CANADA 1-800-325-3010
OUTSIDE USA/CANADA call COLLECT 314-771-5750ATTN: SAFETY DIRECTOR
NATIONAL FISHERY
RESEARCH LABORATORY
P.O. BOX 8182630 FANTA REED ROAD
LA CROSSE WI 54602-0818

EMERGENCY PHONE 1-314-771-5765

DATE: 05/21/92
CUST#: 8-097-59831
PO#: 83420-P-2-0756

M A T E R I A L S A F E T Y D A T A S H E E T P A G E 1

IDENTIFICATION

PRODUCT #: N3510
CAS #: 50-65-7
MF: C13H8CL2N2O4

NAME: NICLOSAMIDE

SYNONYMS

BAY 2353 * BAYER 73 * BAYER 2353 * BAYLUSCID * BENZAMIDE, 5-CHLORO-N-(2-CHLORO-4-NITROPHENYL)-2-HYDROXY- * CHEMAGRO 2353 * N-(2'-CHLORO-4'-NITROPHENYL)-5-CHLOROSALICYLAMID (GERMAN) * 5-CHLORO-2'-CHLORO-4'-NITROSALICYLANILIDE * 2-CHLORO-4-NITROPHENYLAMIDE-6-CHLOROSALICYLIC ACID * N-(2-CHLORO-4-NITROPHENYL)-5-CHLOROSALICYLAMIDE * CLONITRALID * 2',5-DICHLORO-4-NITROSALICYLANILIDE * 2',5-DICHLORO-4'-NITROSALIZYLSAUREANILID (GERMAN) * DICHLORSALE * ENT 25823 * FENASAL * HL 2447 * 2-HYDROXY-5-CHLORO-N-(2-CHLORO-4-NITROPHENYL)BENZAMIDE * IOMESAN * IOMEZAN * NICLOSAMIDE * PHENASAL * VERMITIN * YOMESAN *

TOXICITY HAZARDS

TECS NO: VN8400000

SALICYLANILIDE, 2',5-DICHLORO-4'-NITRO-

TOXICITY DATA

TPR-RAT LD50: 250 MG/KG
L-MUS LD50: 1000 MG/KG
VN-MUS LD50: 7500 UG/KGZTMPA5 13,1,62
85DPAN -,71,76
ARZNAD 10,884,60

TARGET ORGAN DATA

BEHAVIORAL (CONVULSIONS OR EFFECT ON SEIZURE THRESHOLD)
LUNGS, THORAX OR RESPIRATION (DYSPPNAE)
PATERNAL EFFECTS (SPERMATOGENESIS)ONLY SELECTED REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES (RTECS)
DATA IS PRESENTED HERE. SEE ACTUAL ENTRY IN RTECS FOR COMPLETE INFORMATION.

HEALTH HAZARD DATA

ROUTE EFFECTS

HARMFUL IF SWALLOWED.
MAY BE HARMFUL IF INHALED.
MAY BE HARMFUL IF ABSORBED THROUGH THE SKIN.
MAY CAUSE IRRITATION.
MAY CAUSE NAUSEA AND GASTRO-INTESTINAL PAIN AND DISCOMFORT
THE TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY
INVESTIGATED.FIRST AID
IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.
CALL A PHYSICIAN.
IN CASE OF SKIN CONTACT, FLUSH WITH COPIOUS AMOUNTS OF WATER

CONTINUED ON NEXT PAGE

SIGMA CHEMICAL CO. LTD.

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España.SIGMA CHIMIE S.p.A.
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36297 La Verpilliere
Cedex FranceSIGMA CHIMICA
Via P. Toselli, 4
20127 - Milano.SWITZERLAND CHEMIE
P.O. Box 260
CH-9470 Buchs
Switzerland

CHEMICAL COMPANY

THE WORLD'S FOREMOST MANUFACTURER OF RESEARCH
BIOCHEMICALS AND DIAGNOSTIC REAGENTS

FAX: USA/CANADA 1-800-325-6052 OUTSIDE USA/CANADA 314-771-5757
TELEX: 910-761-0593 or 434475 ANSWERBACK "SIG OK COLLECT"

TELEPHONE: USA/CANADA 1-800-325-3010
OUTSIDE USA/CANADA call COLLECT 314-771-5750

M A T E R I A L S A F E T Y D A T A S H E E T P A G E 2

CUST#: 8-097-59831
PO#: 83420-2-0756

PRODUCT #: N3510
CAS #: 50-65-7
MF: C13H8CL2N2O4

NAME: NICLOSAMIDE

HEALTH HAZARD DATA

FOR AT LEAST 15 MINUTES. REMOVE CONTAMINATED CLOTHING AND
SHOES. CALL A PHYSICIAN.
IF INHALED, REMOVE TO FRESH AIR. IF BREATHING BECOMES DIFFICULT,
CALL A PHYSICIAN.
IN CASE OF CONTACT WITH EYES, FLUSH WITH COPIOUS AMOUNTS OF WATER
FOR AT LEAST 15 MINUTES. ASSURE ADEQUATE FLUSHING BY SEPARATING
THE EYELIDS WITH FINGERS. CALL A PHYSICIAN.

PHYSICAL DATA

PEARANCE AND ODOR
SOLID.

FIRE AND EXPLOSION HAZARD DATA

EXTINGUISHING MEDIA
WATER SPRAY.
CARBON DIOXIDE, DRY CHEMICAL POWDER OR APPROPRIATE FOAM.
SPECIAL FIREFIGHTING PROCEDURES
WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO
PREVENT CONTACT WITH SKIN AND EYES.
USUAL FIRE AND EXPLOSION HAZARDS
EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

REACTIVITY DATA

ABILITY
STABLE.
DANGEROUS COMBUSTION OR DECOMPOSITION PRODUCTS
TOXIC FUMES OF:
CARBON MONOXIDE, CARBON DIOXIDE
NITROGEN OXIDES
DANGEROUS POLYMERIZATION
WILL NOT OCCUR.

SPILL OR LEAK PROCEDURES

EPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED
WEAR PROTECTIVE EQUIPMENT.

CONTINUED ON NEXT PAGE

OFFICES AT:

HEMCO, CO. LTD.
at P.O.
117
50c

SIGMA CHEMIE GmbH
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8036 Dessenhofen
Deutschland

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SWITZERLAND CHEMIE
P.O. Box 260
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BIOCHEMICALS AND DIAGNOSTIC REAGENTSTELEPHONE: USA/CANADA 1-800-325-3010
OUTSIDE USA/CANADA call COLLECT 314-771-5750

M A T E R I A L S A F E T Y D A T A S H E E T P A G E 3

CUST#: 8-097-59831
PO#: 83420-2-0756PRODUCT #: N3510
CAS #: 50-65-7
MF: C13H8CL2N2O4

NAME: NICLOSAMIDE

SPILL OR LEAK PROCEDURES

SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
• AVOID RAISING DUST.
• VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.
SEE DISPOSAL METHOD
DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A
CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.

--- PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE ---

WEAR APPROPRIATE NIOSH/MSHA-APPROVED RESPIRATOR, CHEMICAL-RESISTANT
GLOVES, SAFETY GOGGLES, OTHER PROTECTIVE CLOTHING.
MECHANICAL EXHAUST.
BEL PRECAUTIONARY STATEMENTS
HARMFUL
HARMFUL IF SWALLOWED.
WEAR SUITABLE PROTECTIVE CLOTHING.

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE
EXHAUSTIVE AND SHALL BE USED ONLY AS A GUIDE. SIGMA SHALL NOT BE HELD
RESPONSIBLE FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE
PRODUCT. SEE REVERSE SIDE OF INVOICE OR PACKING SLIP FOR ADDITIONAL
TERMS AND CONDITIONS OF SALE.

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DEPARTMENT OF AGRICULTURE

W. RALPH PECK, DIRECTOR
(406) 444-3144

AGRICULTURAL SCIENCES DIVISION
303 N ROBERTS, PO BOX 200201
HELENA, MT 59620-0201

GARY GINGERY, ADMINISTRATOR
(406) 444-2944

FAX (406) 444-7336

INTERNET agr@state.mt.us

TTD (406) 444-4687

January, 1998

MEMORANDUM

TO: Applicants for Special Local Needs (SLN),
FIFRA Section 24(c), Registrations in Montana

FR: Daniel Sullivan
Programs Coordinator
Telephone: 406-444-3731; Fax: 406-444-7336; E-mail: dasullivan@state.mt.us

RE: Application Requirements

The following information is typically needed to evaluate proposed special local needs, 24(c) registrations:

- 1) A completed EPA Application/Notification form.
(EPA Form 8570-25; Date 12/87)
- 2) A copy of the proposed supplemental labeling. For new products, a copy of the complete proposed labeling.
- 3) A copy of the current EPA-approved FIFRA Section 3 labeling.
- 4) Technical data sheets, an MSDS, or other information to assess potential health hazards, including recognized chronic effects. Additional safety data may be needed to determine whether the pesticide is safer than EPA-registered alternatives.
- 5) Documentation of a tolerance or exemption from tolerance if necessary for the proposed use (e.g. a copy of the Federal Register notification).
- 6) Residue data to insure that residues from the proposed use pattern or rates do not exceed established tolerances.

- 7) Efficacy data to demonstrate that the pesticide is more effective than EPA-registered alternatives or to insure that claims made for the pesticide are warranted. If data are not available, expert evaluations may be acceptable.
- 8) A summary of environmental information, including toxicity to fish and wildlife, phytotoxicity, degradation mechanisms, persistence, and mobility. Information from nearby areas will be considered if Montana information is not available.
- 9) Information regarding status of any Reregistration Standard, Special Review, or data-call-in by EPA including a summary of data gaps identified and any plans or studies in progress to support continued registration.
- 10) Documentation for why alternative products are not available in sufficient quantity, if applicable.
- 11) For new products, a certified statement of formula.
- 12) For new products, any additional information that might be useful in making a "no unreasonable adverse effects" determination.
- 13) Describe the special local need - the existing or imminent pest problem within Montana for which there is no appropriate federally registered pesticide product available. A letter(s) of need from potential users in Montana is useful in the evaluation process.

This information should be included in each application package. Three copies of the package should be supplied to facilitate review. The Montana Pesticides Act requires that all 24(c) applications be reviewed by three agencies - the Department of Agriculture, the Department of Public Health and Human Services, and the Department of Fish, Wildlife and Parks.

When the complete application packages are received, we will document that a special local need exists and submit copies of the package to the Department of Public Health and Human Services and to the Department of Fish, Wildlife, and Parks. We will notify you of our decision after the review is completed, usually within a month. If registration is approved, we will assign an SLN Number, send you a registration form and information sheet, and notify EPA about the registration. There is a one-time \$70 fee for every 24(c) registration. Six copies of the final printed labeling should be submitted within 45 days of registration.

If you have any questions or need more information about our 24(c) registration process, please contact me or Janet Kirkland, Registration Specialist, (406) 444-5400. Thank you.

APPENDIX E

Special Local Need Application Form

APPENDIX B2

Reregistration Eligibility Decision:
3-Trifluoro-Methyl-4-Nitro-Phenol
and
nicosamide

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-99-007
November 1999

Reregistration Eligibility Decision (RED)

3-Trifluoro-Methyl-4-Nitro-Phenol and Niclosamide

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case for the active ingredients TFM and Niclosamide. The enclosed Reregistration Eligibility Decisions (REDs), which were approved on September 30, 1999, contain the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Linda Propst at (703) 308-8165. Address any questions on required generic data to the Special Review and Reregistration Division representative Laura Parsons at (703) 305-5776.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

REREGISTRATION ELIGIBILITY DECISION

3-Trifluoro-Methyl-4-Nitro-Phenol

CASE 3082

and

Niclosamide

CASE 2455

Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**—Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk (RED-SRRD-PRB)
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk (RED-SRRD-PRB)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**—EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

**SUMMARY OF INSTRUCTIONS FOR RESPONDING TO
THE REREGISTRATION ELIGIBILITY DECISION (RED)**

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If generic data are required for reregistration, a DCI letter will be enclosed describing such data. If product specific data are required, a DCI letter will be enclosed listing such requirements. If both generic and product specific data are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the product specific response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must make sure that they meet the Agency's acceptance criteria (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	v
I. INTRODUCTION	1
II. CASE OVERVIEW	1
A. Chemical Overview	1
B. Use Profile	2
C. Estimated Usage of Pesticide	4
D. Data Requirements	5
E. Regulatory History	5
III. SCIENCE ASSESSMENT	7
A. Physical Chemistry Assessment for TFM	7
B. Human Health Assessment for TFM	7
1. Toxicology Assessment	7
a. Acute Toxicity	7
b. Subchronic Toxicity	8
c. Developmental Toxicity	9
d. Mutagenicity	10
2. Dose Response Assessment	11
a. Dermal and Inhalation Exposure (any time period)	11
b. Cancer Classification	12
3. Exposure Assessment	12
a. Dietary Exposure	12
b. Occupational/Residential Exposure	12
4. Risk Characterization and Occupational Exposure	12
C. Physical Chemistry Assessment for Niclosamide	14
D. Human Health Assessment for Niclosamide	14
1. Toxicology Assessment	14
a. Acute Toxicity	14
b. Subchronic Toxicity	15
c. Chronic Toxicity/Carcinogenicity	17
d. Developmental Toxicity	18
e. Mutagenicity	19
E. Dose Response Assessment	20
1. Exposure Assessment	20
a. Dietary Exposure From Food and from Drinking Water	20
b. Occupational/Residential Exposure	20
2. Risk Characterization	21

	a.	Dietary Risk including Drinking Water Risk	21
	b.	Occupational/Residential Risk	21
F.		Environmental Assessment for TFM	21
	1.	Ecological Toxicity Data	21
	a.	Summary	21
	b.	Toxicity to Terrestrial Animals	22
		(1) Avian Acute Oral, Subacute Dietary and Chronic	22
		(2) Mammals, Acute and Chronic	22
		(3) Insects	22
	c.	Toxicity to Freshwater Aquatic Organism	22
		(1) Freshwater Fish, Acute and Chronic	22
		(2) Freshwater Invertebrates, Acute and Chronic	23
		(3) Toxicity to Estuarine/Marine Organisms	24
	d.	Toxicity to plants	24
	2.	TFM Environmental Fate and Transport	24
	a.	TFM Degradation	25
	b.	TFM Metabolism	26
	c.	TFM Mobility	27
	d.	TFM Accumulation	28
	3.	TFM Aquatic Exposure Assessment	28
G.		Environmental Assessment for Niclosamide	28
	1.	Ecological Exposure and Risk Characterization for Niclosamide	28
	a.	Summary	28
	b.	Toxicity to Terrestrial Animals	29
		(1) Avian Acute Oral, Subacute Dietary and Chronic	29
		(2) Mammals, Acute and Chronic	29
		(3) Insects	29
	c.	Toxicity to Aquatic Animals	29
		(1) Freshwater Fish, Acute and Chronic	29
		(2) Freshwater Invertebrates, Acute, Chronic	30
		(3) Toxicity to Estuarine and Marine Organisms	30
	d.	Toxicity to Aquatic Plants	30
	2.	Niclosamide Environmental Fate and Transport	31
	a.	Niclosamide Chemical Degradation	31
	b.	Niclosamide Mobility	32
	c.	Niclosamide Bioaccumulation	33
	d.	Niclosamide Field Studies	33
	3.	Niclosamide Aquatic Exposure Assessment	34
H.		Environmental Exposure and Risk Characterization for TFM and Niclosamide	34
	a.	Risk presumptions	34
	b.	Environmental Risk Assessment	35
	c.	Exposure and Risk to Non-target Terrestrial Organisms	36

d.	Exposure and Risk to Non-Target Freshwater Aquatic Organisms	36
(1)	Acute Fish	36
(2)	Chronic Fish	37
(3)	Acute Aquatic Invertebrates	38
e.	Plants	38
f.	Endangered Species	39
I.	Environmental Risk Characterization	39
1.	Terrestrial	42
2.	Aquatic	42
3.	Uncertainties	46
IV.	RISK MANAGEMENT AND REREGISTRATION DECISION	47
A.	Determination of Eligibility	47
B.	Determination of Eligibility Decision	47
1.	Eligibility Decision	47
2.	Eligible and Ineligible Uses	48
C.	Regulatory Position	48
1.	Food Quality Protection Act Findings	50
a.	Determination of Safety for U.S. Population	50
b.	Endocrine Disruptor Effects	50
2.	Tolerance Reassessment	50
3.	Benefits from Use of TFM/Niclosamide	50
4.	Human Health Risk Mitigation	51
5.	Ecological Risk Mitigation	52
6.	Labeling Rationale	53
V.	ACTIONS REQUIRED OF REGISTRANTS	55
A.	Manufacturing-Use Products	55
B.	End-Use Products	56
1.	Additional Product-Specific Data Requirements	56
2.	Labeling Requirements for End-Use Products	57
C.	Required Labeling Changes Table Summary	57
D.	Existing Stocks	65
VI.	APPENDICES	67
A.	TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION	69
B.	TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION	75

C.	CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY)	85
D.	COMBINED GENERIC AND PRODUCT SPECIFIC DATA CALL-IN	99
1.	Chemical Status Sheets	123
2.	Combined Generic and Product Specific DCI Response Forms (Insert A) Plus Instructions	127
3.	Generic and Product Specific Requirements Status and Registrants' Response Forms (Insert B) and Instructions ...	137
4.	EPA's Batching of TFM and Niclosamide Products for Meeting Acute Toxicity Data Requirements for Reregistration	155
5.	List of All Registrants Sent This Data Call-In Notice	161
E.	LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS	163

TFM AND NICLOSAMIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis

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Richard Peacock	LUIS Representative for Niclosamide
William Gross	Herbicide and Insecticide Branch
Timothy Kiely	Economic Analysis Branch

Environmental Fate and Effects Assessment

Thomas Steeger	Environmental Risk Branch IV
Dana Spatz	Environmental Risk Branch IV

Health Effects Risk Assessment

William Hazel	Reregistration Branch 1
Whang Phang	Reregistration Branch 1
Virginia Dobozy	Reregistration Branch 1
Jeffery Dawson	Reregistration Branch 1

Registration Support

Daniel Peacock	Rodenticide and Insecticide Branch
----------------	------------------------------------

Risk Management

Laura Parsons	Reregistration Branch I
Mark Wilhite	Reregistration Branch I

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
Cl	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
LOAEL	Lowest Observed Adverse Effect Level
LUIS	Label User Information System
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
µg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q ₁	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RID	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

EPA has completed its reregistration eligibility decisions for the pesticides trifluoro-4-nitro-m-cresol (TFM; Case 3082) and niclosamide (Case 2455) and determined that all lampricide uses, when labeled and used as specified in this document, are eligible for reregistration. There are two Special Local Needs labels for niclosamide which are eligible for reregistration assuming monitoring programs similar to those conducted by the U.S. Fish and Wildlife Service (USFWS) are instituted for these uses. The public health molluscicide use of niclosamide against snails that carry vectors for swimmer's itch has been voluntarily canceled by the registrant. The public health use for use of niclosamide against snails that carry vectors for schistosomiasis is ineligible for reregistration at this time. These reregistration eligibility decisions include a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products.

This document contains the reregistration eligibility decisions for two compounds which are used alone or in combination against the same pest. TFM is the main chemical used to kill sea lamprey larvae in tributaries to the Great Lakes, the Finger Lakes, and Lake Champlain. Niclosamide is used to kill sea lamprey larvae in combination with TFM; granular niclosamide is also used in situations where TFM would not be appropriate, such as very deep waters, where it is cost prohibitive to treat the entire water column. Tributaries are screened for larvae which are ready to transform to the adult stage and when populations are high enough, the stream is treated. Streams harboring sea lamprey larvae are treated once every three to five years. Additionally, niclosamide is used as a molluscicide to kill freshwater snails which are vectors for human and fish disease agents.

There are no tolerances for TFM and niclosamide because the Agency considers the uses of these compounds to be non-food. Based on current use patterns and exposure profiles, residues in and on food and/or feed or in drinking water are not expected to occur. Therefore, a dietary risk assessment is not required.

Human risks from exposures to TFM and niclosamide do not exceed levels of concern for the currently registered uses. The USFWS exerts tight control over the use of these compounds including: (i) public notification prior to treating Great Lake tributaries to eliminate exposure to riparian water users including fishermen, boaters, and swimmers; (ii) dissemination of information describing the treatment programs and the associated application locations, dates, and duration; (iii) constant monitoring of the treated stream for TFM and niclosamide concentrations during treatment; (iv) if requested by a given state, concentrations at public water utility intakes are monitored and notification of state and local officials is made regarding monitoring results to permit implementation of activated charcoal use, if necessary; and (v) prohibition of irrigation during treatment.

There are ecological concerns with the use of these compounds since impacts are expected to non-target aquatic organism populations; however, the benefits of controlling the populations of the introduced sea lamprey are expected to outweigh the risks to aquatic organisms. Most nontarget species are far less sensitive to the lampricides than are sea lampreys, and only a few are as sensitive. Pretreatment assessments that determine abundance and distribution of sea lamprey larvae are used to identify specific

streams and stream reaches that require lampricide treatment. Sensitive nontarget species in the streams are identified prior to treatment, and measures are taken to protect them during applications of lampricides. Threatened or endangered species are identified through consultation with state and federal agencies. Procedures then are modified or developed, and employed to protect these species. Prior to treatment, toxicity tests and in-stream studies assess the effects of treatment on sensitive species or species of concern, and the results indicate if a modification of treatment procedures is required to assure the safety of nontarget organisms.

The USFWS which holds the registrations for these compounds has refined the use practices over the past several years in order to lower the impacts of these applications on non-target organisms and to lower occupational and non-occupational exposure to people. Additional mitigation required by the Agency includes minor clarifications of label language. Aerial applications were prohibited on some of the current labels and will be prohibited on all new labels in order to lessen chances of nontarget human and other terrestrial animal exposures to these restricted use compounds.

Some additional data are required to understand the photodegradation potential of TFM and niclosamide in water, and the aerobic and anaerobic aquatic behavior of niclosamide. The following data requirements are being held in reserve pending the results of an ongoing monitoring study the USFWS is currently conducting: the potential chronic effects of TFM and TFM/niclosamide mixture on fish and aquatic invertebrates, and the chronic sediment toxicity of niclosamide.

Before reregistering the products containing TFM and niclosamide, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the development and the submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "The Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration" before calling in data on products, and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to evaluate whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of TFM and niclosamide. The document consists of six sections. Section I is the introduction. Section II describes TFM and niclosamide, their uses, data requirements, and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. The human health assessment for TFM is discussed first, followed by the human health assessment for niclosamide. Next the environmental fate and ecotoxicity assessment of TFM is followed by this assessment for niclosamide. The final topic of Section III is a combined exposure and risk characterization of the two chemicals. Section IV presents the reregistration decision for TFM and niclosamide. Section V discusses the reregistration requirements for TFM and niclosamide. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

- Common Name: Lampricid®, TFM
- Chemical Name: 3-Trifluoromethyl-4-nitrophenol (IUPAC)
 α, α, α -trifluoro-4-nitro-m-cresol, sodium salt (CAS)
- Chemical Family: phenol
- CAS Registry Number: 88-30-2

- **OPP Chemical Code:** 036201
- **Empirical Formula:** $C_7H_5F_3NO_3$
- **Basic Manufacturer:** Clariant International (Germany)
H & S Chemical Company,

packed for USFWS (USA) and Fisheries and Oceans
Canada, Ottawa, Ontario (Canada).

- **Common Name:** Bayluscide, niclosamide
- **Chemical Name:** 5-chloro-N-(2-chloro-4-nitrophenyl)-2-hydroxybenzamide (IUPAC)
2-amino ethanol salt of 2',5'-dichloro-4'-nitro salicylanilide (CAS)
- **Chemical Family:** halogenated mononitrobenzamide
- **CAS Registry Number:** 1420-04-8
- **OPP Chemical Code:** 077401
- **Empirical Formula:** $C_{13}H_8Cl_2N_2O_4$
- **Basic Manufacturer:** Bayer, Specialty Products, Inc.

packed for USFWS (USA) and Fisheries and Oceans
Canada, Ottawa, Ontario (Canada).

B. Use Profile

TFM and Niclosamide:

Type of Pesticide:	lampricides
Use Sites:	tributaries to the Great Lakes, the Finger Lakes and Lake Champlain
Target Pests:	Larval stage of the Sea Lamprey (<i>Petromyzon marinus</i>)
Formulation Types:	
TFM:	Liquid concentrate (38%), Bar (solid)
Niclosamide	70% Wettable Powder, Granular (3.2% and 5%)

Niclosamide

Type of Pesticide:	Molluscicide for use against fresh water snails
Use Sites:	Special Local Needs labels: Commercial ponds for growing ornamental fish in FL and AR Public Health Uses: Swimmer's Itch in MI, MN and WI, Schistosomiasis in Puerto Rico

Formulation Types:

70% Wettable Powder in FL, AR, and Puerto Rico
5% Granular in MI, MN, and WI

Method and Rates of Application:

TFM is the primary chemical used to control sea lamprey; niclosamide is used with TFM under circumstances when TFM alone would pose too much risk to non-target organisms or would be cost prohibitive. Niclosamide alone is also used as a survey tool for determining lamprey larval populations and under certain conditions alone to treat deep, turbid waters. Specific application instructions and formulas for application rates are included in the *Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey (Petromyzon Marinus) Control Program including Standard Operating Procedures (1993)*. The different application methods complement each other to achieve effective control. There are various non-chemical means of control, such as weirs, traps, and a sterile male release program in place, but these non-chemical methods are not adequate to control lamprey populations without the use of TFM and niclosamide.

The liquid sodium salt formulation of TFM accounts for the majority of the applications. Most of these liquid TFM applications are made with a direct-siphoning meter pump system in which the liquid formulation is withdrawn from 5-gallon containers and routed directly into the treated stream. A rapid calculation for larger bodies of water is 1 ppm TFM in 1 acre-foot of water requires 0.75 gallons of TFM per surface area treated. Liquid TFM is also applied to many stagnant bodies of water that are connected to or isolated from the main river during treatment by backpack sprayer or by boat.

The TFM bar formulation is sometimes applied to small springs and tributaries to give a controlled release of TFM over a period of time. The rate of release depends on water velocity and temperature. Each bar is used to treat 0.25 ft³ per second of discharge at 1 ppm for 8 hours at 18°C or 0.8 ppm for 10 hours at 12°C. For best results, the USFWS manual recommends that TFM bars should be suspended at least one inch above the stream bottom to permit movement of water on all sides and should be placed where current velocity is < 0.5 feet per second.

The wettable powder (WP) formulation of niclosamide is generally used to make a liquid slurry which is not to exceed 20 pounds of the 70 WP (14 lb ai) in 100 gallons of water. Additionally, the concentration in the treated stream should not exceed 2 percent of the corresponding TFM concentration. The slurries are prepared in an open system and since niclosamide is not readily soluble in water, the slurry is constantly agitated and is delivered to the water surface by a peristaltic pump.

Applications of the granular 3.2% niclosamide formulation are used as a survey tool to "detect and collect sea lamprey larvae in deep and turbid waters where electrofishing is ineffective." Applications are made using a gasoline powered backpack blower device that spreads the granules over a wide area. This formulation can also be used in specific treatment areas where the water depth makes the use of TFM cost prohibitive.

Decisions regarding application rates and times are based on both abiotic and biotic factors including pH, stream discharge, time of day, temperature, total alkalinity, in-field bioassays, and lamprey population assessment data. Spreadsheet-based models incorporating the aforementioned factors have been developed to assist in determining application rates; the inter-relationship of the model input parameters is based on historical data collected from previous applications to specific streams and, as such, these predictive models are stream specific. Predicted treatment concentrations based on physico-chemical data are then modified based on in-field flow-through bioassays used to establish the site-specific $LC_{99.9}$ for sea lamprey larvae and the LC_{25} for brown trout. In Lake Superior and upper Lake Michigan, streams tend to have soft water with pH less than 8.2 and thus require lower application rates and are less likely to be candidates for niclosamide treatment. In the lower tier of the Great Lake, tributaries harboring lamprey may exhibit hardnesses exceeding 200 ppm with a pH range 8.1 - 8.7. These streams tend to have greater diurnal pH fluctuations and may require that lampricide applications be adjusted to reflect changing pH.

The manual states that while water concentrations of TFM are not to exceed 12 ppm, typical target concentrations are generally 1 to 6 ppm. Niclosamide target concentrations in hard water streams have ranged from 25 to 35 ppb; however, treatment concentrations are not allowed to exceed 50 ppb (personal communication, Dorance Brege, U.S. Fish and Wildlife Service Treatment Supervisor 1999).

The wettable powder formulation of niclosamide is also labeled for use in ornamental fish ponds in Florida and Arkansas. The product is applied to the bottom of drained ponds which are filled immediately. The filled ponds are then allowed to sit undisturbed for at least four days before ornamental fish are added (personal communication Craig Watson, Director, Tropical Aquaculture Laboratory, August, 1999).

The Fish and Wildlife Service has made some aerial applications of Bayluscide 3.2% granular formulation to the St. Mary's River in the US and Canada. The application is being made with a helicopter and the rate is similar to the granular application from a boat. This one-time aerial application is to treat 1562 surface acres of the St. Mary's River in Michigan over a three year period from 1998-2000. It is not physically or economically feasible to treat the St. Mary's River by boat since the time period when Bayluscide application can be made is very short in order to protect spawning fish and nesting osprey.

C. Estimated Usage of Pesticide

According to the U.S. Fish and Wildlife Service (Johnson and Weisser 1996), of the 5,339 streams tributary to the Great Lakes, only 309 in the US are known to be or have been infested with sea lampreys; there are 130 infested streams in Canada. Of the US streams, about 300 (<6%) have been treated since the chemical control of sea lampreys began in the 1960's. Currently, 166 streams (<3% of the total number of tributaries) are treated on a 3 - 5 year cycle. In a normal treatment year, 30 to 40 U.S. tributaries receive applications of lampricides. An average of approximately 80,000 pounds of TFM active ingredient and approximately 300 pounds of niclosamide active ingredient were applied in the Great Lakes from 1993 to 1997.

Specific use data were received from the USFWS for the years 1993 through 1997. Tables 1 and 2 summarize the use of both compounds during these years.

Table 1: Summary of TFM use by the USFWS in the Great Lakes Region (1993-1997)					
Lake	1993	1994	1995	1996	1997
pounds active ingredient used					
Superior	6717	19991	15997	12083	18768
Michigan	18150	31219	25507	29811	22959
Huron	40371	26953	24065	14605	27926
Erie	0	9561	414	5981	2815
Ontario	9438	7026	10307	11001	6442
Total	74676	94750	76290	73481	78910

Table 2: Summary of Niclosamide use by the USFWS in the Great Lakes Region (1993-1997)					
Lake	1993	1994	1995	1996	1997
pounds active ingredient used					
Superior	0	53	114	18	197
Michigan	0	251	53	207	103
Huron	74	33	198	16	89
Erie	0	0	0	0	0
Ontario	7	16	0	33	21
Total	81	353	365	274	410

D. Data Requirements

The Agency required the registrants to submit studies as specified in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

The sea lamprey (*Petromyzon marinus*) is a primitive eel-like fish distinguished from other fishes by its lack of paired fins and jaws. Sea lampreys are closely related to the hagfish, and are generally found as adults in saltwater. Most of the life of a sea lamprey is spent as a larva burrowed in the sediment of fresh water streams. In this life stage, the animal is not harmful to other fish and feeds by

filtering food from stream water. Sea lampreys may remain in the larval stage from 3 to more than 17 years before transforming into the parasitic (predatory) stage. Parasitic stage lampreys feed by attaching to fish and rasping deep wounds from which they suck blood, body fluids, and pieces of flesh. The results of such attacks are often fatal for the host fish.

Sea lampreys were introduced to the Great Lakes when the Welland Canal around Niagara Falls was constructed in 1829; by the late 1940's, lampreys had severely impacted the commercial and sport fisheries in the Great Lakes. Early attempts to control sea lampreys began in 1953 with the installation of mechanical traps in spawning streams, but these measures were largely unsuccessful. No effective control was accomplished until the advent of a chemical control program with TFM (Lamprecid®) and niclosamide (Bayluscide) in the late 1950's. According to the USFWS "the successful chemical control of sea lampreys has allowed reestablishment of a robust sport and commercial fishery in the Great Lakes." These compounds have been used since that time to manage the sea lamprey populations in the Great Lakes, the Finger Lakes, and Lake Champlain. The use of these chemicals is managed by the Great Lakes Fisheries Commission and its agents. The Commission was established by the *Convention on Great Lakes Fisheries Between the United States of America and Canada* to enhance and protect fisheries in the Great Lakes.

In 1964, the U.S. Department of Agriculture (USDA), the Agency's predecessor for pesticide regulation under FIFRA, registered its first product with TFM, a liquid formulation for control of sea lamprey larvae. In the same year, USDA first registered a product containing niclosamide, a wettable powder formulation for control of sea lamprey larvae and snails. In 1967, USDA registered two manufacturing-use products containing niclosamide. In 1968, USDA registered its first granular niclosamide products for sea lamprey larvae and snail control. In 1984, the EPA registered a new form of TFM, a bar formulation, for sea lamprey control.

Currently the Agency has two registered TFM products, a liquid and bar formulation, for sea lamprey larvae. It has also currently registered seven niclosamide products, five federal (Section 3 under FIFRA) and two Special Local Need (Section 24c under FIFRA) products.

TFM (Lamprecid®) is an aquatic non-food outdoor use chemical. The lampricides (TFM and niclosamide) Phase 4 review dated 03/21/92 summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Additional submissions of data have been received since the Phase 4 Review was issued. There are currently no tolerances for TFM or niclosamide residues in/on food/feed commodities. The Agency has determined that the TFM residues in fish are parent TFM and the TFM-glucuronide conjugate.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment for TFM

TFM (Lamprecid®) is chemically α,α,α -trifluoro-4-nitro-m-cresol. Pure TFM is a yellow to orange crystalline solid, with a melting point of 76° C and ionization constant of 4.4×10^{-7} . The TGAI is a dark red-brown liquid with a boiling point of 135-138° C, a density of 1.463 g/mL, and a vapor pressure of 22 mm Hg at 25° C. TFM is soluble in water (0.498 g/100 g water at 25° C), and highly soluble in most organic solvents. Aqueous solutions of TFM are acidic with free phenol ($pK = 6.07$) and form phenolate salts in alkali conditions.

B. Human Health Assessment for TFM

1. Toxicology Assessment

a. Acute Toxicity

The data on acute mammalian toxicity are summarized in Table 3. TFM has acute oral LD_{50} values of 141 and 160 mg/kg for males and females, respectively (Toxicity Category II). The acute dermal toxicity is minimal, as indicated by a $LD_{50} > 2000$ mg/kg (Toxicity Category III). It produced slight skin irritation (Toxicity Category IV) and caused eye irritation which was cleared within seven days after application (Toxicity Category III). It was not a dermal sensitizer. The acute inhalation data are not available.

Table 3. Summary of the Results of Acute Toxicity Studies on Technical Grade TFM¹

GUIDE-LINE #	STUDY TYPE	MRID #	RESULTS	TOXICITY CATEGORY
81-1	Acute oral-rat	40999204 41898102	LD ₅₀ = 160 mg/kg (M) LD ₅₀ = 141 mg/kg (F);	II
81-2	Acute dermal-rabbit	40999205 41898103	LD ₅₀ > 2000 mg/kg;	III
81-3	Acute inhalation			Not available
81-4	Primary eye irritation - rabbits	40999207 41898104	Eye irritant (corneal opacity, conjunctival redness, chemosis, & discharge; all clear by day 7 after treatment)	III
81-5	Primary dermal irritation - rabbits	40999206 41898105	Slight erythema seen on the treatment site.	IV
81-6	Dermal sensitization	41898106	Not a dermal sensitizer	

1. The acute toxicity endpoints, listed above, are for informational purposes only. The data supporting these endpoints may or may not meet current acceptability criteria. The acceptability status of these data may be reassessed during product reregistration.

b. Subchronic Toxicity

The results did not show significant toxicity in two 90-day feeding studies in rats and in a 6-month feeding study in dogs.

In a 90-day feeding study in rats (MRID 00112726), groups of weanling SD rats (10/sex/group) were fed diets containing TFM (82.4%) at concentrations of 500, 900, 1620, 2916, or 5248 ppm for 90 day. The control groups (20/sex) received the untreated diet. The results showed that body weight, food consumption, food efficiency, and hematological parameters were similar to those of the controls. Observation data did not indicate any clinical signs in the treated rats. For clinical chemistry, there was a decrease in aspartate aminotransferase (SGOT or AST) in both treated males and females of all groups. However, this change did not show a dose-related effect, and was not considered biologically significant. All other clinical parameters were similar to those of the controls. Organ weights, gross pathology, and histological data did not show a treatment-related effect. The NOAEL for this study was 5248 ppm (525 mg/kg/day, based on 1 ppm=0.1 mg/kg for young rats) which was the highest dose tested. No LOAEL was established.

In a second 90-day feeding study in rats (MRID 00112727), groups of weanling SD rats (10/sex/group) were fed diets containing TFM (90%) at concentrations of 500, 900, 1620, 2916, or 5248 ppm for 90 days. The control groups (20/sex) received the untreated diet. The results showed that body weights of the 2916 and 5248 ppm groups were consistently decreased (10-13%) in males from week 3 to the end of the study. The decrease was statistically significant. Food consumption, and

hematological parameters were similar to those of the controls. Clinical signs were not seen in the treated or control rats. There was a decrease in the aspartate aminotransferase (SGOT) activity in both males and females at 5248 ppm on the 21 day examination period, but by 90 day examination period the SGOT values of 5248 ppm animals were similar to those of the controls. The alkaline phosphatase level was slightly increased in both males and females of 5248 ppm groups, but no statistical significance was found. At sacrifice, liver weights of the 2916 and 5248 ppm females were slightly increased. No gross pathology and histological changes were observed. The LOAEL of this study was 2916 ppm (292 mg/kg/day, based on 1 ppm=0.1 mg/kg/day) based on decreased in body weights; the NOAEL was 1620 ppm (162 mg/kg/day).

A 90-day feeding study in dogs is not available, but there is a 6-month feeding study in dogs. In the 6-month feeding study in dogs (MRID 00112725), groups of beagle dogs (4/sex/dose; 8-10 weeks old) received TFM (85.6%) in the diet at concentrations of 300, 1250, or 5000 ppm for 6 months. The controls (4/sex) received 2% corn oil by weight. The results showed that a decrease in body weights was seen in both males (12-15%) and females (8-16%) of the 5000 ppm level beginning at 10 weeks. The body weight gains in these dogs were also decreased. Food consumption and food efficiency in 5000 ppm males and females also decreased, but not markedly. Clinical signs, hematology, clinical chemistry, and urinalysis values were similar between the control and the treated animals. No treatment-related changes in organ weight were seen in any treatment groups. Treatment-related gross and histological changes were not found in TFM treated dogs. Under the conditions of this study, the LOAEL was 5000 ppm (125 mg/kg/day; based on 1 ppm=0.025 mg/kg/day) based on decreases in body weights and body weight gains; the NOAEL was 1250 ppm (31.25 mg/kg/day).

c. Developmental Toxicity

In a developmental toxicity study (MRID 00131201), pregnant COBS® CD® (SD) Br rats (25/group) received TFM (85.9% a.i.) by gavage at doses of 0 (corn oil vehicle), 25, 125, or 250 mg/kg/day on gestation days (GD) 6-15, inclusive. It was not specified whether doses were adjusted for percent active ingredient. On GD 20, all dams were sacrificed and all fetuses were examined for external malformations/variations. Approximately one-half of each litter was placed in Bouin's fixative for subsequent visceral examination and the remainder stained for skeletal examination.

All animals in the control, low-, and mid-dose groups survived until scheduled sacrifice. Two high-dose dams died during the treatment interval, one on GD 6 and the other on GD 12 and the study author stated that the deaths were treatment related. The only other clinical sign of toxicity was salivation which was observed in 0/25, 0/25, 2/25, and 22/25 ($p \leq 0.01$) animals in the 0, 25, 125, and 250 mg/kg/day groups, respectively. There were no significant differences in maternal body weights between the treated and control groups at any time during gestation. Food consumption was not measured. Therefore, the maternal toxicity LOAEL is 250 mg/kg/day based on salivation and mortality. The corresponding maternal toxicity NOAEL is 125 mg/kg/day.

No treatment-related effects were observed for gravid uterine weights, number of fetuses/litter, pre- and postimplantation loss, numbers of corpora lutea/dam, number of implantations/dam,

resorptions/dam, fetal body weights, or fetal sex ratios. No statistically significant differences in the incidence rates of any external, visceral, or skeletal malformations/variants were observed in the treated litters as compared to the controls. Therefore, the NOAEL for developmental toxicity is 250 mg/kg/day (highest dose tested).

d. Mutagenicity

The available mutagenicity studies showed that TFM did not induce mutation in Ames assays (MRID 42551801). TFM was shown to be negative in a mouse micronucleus assay (*in vivo*) (MRID 42187101) and in an unscheduled DNA synthesis assay with primary rat hepatocytes (MRID 40999202). However, TFM produced chromosomal aberrations in an *in-vitro* cytogenetic assay in CHO cells, in the presence and absence of metabolic activation (MRID 40999201).

In an Ames assay (MRID 42551801), TFM (40.24%) was tested on *Salmonella* strains TA98, TA100, TA1535, TA1537, and TA1638. The doses used were 75, 100, 200, 300, or 400 $\mu\text{g}/\text{plate}$ in the presence and absence of the metabolic activation. The positive controls were 4-nitroquinoline-N-oxide, benzo(a)pyrene and N-methyl-N-nitro-N-nitroso-2-amino fluorene. TFM was shown to be negative for mutagenicity under the conditions of this test.

In a mouse micronucleus assay (MRID 42187101), groups of mice (5/sex/dose) received a single administration of TFM by gavage at doses of 80, 400, or 800 mg/kg. A negative control group (corn oil), a positive control group (cyclophosphamide, 80 mg/kg), and a secondary dose group (10 mice/sex)(TFM at 800 mg/kg) were included in this study. At 800 mg/kg of TFM, there were deaths within the first 24 hours after dosing. The results showed that under the conditions of this study, TFM did not induce a significant increase in the incidence of micronucleated marrow polychromatic erythrocytes. Therefore, TFM is considered as negative in the *in vivo* mouse micronucleus assay.

In an unscheduled DNA synthesis assay (MRID 40999202), freshly prepared rat hepatocytes were exposed to TFM (=86%) at final concentrations of 0.025, 0.05, 0.101, 0.252, 0.504, 1.01, 2.52, or 5.04 $\mu\text{g}/\text{ml}$. Concentrations $\geq 10.09 \mu\text{g}/\text{ml}$ were not listed because there was complete cytotoxicity and some precipitation. At 5.04 $\mu\text{g}/\text{ml}$, 5% of the cells died. Under the conditions of this study, TFM was negative for mutagenicity.

In an *in vitro* cytogenetic assay (MRID 40999201), cultured CHO cells were exposed to TFM (86%) at concentrations of 49.6, 99.2, 149, or 198 $\mu\text{g}/\text{ml}$ for 17.25 hrs. In absence of the S9 metabolic activation. In the presence of the S9 activation, the CHO cells were exposed to TFM at concentrations of 115, 384, 769, 1150, or 1540 $\mu\text{g}/\text{ml}$ for 2 hrs. After exposure to TFM, the treated cells were washed with buffered saline, and complete McCoy's a medium containing 0.1 $\mu\text{g}/\text{ml}$ Colcemid was added to the washed cells. The cells were then incubated for 2.5 hrs (without S9) or 7.5 hrs (with S9). The metaphase cells were then harvested, and slides prepared for analysis. The results showed that, without S9 activation, TFM at concentrations of 149 and 198 $\mu\text{g}/\text{ml}$ induced chromosomal aberrations, consisting mainly of simple chromatid breaks. In the presence of S9 activation, 1150 and 1540 $\mu\text{g}/\text{ml}$ of TFM

caused a statistically significant and dose-related increase in chromosomal aberrations, consisting of simple chromatid and chromosome breaks.

2. Dose Response Assessment

TFM has been classified as a low-volume and nonfood use chemical based on the quantity used, the method of application, and the rapid dissipation of any possible residues in fish and water. Therefore, the acute and chronic dietary toxicity endpoints and a dietary risk assessment are not required for TFM.

Based on the use and possible exposure scenarios, the relevant exposure is short-term occupational dermal exposure. No residential exposure is expected because TFM is applied in a very limited use area and extensive public notification is required by the USFWS to eliminate exposure to riparian water users including fishermen, boaters and swimmers. Inhalation toxicity endpoints for risk assessment were not selected because significant inhalation exposure is not expected; also TFM is a viscous dark liquid and certain formulations are in the form of solid bars.

Table 4. Summary of the Results of Subchronic Toxicity Studies on TFM

GUIDE-LINE #	STUDY TYPE	MRID No.	RESULTS	ENDPOINT
82-1a	feeding studies	00112726 rats	no treatment related effects	NOAEL = 5249 ppm (525 mg/kg/day) LOAEL not established
82-1a		00112727 rats	decreased body weights	NOAEL = 1620 ppm (162 mg/kg/day) LOAEL = 2916 ppm (292 mg/kg/day)
82-1b		00112725 dogs	decreased body weights and body weight gains	NOAEL = 1250 ppm (31 mg/kg/day) LOAEL = 5000 ppm (125 mg/kg/day)
83-3	developmental	00131201 rats	maternal salivation and mortality	NOAEL = 125 mg/kg/day LOAEL = 250 mg/kg/day
			litter no treatment related effects	NOAEL = 250 mg/kg/day LOAEL not established
84-2	mutagenicity	42551801	negative (Ames assay)	
		42187101	negative (mouse micro-nucleus assay)	
		40999202	negative (UDS assay)	
		40999201	positive (<i>in vitro</i> cytogenetic assay)	

a. Dermal and Inhalation Exposure (any time period)

A short-term dermal endpoint of 125 mg/kg/day was chosen based on a rat developmental toxicity study. The toxic effect was not developmental in nature with salivation and mortality as the effect in the dams. This is the most pertinent toxicity study to use for a dermal endpoint, and although no males

were evaluated, the endpoint has been applied to account for exposures to the general population including both males and females.

Although an inhalation toxicity endpoint was not selected, exposures contributed by the inhalation route were combined with the dermal exposures as a conservative measure.

b. Cancer Classification

There is an acceptable chronic feeding study in hamsters, and the results do not indicate that TFM induced an increase in any tumor incidence (MRID 00081184). A chronic feeding study in rats was also conducted in 1975 (MRID 00059379), but the results are not conclusive regarding whether TFM induced an increase in any specific tumor incidence. It should be noted that the chronic toxicity studies were conducted in the 1970's prior to implementation of the EPA Guidelines (1982) for toxicity testing. Because TFM is a nonfood use, the Agency does not require a cancer study.

3. Exposure Assessment

a. Dietary Exposure From Food and Drinking Water

TFM has been classified as a low-volume and nonfood use chemical based on the quantity used, the method of application, the USFWS restrictions against irrigation and drinking water removal from streams during treatment, and the rapid dissipation of any possible residues in fish and water. Therefore, the dietary exposure is expected to be minimal and a dietary risk assessment is not required for TFM.

b. Occupational/Residential Exposure

Based on the use and possible exposure scenarios, the relevant exposure is occupational dermal and inhalation exposure. No residential exposure is expected because TFM is applied in a very limited use area and extensive public notification is required by the Fish and Wildlife Service to eliminate exposure to riparian water users including fishermen, boaters, and swimmers.

4. Risk Characterization and Occupational Exposure

The USFWS program for the chemical control of sea lampreys using TFM and niclosamide is presented in the *Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey Control Program including Standard Operating Procedures* (1993). This manual focuses on minimizing occupational and general public exposures by specifying the manner in which applications are made (i.e., techniques and equipment), the level of risk mitigation for those occupationally exposed, and the approaches commonly used to reduce risks to the general public resulting from the use of treated waterways (e.g., swimming, fishing, or boating) or through drinking water exposures are mandated. This program served as the basis for the exposure/risk assessment completed for TFM and niclosamide.

Several issues pertain to the quality of the assessment and should be considered when interpreting the results of the occupational handler risk assessment. These include:

- No chemical-specific exposure data were submitted. As a result, all handler analyses were completed using surrogate data from the Pesticide Handlers Exposure Database (PHED).
- The backpack handler assessment was completed using "low quality" PHED data, due to the lack of a more acceptable data set.
- Use information provided for the years 1993 through 1997 served as the basis for this assessment. Specifically, data from 1997 were selected as being representative of TFM and niclosamide use patterns. The upper ranges of these application rates were accepted as representing a reasonable limit to the daily use capacity (i.e., maximum amount in a single day that can be applied). However, based on personal communication between J. Dawson (EPA) and Terry Morse (USFWS) on 9/28/98, handling of the TFM necessary to treat larger rivers (e.g. 1500 to >3000 kg/stream) would actually be conducted by 3-5 workers over, perhaps, 3-5 days.

The use patterns, based on the USFWS manual, and current labeling indicate 4 major occupational exposure scenarios for TFM based on the specified types of equipment and application techniques that can potentially be used to make applications. These scenarios include:

- (1a) mixing/loading/application of liquid TFM via direct metering pump from 6 gallon end-use product drums (low chemical use treatment events);
- (1b) mixing/loading/application of liquid TFM via direct metering pump from drum filled by open pour of 6 gallon end-use product drums (larger chemical use treatment events);
- (2) mixing/loading/application of liquid TFM using backpack sprayers for supplementary still water applications; and
- (3) applicator (i.e., placement) of TFM bars.

Even though 4 exposure scenarios were identified for the use of TFM, exposures/risks were only calculated for scenarios 1b and 2 because these scenarios present the highest exposures for TFM.

Risks associated with two occupational TFM scenarios were calculated using the variables associated with 41 actual USFWS treatments of Great Lakes tributaries conducted in 1997. Exposure estimates were based on PHED data, assumed 100% dermal and inhalation absorption, and assumed a 70-kg body weight. A margin of exposure (MOE) of 100 or greater is considered to not be of concern. MOEs for mixer/loader/applicators applying TFM via metering pumps and wearing maximum PPE as per the USFWS Manual were 100-14,186 for 38 of the 41 stream applications. In the remaining three streams, MOEs were 66, 68, and 96 for high treatment volumes of greater than 2100 kg/treatment/day. This assessment assumes that the treatment amount was handled per day by one mixer/loader/applicator and so the values are thought to be conservative because the USFWS has informed the Agency that larger applications are actually made by a crew of 3-5 handlers over a period of 3-5 days.

MOEs were calculated for the backpack sprayer scenarios assuming that 1% of the treatment amount for the 41 stream treatments from 1997 was applied via a backpack sprayer. MOEs were 106-15,571 for 39 stream scenarios; the other two treatments resulted in MOEs of 73 and 75. Again, this assessment assumes that the treatment amount was handled per day by one mixer/loader/applicator and so the values are thought to be conservative because the USFWS has informed the Agency that larger applications are actually made by a crew of 3-5 handlers over a period of 3-5 days. In the case of the backpack spray scenario, The USFWS provided additional information that details how much TFM was applied by backpack spray in 1997. The amount applied in four treatments ranged from 3.1 to 55.2 kg/treatment which would result in MOEs of 45 to 807 if these applications were made by one mixer/loader/applicator in one day. Again, since these were also assumed to be 3-5 handlers over a period of 3-5 day, the Agency has no concern for those fairly infrequent scenarios where large treatments result in apparent MOEs below 100.

C. Physical Chemistry Assessment for Niclosamide

Niclosamide is a yellow crystalline solid; pure niclosamide (ethanolamine salt) decomposes at 208° C, has a bulk density of 1.59 g/cm³ at 22° C, and a vapor pressure of 9.9×10^{-9} mm Hg at 25° C. Niclosamide is practically insoluble in water (1.05×10^{-5} g/100 mL).

D. Human Health Assessment for Niclosamide

1. Toxicology Assessment

a. Acute Toxicity

The following table summarizes the available acute toxicity data for niclosamide.

Table 5: Acute Toxicity of Niclosamide.

Guideline #	Study Type	MRIDs #	Results and Toxicity Category
81-1	Acute Oral - rat	42552301*	Single dose 1000 mg/kg; no mortality or clinical signs LD50 > 1000 mg/kg. Toxicity Category in females III or higher; could not be determined in males.
81-2	Acute Dermal - rabbit	42552301*	No mortality or clinical signs; LD50 > 2000 mg/kg. Toxicity Category III for females; could not be determined for males.
81-4	Primary Eye Irritation	42552305*	Evidence of eye irritation (iritis, corneal opacity, chemosis, redness) at 72 hours. Toxicity category not assigned because eyes were not examined beyond 72 hours.
81-5	Primary Skin Irritation	42552305	Toxicity Category IV based on no irritation in animals with unabrased skin.
81-6	Dermal Sensitization	42552306	Moderate dermal sensitizer.

* Submitted studies were not acceptable to fulfill guidelines, but provided some useful information for risk assessment.

b. Subchronic Toxicity

The available subchronic studies are summarized below.

Subchronic toxicity in rats

In a subchronic toxicity study (MRID 42552307), Bayer 73 (niclosamide) (purity not given; batch 8059410, formula 11089) was administered to 20 Sprague-Dawley rats/sex/dose in the diet at dose levels of 0, 300, 1250, or 5000 ppm (0, 30, 125 and 500 mg/kg/day, respectively), for 90 days.

There were no treatment-related deaths. Clinical signs were not provided, but were reportedly similar in control and treated groups. The weekly and terminal body weights of treated rats were $\leq 7.4\%$ lower than that of controls ($p \leq 0.05$) for terminal body weight in both sexes given 5000 ppm and in males given 1250 ppm and overall body weight gains were $\leq 8.6\%$ lower than of controls, but these small decreases were not toxicologically significant. There were no treatment-related effects on food consumption or food utilization efficiency. Urinalysis, clinical chemistry and hematology analysis revealed no notable differences from the controls, although most clinical chemistry and some hematology parameters required by EPA Guidelines were not assayed. The small but statistically significant alterations ($\leq 9.9\%$, $p \leq 0.05$ or 0.01) in the absolute and/or relative weights of the liver, kidneys, heart, spleen, and gonads in one or both sexes lacked histopathological correlates, were often unrelated to dose, and were not toxicologically significant. There were no treatment-related gross or microscopic lesions.

Under the conditions of this study, a LOAEL cannot be established for either male or female rats because there were no treatment-related findings. The NOAEL is ≥ 5000 ppm (500 mg/kg/day).

This subchronic toxicity (Guideline 82-1a) study is classified as unacceptable and not upgradeable because the animals were not adequately dosed; the maximum dose was well below the limit intake of 1000 mg/kg/day. Additionally, numerous parameters required by the Agency study guidelines (e.g. compound analysis in the diet, clinical chemistry) were not measured.

Subchronic toxicity in dogs

In a subchronic toxicity study (MRID 42552309), Bayer 73 (niclosamide) (70% wettable powder; batch 0053050) was administered for 180 days to 3 beagle dogs/sex/dose in the diet at dose levels of 0, 62.5, 250, or 1000 ppm (0, 1.56, 6.25, or 25 mg/kg/day, respectively). No statistical analysis was performed on the study results.

No animals died or exhibited any toxic signs during the study. The biweekly body weights and daily food consumption of treated and control dogs were similar. Body weight gains were not clearly treatment-related in either sex, and were within approximately 8% of controls at 1000 ppm for the major part of the study (weeks 1/2-24 for males and 1/2-20 for females). There were no treatment-related effects on any clinical chemistry, hematology, or urinalysis parameters, and the rates of bromsulfophthalein and phenol-sulfonephthalein clearance were similar in treated and control groups. The bone marrow myeloid/erythroid ratio of high-dose males and females was much lower than that of controls (4.3/1 in controls vs. 1.0/1 for males and 2.0/1 for females), suggestive of lowered WBC production or elevated erythrocyte production, but neither possibility was substantiated by the hematology results.

Microscopic lesions were seen primarily in the lungs, kidneys, and liver of both sexes, but these lesions could not be definitively attributed to treatment because they were seen in both treated and control dogs (incidence of 0/3 to 2/3 per dose). Additionally, none of the histology findings were correlated with gross lesions or alterations in clinical chemistry parameters.

Based on the lack of definitive treatment-related findings under the conditions of this study, a LOAEL cannot be established for either male or female dogs. The NOAEL is ≥ 1000 ppm (highest dose tested; calculated as 25 mg/kg/day).

This subchronic toxicity (Guideline 82-1b) study is classified as unacceptable and not upgradeable because the animals were not adequately dosed; the maximum dose was well below the limit intake of 1000 mg/kg/day recommended by the guideline. Additionally, 4 dogs/sex should have been used and data for a number of other parameters (e.g. compound analysis in the diet, some clinical chemistry parameters) were not provided.

Subchronic toxicity in hamsters

In a subchronic toxicity study (MRID 42552308), Bayer 73 (niclosamide) (purity not given; batch 8059410, formula 11089) was administered to 20 Syrian hamsters/sex/dose in the diet at dose levels of 0, 300, 1250, or 5000 ppm (0, 39, 177, and 726 mg/kg/day, respectively, calculated by the reviewer) for 90 days.

No treatment-related clinical signs of toxicity were observed in the study, and there were no treatment-related deaths. However, the treatments caused the hamsters in all dose groups, except for low-dose females, to have significantly lower body weights compared to controls ($P < 0.05$) at the termination of the experiment and probably much earlier. At the termination of the experiment, the reductions in body weights compared to controls were 8.6%, 9.3%, and 14.3% in males fed 300 ppm, 1250 ppm, and 5000 ppm, respectively. In females, the reductions were 5.5% (not significant), 9.7%, and 11.0%, at the same doses, respectively. The percent reductions in body weight gain over the 13 weeks were 12.0%, 12.0%, and 20.7% in males, and 8.2%, 14.3% and 17.3% in females at the respective doses. Food consumption was decreased in the 5000 ppm group males and females at week 1 but was then relatively consistent across treated groups. If the reduced food consumption had been caused by palatability alone, it is expected that the animals would adjust and consume equal or increased amounts for the remainder of the study and that the body weights would rebound. However, there was continued decreased body weights in the treated animals, especially the 5000 ppm group males and females. Therefore, it is concluded that there was a treatment-related effect on body weight and body weight gain. The effect is more pronounced in the 5000 ppm group males and somewhat in the 5000 ppm group females. There was an associated decrease in the weights of certain organs and in the animals' efficiency of food utilization. There were no treatment-related effects on hematology, clinical chemistry, urinalyses, gross pathology, or histopathology.

The LOAEL is 5000 ppm (726 mg/kg/day) in males and females based on decreased body weight and body weight gain. The NOAEL is 1250 ppm (177 mg/kg/day).

This subchronic study is classified as unacceptable/guideline but upgradeable to acceptable/guideline upon furnishing missing information regarding compound purity. Numerous endpoints were not tested for, including many clinical chemistry parameters and a few hematology parameters; however the study can be used for regulatory purposes if the compound purity is supplied.

c. Chronic Toxicity/Carcinogenicity

Chronic toxicity and carcinogenicity studies are not required for non-food use chemicals. However, if available, the studies could substitute for missing subchronic studies. A chronic toxicity study in rats (MRID 42698001C) has been submitted, but it has been classified as unacceptable. The National Cancer Institute conducted bioassays in rats and mice with niclosamide in 1978. Osborne-Mendel rats and B6C3F1 mice were treated with clonitralid (synonym for niclosamide) in the diet at concentrations of 28,433 (≈ 1421 mg/kg/day) or 14,216 (≈ 711 ppm) for rats, and 549 (≈ 78 mg/kg/day) or 274 ppm (≈ 39 mg/kg/day) for mice for 78 weeks. Because of inadequate survival among male mice, the results could

not be considered conclusive in this sex. There was no evidence that clonitralid was carcinogenic to male and female rats and female mice.

d. Developmental Toxicity

The available study does not satisfy the developmental toxicity testing requirements.

Developmental toxicity in rabbits

In a developmental toxicity study (MRID 42552310), pregnant New Zealand white rabbits were administered Bayer 73 (niclosamide, 70%, a.i.; Batch No. 0053050) by gavage at doses of 0, 20, 60, and 180 mg/kg/day on gestation days (GD) 8-18, inclusive. Does were deemed pregnant if live fetuses were observed at cesarean section (GD 29) resulting in only 10, 10, 10, and 7 animals used per group, respectively. All fetuses were sexed, weighed, examined for external malformations/variations, and X-rayed for subsequent skeletal examination. One-half of the fetuses were preserved in Bouin's solution for razor blade sectioning by the Wilson technique. The other half were preserved in formaldehyde and subjected to gross necropsy.

No evidence of maternal toxicity was observed in this study. Mean fetal body weights of the treated groups were 83-89% of the control group level, but there was a corresponding increase in the number of fetuses/litter. Statistical analysis of fetal body weights did not account for litter size and fetal body weights of the treated groups were within the expected range for the rabbit. Therefore, the decrease in fetal body weights is not considered treatment-related. When the incidence rates of peritoneal hemorrhage observed in fetuses during either Wilson's examination or gross necropsy are combined, 0/10, 4/10, 5/10, and 4/7 litters in the 0, 20, 60, and 180 mg/kg/day groups, respectively, contained affected fetuses. The incidence rate is statistically significant ($p \leq 0.05$) in all treated groups. Lack of a clear dose-response in the number of litters affected, involvement of only one fetus in each affected litter, and few numbers of litters evaluated, make peritoneal hemorrhage an equivocal treatment-related effect.

Several major deficiencies in the conduct of this study make it inadequate for the evaluation of the potential developmental toxicity of Bayer 73 in the rabbit. Therefore, LOAELs for maternal and developmental toxicity could not be established.

This Guideline 83-3b study is classified as unacceptable (not upgradable) and does not satisfy the Agency guideline requirements for a developmental toxicity study in rabbits. This study is inadequate for determining either a maternal or developmental toxicity LOAEL. All animals were not treated concurrently, only females with live fetuses were included in the study, inappropriate statistical analyses were used for fetal body weight data, the use of X-ray films is inadequate for fetal skeletal evaluation, and the dosing solutions were not analyzed for concentration, homogeneity, or stability.

e. Mutagenicity

The mutagenicity testing requirements have not been fully satisfied. The *Salmonella typhimurium* reverse mutation assay (Ames assay) has not been fulfilled.

Chromosome Aberration in Bone Marrow Cells

In a mammalian cell cytogenetics assay (chromosome aberration in bone marrow cells) (MRID 43677902), male and female Crl:CD(ICR) BR mice, 15/sex/group, were exposed to niclosamide (98.9%) at doses of either 1250, 2500 or 5000 mg/kg by a single gavage administration. At 6, 18, or 30 hours after test substance administration, 5/sex/group were sacrificed at each period. Bone marrow cells were harvested immediately after sacrifice. The vehicle control was corn oil. The positive control, which was cyclophosphamide, was adequate. There is no evidence of chromosome aberrations in bone marrow cells induced over background.

This study is classified as acceptable/guideline. It satisfies the requirement for FIFRA Test Guideline 84-2 for *in vivo* cytogenetic mutagenicity data.

Mammalian Forward Gene Mutation Assay

In a mammalian cell gene mutation assay (thymidine kinase locus) (MRID 43677901), L5178Y mouse lymphoma cells cultured *in vitro* were exposed to niclosamide (98.9%) in dimethylsulfoxide at concentrations of 2.50 to 80.0 ug/ml in the presence and absence of mammalian metabolic activation.

Without S9 activation, trial 1 was aborted due to excessive cytotoxicity. In trial 2, doses of 30 to 80 ug/ml were excessively cytotoxic; the remaining six doses of 2.50 to 25.0 ug/ml produced no increase in the number of mutant colonies. Survival (relative growth) was relatively constant at 15.5 to 19.9% over the six doses.

With S9 activation, trials 1 and 3 were aborted due to excessive cytotoxicity. In trial 2, at doses of 1.25 to 40 ug/ml, severe cytotoxicity was observed at > 3.75 ug/ml. At 1.25, 2.5 and 3.75 ug/ml, there was no increase in mutant colonies. In trial 4, at doses of 2.5 to 40.0 ug/ml, there was no increase in mutation frequency. There was a dose-related increase in relative growth (9.0% at 40.0 ug/ml to 76% at 2.5 ug/ml). There was no increase in the mutant frequency with niclosamide at cytotoxic doses (25.0 ug/ml -S9; 40 ug/ml +S9). The positive controls induced the appropriate response.

This study is classified as acceptable/guideline. It satisfies the requirement for FIFRA Test Guideline 84-2 for *in vitro* mutagenicity (mammalian forward gene mutation) data.

E. Dose Response Assessment

a. Dietary

Niclosamide is classified as a low-volume, and nonfood use chemical based on the quantity used, the method of application, and the rapid dissipation of residues in fish and water. As a nonfood use chemical, the acute and chronic dietary endpoints for niclosamide are not necessary and a reference dose is not required.

b. Short/Intermediate Term Occupational and Residential

No endpoints were established for niclosamide. Short and intermediate term exposures may occur, but are not expected to be substantial based on the low volume used. Long term exposure and, therefore, long-term risk is not expected.

There are no residential uses.

1. Exposure Assessment

a. Dietary Exposure From Food and from Drinking Water

Niclosamide is classified as a low-volume and nonfood use chemical based on the quantity used, the method of application, the USFWS restrictions against irrigation and drinking water removal from streams during treatment, and the rapid dissipation of any possible residues in fish and water. Therefore, the dietary exposure is expected to be minimal and a dietary risk assessment is not required for niclosamide.

b. Occupational/Residential Exposure

It is anticipated that regardless of whether niclosamide is used to control sea lampreys or fresh water snails, the application methods and exposure issues are similar for handlers. As a result, the USFWS sea lamprey control program manual was used as a basis for the niclosamide and TFM exposure/risk assessment. The specifics of this manual and available labeling should be the basis for any niclosamide and TFM use. Postapplication scenarios to swimmers, boaters and fisherman should result in minimal exposure from the lampricide use of niclosamide based on the USFWS program.

There are currently two Special Local Needs labels for use of niclosamide in commercial aquaculture for the production of ornamental fish in Florida and Arkansas. The water from this treatment is not released and the fish are not used as a food source. There should be limited occupational and no residential exposure from these uses.

2. Risk Characterization

a. Dietary Risk including Drinking Water Risk

There is no reasonable expectation of humans being exposed to niclosamide residues in the diet via water, fish, irrigated crops, and livestock for the following reasons: (i) the low use volume (300 lb ai/yr); (ii) the infrequency of use (every 3-5 yr if a given stream harbors lamprey); (iii) the very tight control USFWS has over the use of niclosamide including 24-hr irrigation and potable water intake restrictions, other label restrictions, door-to-door as well as broadcast riparian user notification and enforcement particularly for sport fishermen, etc.; (iv) the fact that the treated water moves as a slug down the treated stream resulting in only a 1-3 day exposure interval every 3-5 years; (v) what is, in effect, infinite dilution as treated stream water enters the Great Lakes, where virtually all of the commercial fishing occurs; (vi) the rapid and complete dissipation of niclosamide residues from treated streams; (vii) the very low level of bioconcentration as well as the rapid and complete depuration of niclosamide residues from exposed fish; and (viii) based on reasons given above, residues of niclosamide in irrigated crops and livestock are not expected.

b. Occupational/Residential Risk

It has been determined that there is a potential for exposure from handling niclosamide-containing products during the application process (i.e., mixer/loaders and mixer/loader/applicators) as well as from various post-application activities such as recreational boating and swimming. The two potential niclosamide exposure scenarios are: (i) mixing/loading/application of niclosamide wettable powder slurry and (ii) loading/application of niclosamide granules using powered backpack blowers for population survey applications. However, based on the extremely low usage (300 lb ai/yr), the infrequency of use, and the risk mitigation measures already implemented by USFWS, occupational exposure and risk assessments have not been conducted for niclosamide.

F. Environmental Assessment for TFM

1. Ecological Toxicity Data

a. Summary

The information in this assessment is based on a combination of both open literature and studies specifically conducted to meet EPA data requirements. While all of the data included in this assessment were considered scientifically sound, open literature studies were not subject to the rigorous standards currently required under Good Laboratory Practice (GLP) protocols. Given the range of protocols over which ecotoxicity data were collected, there is some uncertainty over how the toxicity of TFM may have been effected had the studies been conducted under GLP standards. Based on ecological effects data, the toxicity potential of TFM can be characterized as follows:

- Avian acute-nontoxic ($>5,000$ ppm)
- Mammalian acute-moderately toxic (>141 to 160 mg/kg)
- Mammalian chronic ($>5,000$ mg/kg)
- Fish (freshwater acute)- slightly to highly toxic (0.60 to 37 mg/L)
- Invertebrates (freshwater) acute- slightly to moderately toxic (3.8 to 22.3 mg/L)
- Aquatic plants- toxic (1.2 to >15 mg/L)

Mammals were the only animal group for which chronic toxicity data were available and for this group there were no chronic effects noted.

Environmental factors influenced the toxicity of TFM. In general TFM was more toxic as water temperature increased and pH and water hardness decreased. When TFM is used in combination with niclosamide, the toxicity potential of the combined lampricides was additive.

b. Toxicity to Terrestrial Animals

(1) Avian Acute Oral, Subacute Dietary and Chronic

The acute oral toxicity data suggest that TFM analytical and formulated grade material is moderately to slightly toxic (LD_{50} 250 - 546 mg/kg) to avian species and practically non-toxic (LC_{50} $>5,000$ ppm) on a subacute dietary basis (MRID 00022923; Acc # 160000). Avian chronic reproduction studies are not required.

(2) Mammals, Acute and Chronic

TFM has acute oral LD_{50} values of 141 and 160 mg/kg for males and females, respectively (MRID 40999204 and 41898102).

(3) Insects

A honey bee acute contact study using the TGAI is not required for TFM because its use, i.e., streams and rivers, will not result in honey bee exposure.

c. Toxicity to Freshwater Aquatic Organism

(1) Freshwater Fish, Acute and Chronic

Acute toxicity of TFM ranges from being slightly toxic to highly toxic for freshwater fish species. The most sensitive species tested was the channel catfish, *Ictalurus punctatus* (96 hour LC_{50} = 0.60 mg/L in soft, reconstituted well water, pH 7.2 to 7.6), while the least sensitive species tested was the bluegill sunfish, *Lepomis macrochirus* (96 hour LC_{50} = 37 mg/L in hard well water, pH 8.3 to 8.5).

In a study comparing the toxicity of TFM to native species of lampreys with sea lampreys, the toxicity of TFM to lamprey larvae was highest in the sea lamprey, intermediate in the northern brook lamprey (*Ichthyomyzon fossor*), and lowest in the American brook lamprey (*Lamptera appendix*) (King *et al.* 1985).

Because TFM is also used in combination with niclosamide, toxicity tests for the combination of these two chemicals were conducted by Bills and Marking (1976). Of the fish tested, channel catfish was again the most sensitive species to TFM alone ($LC_{50} = 0.75$ mg/L) and to the combination of the two chemicals ($LC_{50} = 0.615$ mg/L). In general, the data show that the combination of TFM and niclosamide was at most additive under various test conditions.

Although fish life cycle data are not available for TFM, there are acute data available for various developmental stages of fish. All the early developmental stages of walleye (*Stizostedion vitreum*) from gametes to sac fry were more resistant to TFM than were similar developmental stages of sea lamprey larvae. Olson and Marking (1973) examined the toxicity of TFM to six developmental stages of the rainbow trout and found that sac fry were the most sensitive life stage studied. Exposure to TFM during sea lamprey embryonic development increased the frequency of abnormalities that lead to increased mortalities (Piavis and Howell 1975; NRCC 1985).

TFM treatments have been associated with induction of hepatic mixed function oxygenase activity and altered levels of circulating steroids in fish and induced hepatic vitellogenesis in primary cultures of rainbow trout hepatocytes (Hewitt *et al.* 1997). As such, TFM acts as an estradiol agonist and has a demonstrated endocrine disrupting effect. Since the data on various developmental stages represented disjointed acute studies, chronic toxicity data on fish were not available and as such, a fish full life cycle study of both technical grade TFM and TFM/niclosamide mixture is required to address this deficiency.

Abundance of sea lamprey peaked in several Great Lakes before chemical control began. The sex ratio in these peak populations were predominately males (68-71%). Following a decade of lampricide treatments, populations of sea lampreys showed marked declines and the sex ratios in these populations shifted toward a predominance of females accounting for 72% of the population (Henrich, *et al.* 1979). This publication by Henrich concludes that lampricides reduced the populations of sea lampreys in the Great Lakes and contributed to the sequential shifting of the sex composition from a predominance of males to a predominance of females. There are no data to support that the endocrine mediated effect associated with TFM is related to the observed sex-ratio shifts among TFM-treated populations of sea lamprey.

(2) Freshwater Invertebrates, Acute and Chronic

In acute toxicity tests, TFM was moderately to slightly toxic to aquatic invertebrates (24 hour LC_{50} range: 3.8 to 22.3 mg/L). When TFM is used in combination with niclosamide (98:2 by weight), LC_{50} values for the mixture ranged from 1.5 mg/L (moderately toxic) to greater than 100.0 mg/L (practically non-toxic). The most tolerant species tested were crayfish, dragonflies, snipeflies, and

dobsonflies. The most sensitive species were snails and aquatic earthworms. These data indicate that the mixture of TFM and niclosamide enhanced the toxicity of TFM to some aquatic invertebrates.

There are no chronic toxicity data available for aquatic invertebrates. An aquatic invertebrate life cycle study (72-4) of both technical grade TFM and TFM/niclosamide mixture is required to address this deficiency.

(3) Toxicity to Estuarine/Marine Organisms

Because the use of TFM is unlikely to directly enter into estuarine/marine environments, toxicity testing for these species is not required.

d. Toxicity to plants

TFM inhibited the growth of aquatic plants; 9 out of 10 species of algae tested suffered 50% growth inhibition at concentrations less than 10 ppm (Maki *et al.* 1975). Concentrations as high as 30 mg/L arrested growth, but did not kill algae. The algae resumed normal growth when exposure to TFM was stopped (Maki *et al.* 1975). The Tier II results indicate that *Nitzschia sp.* is the most sensitive (EC₅₀ 1.2 mg/L) of the nonvascular aquatic plants tested. The Tier II guideline is fulfilled (Maki *et al.*, 1975).

The herbicidal activity of various salts of TFM has been reported (Gilderhus and Johnson 1980). TFM decreased the growth of *Anacharis sp.*, *Cabomba sp.*, and *Ceratophyllum sp.* at concentrations of 15 - 25 ppm in standing water and at 100 ppm in flowing water (Schnick 1972). Canadian pondweed (*Elodea canadensis*), when exposed to TFM for 24 hours, suffered a loss in weight at exposure concentrations greater than 5 ppm, while plants exposed to 35 ppm died (Maki and Johnson 1977). However, plants exposed at concentrations as high as 20 ppm recovered after TFM exposure was terminated. TFM was toxic to Eurasian water milfoil (*Myriophyllum spicatum*) causing a 60-85% reduction in biomass at concentrations between 10 - 25 ppm. In general, TFM does not appear to cause long-term adverse effects to aquatic plants except for a temporary reduction in growth (NRCC, 1985).

2. TFM Environmental Fate and Transport

The information in this assessment is based primarily on open literature studies submitted by the registrant to fulfill EPA data requirements. Unless otherwise noted, the data cited here are not from studies conducted according to Subdivision N guidelines, but nonetheless are considered scientifically valid and may be used in assessing the fate and transport of TFM in the environment. Because the open literature studies were not conducted according to the rigorous standards required under Subdivision N, there is some degree of uncertainty associated with the data, particularly if one is comparing the results of these studies to studies for other chemicals conducted according to Subdivision N guidance.

- TFM is chemically and biologically very stable. The compound possesses many of the chemical features known to impart persistence to organic compounds.

- There is conflicting evidence on whether TFM photodegrades in water.
- TFM remains toxic for long periods (>80 days) in aqueous systems; however, toxicity decreases in sediment-water systems over time. In sediment-water systems, irreversible sorption of reduced-TFM [R-TFM; 4-amino-3-(trifluoromethyl)phenol] to sediments was reported. R-TFM is capable of binding to other organic components of the sediment through the amino group or be polymerized to longer chain compounds.
- TFM was converted to reduced-TFM with a half-life of less than one week under both aerobic and anaerobic aquatic metabolism conditions. It must be stressed that when reduced-TFM is reported as a reaction product, degradation has not occurred. TFM has just undergone a chemical reduction and under appropriate conditions, reduced-TFM may be re-oxidized to TFM.
- The tendency for TFM to bind to sediments is not strong, readily reversed, and is very pH dependent. Binding tends to decrease as pH increases.
- Based on studies with the rainbow trout, TFM is not expected to accumulate in fish.
- In the environment, the sorption and degradation of TFM by sediments is expected to occur primarily in the lakes and not in the tributary streams. TFM is expected to remain in solution in the lake system and persist for long periods of time.

TFM ($C_7H_4F_3NO_3$; M.W. 207.11) is chemically and biologically very stable. An examination of its structure, *i.e.*, aromatic, fluoro-containing, m-substituted phenol, shows that the compound possesses many of the chemical features known to impart persistence to organic compounds. Its pK_a is 6.07 and the effect of pH on the toxicity appears to follow closely to the concentration of the lipid-soluble, free phenol form of TFM. This pH sensitivity is used to maximize effectiveness. As pH increases, toxicity, bioaccumulation, and adsorption to sediment decrease. Aqueous solubility of the sodium salt is 5 g/L.

a. TFM Degradation

In an acceptable Hydrolysis guideline study, Reynolds (1997, MRID 44429501) found that ^{14}C -TFM was stable in sterile buffered aqueous solutions at pH's 5, 7, and 9 at 25°C in the dark for 30 days. No degradation products were identified. In bioassay experiments, Thingvold (1975) found that the toxicity of TFM was not altered over the course of 5 to 8 weeks by buffering aqueous solutions at pH values of 6.5, 7.7, 8.5, or 9.5. Carey and Fox (1981) demonstrated in distilled water systems buffered at pH 5, 6, 7, 8, or 9 that TFM was stable in the dark controls of a photodegradation study. The hydrolysis study requirement is fulfilled.

Photolysis may be an important route of degradation in the environment, however there is conflicting evidence on this. In the Carey and Fox study, the authors found that TFM photodegraded in unbuffered distilled water under natural sunlight with a half-life of 3.3 days. The principle identified

photoproduct was 2,5-dihydroxybenzoic acid. There was no build-up of photoproducts and by the end of the experiment (11 days), most of the TFM degradation products were unextractable. These authors believe that under appropriate weather conditions, the photodegradation half-life in a shallow stream would be on the order of several days. Contrary to this, Thingvold (1975) found that solutions of TFM were very stable in the presence of sunlight thus indicating that photodecomposition is an unlikely dissipator of TFM from the Great Lakes environment. This contradiction leads to some uncertainty as to whether photolysis plays a role in the dissipation of TFM. Based on this uncertainty, an additional aqueous photolysis study is required.

b. TFM Metabolism

In a study designed to evaluate the degradation of TFM where aquatic sediments are not an influential factor, Thingvold (1981) found no evidence of microbial degradation of TFM over test periods of up to 80 days. Thingvold demonstrated, using bioassay experiments, that TFM remains toxic for long periods in aqueous systems; however, toxicity decreases in sediment-water systems. In sediment-water systems, irreversible sorption to sediments was reported. It is likely that the bound residue was not TFM, but the reduced form of TFM (4-amino-3-(trifluoromethyl)phenol). Thingvold (1975) found no evidence that indicated that TFM degrades in the presence or absence of auxiliary carbon sources, or under aerobic or anaerobic conditions, in sediment-free aqueous systems. Carey, Fox and Schleen (1988) report that with the exception of reduction of the nitro group to an amino group under anaerobic conditions, TFM is chemically and biologically very stable. However, these authors believe that this reduction is not likely to be an important route of environmental degradation since TFM is almost completely ionized at the pH of most natural waters and does not partition strongly to sediment where anaerobic conditions exist. In addition, it must be noted that when reduced TFM is reported as a reaction product, degradation has not occurred. TFM has merely been reduced and under appropriate conditions, reduced-TFM may be re-oxidized to TFM (Carey and Fox, 1981).

In an acceptable anaerobic aquatic metabolism guideline study, Fathulla (1996, MRID 43887601) found that ^{14}C -TFM applied to a loamy sand sediment/water system degraded rapidly in the dark under anaerobic conditions with a half-life of 2.1 days. The major degradate was 4-amino-3-(trifluoromethyl)phenol, reduced TFM (R-TFM), which comprised 38.2% at approximately 4 hours, and increased to a maximum of 94.1% of the applied radioactivity on day 14 of anaerobicity and then decreased to 26.6% on day 178 and finally disappeared by day 273. $^{14}\text{CO}_2$ was the only volatile component found in the traps, reaching 7.7% of applied on day 273. Radioactivity recovered in the water layer ranged from 71.7 to 87.7% of applied on days 0 through 92. After day 92, the majority of the radioactivity partitioned to the sediment (41-49% of this radioactivity was bound). pH ranged from 5.43 (day 3) to 8.34 (day 273). Under aerobic conditions, Fathulla (1995, MRID 43781801) demonstrated in an acceptable aerobic aquatic metabolism study that ^{14}C -TFM applied to a loamy sand sediment/water system degraded rapidly in the dark under aerobic conditions with a half-life of 5.4 days. The major degradate was reduced TFM, which comprised 38.4% at approximately 7 days, 30.2% on day 15, 1.2% on day 21 and 0.7% on day 30. $^{14}\text{CO}_2$ was the only volatile component found in the traps, reaching 7.8% of applied on day 30. The pH ranged from 7.51 (day 1) to 8.83 (day 30). Radioactivity recovered in the water layer ranged from 91.6 to 30.2% of applied on days 0 through 30. On day 30,

the majority of the radioactivity partitioned to the sediment (45% of this radioactivity was bound). Based on these data, the anaerobic aquatic metabolism and aerobic aquatic metabolism study requirements are fulfilled.

c. TFM Mobility

Dawson (1986) studied the adsorption of TFM by bottom sediments (Table 6), and found that increases in pH lead to decreases in K_d , while increases in organic carbon result in increases in K_d . Overall, the mobility of TFM, as determined by Dawson is medium to very high. The table below provides the results at 20°C for systems at pH 6 and 8. Based on these data, the leaching and absorption/desorption study requirement is fulfilled.

Table 6: Absorption (K_d) of Trifluoromethyl nitrophenol (TFM) by four different bottom sediments at pH 6 and 8 (Dawson 1986).

sediment	soil type	sand/silt/clay	organic matter	CEC meq/100g	K_d pH 6	K_d pH 8
Cedar River	sandy loam	64/32/4	9.0	13.2	11.7	2.01
Ford River	loamy sand	84/14/2	5.0	4.6	6.65	1.46
Tahquamenon River	sand	96/2/2	0.9	1.1	1.11	0.157
Arkansas River	loam	44/46/10	2.5	6.2	5.66	0.749

Carey, Fox, and Schleen (1988) also noted that the tendency for TFM to bind to sediments is not strong, readily reversed, and is very pH dependent. Un-ionized TFM (acidic solution) is more readily absorbed than ionized forms (basic solutions) (Dawson *et al.* 1986). On the other hand, Thingvold (1975) claims that TFM is sorbed by sediments in a rapid and irreversible manner, so much so that it is difficult to extract with organic solvents. Thingvold believes the binding may involve the NO_2 group converting to the NH_2 form. This then would mean that rather than TFM binding, it is reduced-TFM that is bound. R-TFM is capable of binding to other organic components of the sediment through the amino group, or being polymerized to longer chain compounds, which would explain the difficulty in extracting TFM from the sediment.

In the environment, the sorption and degradation of TFM by sediments is expected to occur primarily in the lakes and not in the tributary streams. Most of the TFM will be quickly flushed into the lakes. The amount removed by sorption to the stream sediments is unknown, but is likely to be minimal. In the lake environment, degradation of TFM must occur in a primarily sediment-free system, given the high ratio of water to sediment and the lack of sediments containing appreciable amounts of organic material (Thingvold, 1975). As such, TFM is expected to remain in solution in the lake system and persist for long periods of time at low concentrations.

d. TFM Accumulation

The amount of TFM uptake by fish has been correlated to pH and total hardness of the water. Ten times as much TFM was found in fish residing in soft-acid water as compared to hard-alkaline water (Thingvold, 1975). According to Thingvold, TFM is not readily metabolized by aquatic organisms and is generally excreted in an unaltered form. In an acceptable fish accumulation study conducting according to Subdivision N guidelines (MRID 44666501), TFM residues accumulated in rainbow trout that were exposed to nonradiolabeled plus uniformly phenyl ring-labeled [^{14}C]TFM, at a nominal concentration of 62.0 $\mu\text{g/L}$, under flow-through aquarium conditions at a pH of 7.8. Maximum bioconcentration factors, based on total radioactivity, were 50.3X for viscera, 1.3X for fillet, and 8.4X for whole body tissues. The maximum mean concentrations of [^{14}C]residues were 3.0 ± 0.9 -1.7 ppm for the viscera tissue, 0.08 ± 0.03 ppm for the fillet tissue and 0.5 ± 0.1 -0.2 ppm for the whole fish tissue. Accumulation plateaus were generally reached by 3 days in the viscera, fillet, and whole fish tissues. Parent compound was present at 1.4 ± 0.05 ppm in the viscera, and 0.006 ± 0.006 ppm in the fillet tissues. The major metabolite TFM-glucuronide was present at 0.9 ± 0.2 ppm in the viscera, and 0.036 ± 0.003 ppm in the fillet tissue samples. Two unidentified metabolites (Unknowns 1 and 3) were present at 0.7 ± 0.03 ppm and 0.09 ± 0.01 ppm, respectively, in the viscera; an unidentified minor metabolite (Unknown 2) was present at 0.034 ppm (1 of 4 replicates). Depuration was rapid, with >98.7% of total accumulated [^{14}C]residues eliminated by days 4, 15, and 11, respectively, from the viscera, fillet, and whole body tissue samples. Based on these data, the accumulation in fish study requirement is fulfilled.

3. TFM Aquatic Exposure Assessment

Since TFM is added directly to water, the estimated environmental concentrations (EECs) used in this evaluation were based on projected treatment concentrations. Application rates for TFM are based on pH, alkalinity, temperature, stream/river discharge rates, and bioassay data. Spreadsheet-based models incorporating the aforementioned factors have been developed to assist in determining applications rates and were used in predicting exposure concentrations used in the present risk assessment.

G. Environmental Assessment for Niclosamide

1. Ecological Exposure and Risk Characterization for Niclosamide

a. Summary

The information in this assessment is based on a combination of both open literature and studies specifically conducted to meet EPA data requirements. While all of the data included in this assessment were considered scientifically sound, open literature studies were not subject to the rigorous standards currently required under Good Laboratory Practice (GLP) protocols. Given the range of protocols over which the ecotoxicity data were collected, there is some uncertainty over how the toxicity results may have been impacted by this lack of GLP standards. Based on ecological effects data, the toxicity potential of niclosamide can be characterized as follows:

- Avian acute- moderately toxic (LD_{50} 60 mg/kg)
- Avian subacute dietary- practically nontoxic ($LC_{50} > 5,419$ mg/kg diet)
- Mammalian acute- practically nontoxic ($LD_{50} > 1,000$ mg/kg)
- Fish (freshwater acute)- highly toxic to very highly toxic (LC_{50} 0.03 - 0.23 mg/L)
- Invertebrates (freshwater) acute- slightly to very highly toxic (EC_{50} 0.034 - > 50 mg/L)
- Invertebrates (freshwater) chronic- (NOAEC 0.03 mg/L; LOEC 0.05 mg/L)
- Aquatic plants- toxic (0.04 to $> 1,450$ mg/L)

Environmental factors influenced the toxicity of niclosamide. In general niclosamide was more toxic as pH and water hardness decreased. When niclosamide is used in combination with TFM, the toxicity potential of the combined lampricides was additive.

b. Toxicity to Terrestrial Animals

(1) Avian Acute Oral, Subacute Dietary and Chronic

The acute oral toxicity data suggest that niclosamide ranges in toxicity from being moderately toxic to practically nontoxic (LD_{50} 60 to $> 2,000$ mg/kg) to avian species (MRIDs 43677701, 43677702, and 44180301) and practically non-toxic ($LC_{50} > 5,419$ ppm) on a subacute dietary basis (MRIDs 44180302 and 44180303). Avian chronic reproduction studies are not required. The guideline requirements for acute studies have been fulfilled.

(2) Mammals, Acute and Chronic

Niclosamide was practically nontoxic to small mammals on an acute oral basis ($LD_{50} > 1,000$ mg/kg) (MRID 4255223-01). No chronic toxicity data were available.

(3) Insects

A honey bee acute contact study using the TGAI is not required for niclosamide because its use (aquatic sites) will not result in honey bee exposure.

c. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute and Chronic

The data indicate that the acute toxicity of niclosamide ranges from being highly toxic to very highly toxic for freshwater fish species. The most sensitive species tested were the rainbow trout, *Onchorhynchus mykiss* ($LC_{50} = 0.03$ mg/L), sea lamprey, *Petromyzon marinus*, ($LC_{50} = 0.049$ mg/L) and the bluegill sunfish, *Lepomis macrochirus*, ($LC_{50} = 0.049$ mg/L). The freshwater fish acute toxicity requirement has been fulfilled (MRID 43679302, 44206101).

Because niclosamide is also used in combination with TFM, toxicity tests for the combination of these two chemicals are used to assess risk. Results of tests specifically conducted to address this issue show that the channel catfish was the most sensitive species to TFM ($LC_{50} = 0.75 \text{ mg/L}$), niclosamide ($LC_{50} = 0.0125 \text{ mg/L}$) and to the combination of these chemicals ($LC_{50} = 0.615 \text{ mg/L}$). Based on the results of this study the authors concluded that the mixture of TFM:niclosamide was at most additive under various test conditions (Bills and Marking 1976).

No data were provided on the chronic toxicity of niclosamide to fish. Thus, the guideline studies for the fish early life stage and fish full life cycle are not fulfilled and represent data gaps.

(2) Freshwater Invertebrates, Acute, Chronic

In acute toxicity tests, niclosamide was slightly to very highly toxic to aquatic invertebrates (EC_{50} range: 0.034 to $> 50 \text{ mg/L}$). The acute freshwater invertebrate study requirement has been fulfilled (MRID 44174804).

When TFM is used in combination with niclosamide (98:2 by weight), LC_{50} values for the mixture ranged from 1.5 mg/L (moderately toxic) to greater than 100.0 mg/L (practically non-toxic) among freshwater invertebrates. The most tolerant species tested were crayfish, dragonflies, snipeflies, and dobsonflies. The most sensitive species were turbellarians, snails, and aquatic earthworms and appeared to affect organisms inhabiting sediments. These data indicate that the mixture of TFM and niclosamide are additive for the toxicity of TFM to aquatic invertebrates.

Given niclosamide's potential to adsorb to sediments, the use of formulations specifically designed to slowly release the chemical at the water-sediment interface, and the acute toxicity of niclosamide to aquatic invertebrates, acute and chronic data on sediment toxicity testing using chironomids is necessary since these organisms would be highly exposed.

(3) Toxicity to Estuarine and Marine Organisms

Because the use of niclosamide is unlikely to directly enter into estuarine/marine environments, toxicity testing for these species is not required.

d. Toxicity to Aquatic Plants

Niclosamide inhibited the growth of aquatic plants; diatoms suffered 50% growth inhibition at concentrations less than 130 ppb. Green algae exhibited a considerable range in sensitivity to the effects of niclosamide; EC_{50} values ranged from 0.41 to 1,450 ppm. The studies submitted for review did not comply with recommended guidelines, and were classified as supplemental.

2. Niclosamide Environmental Fate and Transport

The information in this assessment is based primarily on open literature studies submitted by the registrant to fulfill EPA data requirements. Unless otherwise noted, the data cited here are not from studies conducted according to Subdivision N guidelines, but nonetheless are considered scientifically valid and may be used in assessing the fate and transport of niclosamide in the environment. Because the open literature studies were not conducted according to the rigorous standards required under Subdivision N, there is some degree of uncertainty associated with the data, particularly if one is comparing the results of these studies to studies for other chemicals conducted according to Subdivision N guidance.

There are insufficient data available to adequately assess the environmental fate of niclosamide.

- In addition to dilution and dispersion, sorption to sediments and suspended particulates and possibly photodegradation (in clear shallow waters), are the major routes of dissipation of niclosamide. Neither hydrolysis nor volatilization from soil or water surfaces should be major fate processes for this compound.
- In most aquatic environments, niclosamide will adsorb to suspended solids and sediment. Though niclosamide does tend to bind to sediments, the binding is by no means irreversible, thus non-target species and benthic organisms, in particular, will be exposed to niclosamide for extended periods of time.
- It is unclear what role, if any, aerobic and anaerobic microbial degradation plays in the dissipation of niclosamide in the aquatic environment.
- In the lake environment, degradation of niclosamide would be expected to occur in a primarily sediment-free system, given the high ratio of water to sediment. As such, niclosamide is expected to remain in solution in the lake system and persist for long periods of time.
- Based on the bioconcentration factors and the rapid rate of depuration, accumulation in fish is not expected.

a. Niclosamide Chemical Degradation

Niclosamide does not appear to undergo hydrolytic degradation, however it does photodegrade in water. In a supplemental study that addressed both the hydrolysis and aqueous photolysis data requirements (MRID 42552313), [^{14}C]niclosamide did not degrade either in buffered solutions adjusted to pH 5.0, 6.9, or 8.7; or in pond water (pH 7.0-7.8) incubated in the dark for up to 56 days. Niclosamide ranged from 93 to 99% of the total radioactivity from each TLC plate in the study. Under photolytic conditions, niclosamide degraded with a half-life of 3.3 days in a pH 6.9 buffered solution that was irradiated by long-wave UV light for up to 14 days. A new photodegradation in water study is needed because, among other deficiencies, degradates were not identified, material balances were not

reported, and the output of the light source may not have been comparable with natural sunlight. Therefore, there is a high degree of uncertainty surrounding the photolysis half-life. However, based on this supplemental study and the UV/visible spectrum of niclosamide (max. 330 nm), it does appear that niclosamide is susceptible to photodegradation in water, and this will be a significant route of dissipation only in clear and shallow water bodies.

b. Niclosamide Mobility

In an acceptable batch equilibrium study (Dawson *et al.*, 1986) (MRID 42552315, 42552316), it was found that the mobility of niclosamide was dependent on the pH of the system. Mobility appeared to increase at higher pH's. It should be noted that niclosamide reportedly precipitates from aqueous solutions when the pH is less than 6.5.

Table 7: Average dissociation constants (K_d) for niclosamide at differing pH and sediment type.

sediment	% organic matter	pH 6.5	pH 7.0	pH 8.0	pH 9.0
		average K _d			
Tahquamenon River sand	0.9	17	14	5	1
Ford River loamy sand	5.0	60	79	41	12
Arkansas loam	2.5	199	129	39	15
Cedar River sandy loam	9.0	316	85	69	7

Under acidic and neutral conditions, niclosamide was not mobile. At pH 8, niclosamide was moderately mobile in the sand sediment, but not mobile in the other three sediments. In alkaline (pH 9) conditions, niclosamide was very mobile in the sand and moderately to slightly mobile in the loamy sand, loam, and sandy loam sediments. In most aquatic environments, niclosamide will adsorb to suspended solids and sediment.

A supplemental mobility study identified the major route of dissipation for niclosamide from the water column, excluding dilution or dispersion, is adsorption to the sediment (MRID 42552317). Niclosamide concentrations decreased in the water column at a faster rate in beakers with lake water and sediment exposed to sunlight than in beakers without sediment exposed to sunlight. There was no difference in disappearance rates of niclosamide between light and dark beakers without sediment, indicating that photolysis may not play a major role in the dissipation of niclosamide. After 96 hours, 71% of the niclosamide was still present in beakers with sediment exposed to sunlight, versus 107% in light exposed beakers without sediment and 110% in dark beakers without sediment. In a test that eliminated microbial and photolytic processes, niclosamide concentrations decreased faster in sterile dark test tubes with sediment than in sterile dark test tubes without sediment. This study also found no difference in disappearance rates of niclosamide among non-sterile light test tubes with sediment, sterile light test tubes with sediment and sterile dark test tubes with sediment. In the presence of sediment, the half-life of niclosamide in the water column was less than 10 days.

In the lake environment, degradation of niclosamide must occur in a primarily sediment-free system, given the high ratio of water to sediment. As such, niclosamide is expected to remain in solution in the lake system and persist for long periods of time.

Volatilization from dry and moist soil surfaces, or from water surfaces should not be a major fate process for this compound. The measured vapor pressure is 9.9×10^{-6} mm Hg at 25°C and the estimated Henry's Law constant is 6.5×10^{-10} atm-m³/mole.

No data have been provided concerning the mobility of niclosamide degradates. However, previous information suggested that aminoniclosamide binds to sediment as well. Since aminoniclosamide is said to be 80-fold less toxic than parent niclosamide, confirmatory mobility data on this degradate is not required.

c. Niclosamide Bioaccumulation

In a supplemental study (MRID 44128201), bioconcentration factors were determined to be 49x for edible tissue, 215x for whole fish, and 916x for viscera in rainbow trout. The concentration of radioactive residues in the fish increased very rapidly to a plateau during the first three days of exposure. Depuration was rapid and fairly complete by day 10 of the elimination period. There is some degree of uncertainty surrounding the results of this study since neither the radioactivity in the water, nor the accumulated radioactivity in the fish tissues was identified, but was assumed to be parent niclosamide. There is reason for concern that photodegradates may have been present in the test tank, particularly since it appears that niclosamide may be susceptible to photolysis and that a small amount of acetone, a photosensitizer, was used as a co-solvent. However, given the stability of niclosamide to hydrolysis at the pH values in the study, and the flow-through design of the experiment, significant degradation of niclosamide in the exposure tank would not be expected.

d. Niclosamide Field Studies

A monitoring study (MRID 42552317) was conducted in Seneca Lake, New York to describe the distribution, dispersion, and dissipation of niclosamide in the water column after an application and to assess its bioaccumulation by, and toxicity to, two species of caged, non-target fish.

Granular Bayer 73 was applied at a nominal rate of 110 kg/ha (2300 ug/L, assuming dissolution into the bottom 10 cm of water). Niclosamide concentrations in the lake water samples ranged from <10 to 573 ug/L. Concentrations were generally lowest at the surface and highest at the bottom (0.1 m). Although there is an expectation that niclosamide is released from granules into the bottom 5 cm of the water column, it was found throughout the water column; a result of either mixing or premature release. Concentrations greater than 40 ug/L were measured at all depths and stations within the treatment area. After 48 hours, all concentrations were below 30 ug/L. Concentrations were below the detection limit (10 ug/L) by 96 hours after application.

Niclosamide residues in fish muscle tissue were consistent with water concentration and distribution patterns. Residues ranged from 0 to 858 ng/g and were highest in fish from the bottom depth at all stations. Residues increased until 14-24 hours after application and then declined.

The selective toxicity of granular niclosamide is based on the assumption that dissolution takes place at the sediment-water interface, implying that non-target fish could escape lethal concentrations whereas sea lamprey larvae, which live in the substrate and are relatively weak swimmers, would be killed. However, the results of this investigation show that both lampreys and non-target fish will be exposed to niclosamide throughout the water column.

3. Niclosamide Aquatic Exposure Assessment

Since niclosamide is added directly to water, the estimated environmental concentrations (EECs) used in this evaluation were based on projected treatment concentrations derived from when niclosamide is applied with TFM. Application rates for the TFM/niclosamide mixture are based on pH, temperature, stream/river discharge rates and bioassay data. Treatment levels of niclosamide have historically ranged between 25 to 35 ppb (personal communication, Terry Bills, Fishery Biologist, U. S. Geological Survey Biological Resource Division 1999); this range of treatment levels was used in the aquatic risk assessment.

H. Environmental Exposure and Risk Characterization for TFM and Niclosamide

a. Risk presumptions

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of this integration is called the quotient method. Risk quotients (R.Q.) are calculated by dividing exposure estimates by acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQ values are then compared to OPP's levels of concern (LOCs). These LOCs are used by OPP to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** -- potential for acute risk is high; regulatory action may be warranted in addition to restricted use classification, (2) **acute restricted use** -- the potential for acute risk is high, but may be mitigated through restricted use classification, (3) **acute endangered species** - endangered species may be adversely affected, and (4) **chronic risk** - the potential for chronic risk is high regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to birds or mammals.

The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory

studies that assess acute effects are: (1) LC50 (fish and birds), (2) LD50 (birds and mammals), (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEC (birds, fish, and aquatic invertebrates), (2) NOAEC (birds, fish and aquatic invertebrates), and (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOAEC generally is used as the ecotoxicity test value in assessing chronic effects, although other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOAEC and LOAEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOAEC is used if the measurement end point is production of offspring or survival.

Risk presumptions and the corresponding RQ values and LOCs, are tabulated below.

Table 8: Risk Presumptions for Terrestrial and Aquatic Animals				
Risk Presumption	RQ	LOC		LOC
Birds and Mammals			Aquatic Animals	
Acute High Risk	EEC/LC50 or LD50/sqft ² or LD50/day ²	0.5	EEC/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/NOAEC	1	EEC/MATC or NOAEC	1

abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

² (mg/ft²)/(LD50 x wt. of bird)

³ (mg of toxicant consumed/day)/(LD50 x wt. of bird)

Table 9: Risk Presumptions for Plants				
Risk Presumption	Terrestrial and Semi-Aquatic Plants		Aquatic Plants	
	RQ	LOC	RQ	LOC
Acute High Risk	EEC/EC25	1	EEC ³ /EC50	1
Acute Endangered Species	EEC/EC05 or NOAEC	1	EEC/EC05 or NOAEC	1

¹ EEC = lbs ai/A

² EEC = (ppb/ppm) in water

b. Environmental Risk Assessment

In order to evaluate the potential risk to aquatic and terrestrial organisms from the use of TFM and niclosamide, risk quotients (RQ) are calculated from the ratio of estimated environmental concentrations (EECs) to ecotoxicity values; all calculated values can be found in an appendix to the Environmental Fate and Effects Division Niclosamide Risk Assessment (July, 1999). For this analysis, avian EECs were based on the maximum application rate reported, i.e., 12 ppm of TFM. Aquatic EECs were based on actual predicted application rates for TFM. Since much of the TFM toxicity data were

collected using pH range 7.2-7.6, the predicted concentrations of TFM in the water, based on model outputs, ranged from 0.7-2.2 ppm (personal communication, Dorrance Brege, U. S. Geological Survey Biological Resource Division 1999). These rates are based on pH, alkalinity, temperature, stream/river discharge rates and bioassay data that have been incorporated into a spread-sheet format by the U. S. Fish and Wildlife Service. Based on application rates and past use history it has been determined that typical EECs from the use of niclosamide will range from 25 to 35 ppm. All risk quotient calculations for niclosamide will be based on these EECs. RQ values are then compared to levels of concern (LOC) criteria that are used by the Office of Pesticide Programs in the determination of potential risk to nontarget organisms and the resulting need for possible regulatory action.

c. Exposure and Risk to Non-target Terrestrial Organisms

TFM and niclosamide are only registered for use on aquatic sites; therefore, the typical terrestrial analysis of risk, based on exposures developed by Hoerger and Kenega (1972) and as modified by Fletcher *et al.* (1994) is not applicable for establishing the risk of TFM to non-target terrestrial species. However, because numerous avian, *i.e.*, waterfowl and shorebirds, and mammalian species (muskrats, beavers, raccoons and numerous other small mammals) typically utilize aquatic environments as nesting and/or feeding habitats and may be exposed to TFM and or niclosamide via contaminated water, it is appropriate to use the aquatic EECs for conducting the risk assessment to terrestrial species.

Calculated acute RQ values show that there is virtually no acute risk to birds or mammals from the use of TFM or niclosamide (RQ < 0.1). RQ values for chronic exposure were not calculated; no chronic concerns are expected.

d. Exposure and Risk to Non-Target Freshwater Aquatic Organisms.

(1) Acute Fish

For TFM, RQ values based on 1, 24, and 96-hr LC₅₀ values and predicted treatment levels of 2.2 ppm and 0.7 ppm exceeded acute high risk levels of concern. Based on 1-hr LC₅₀ values and an exposure level of 0.7 to 2.2 ppm, acute high risk LOCs were exceeded for 33% of the species tested. Using 24-hr LC₅₀ values and an exposure level of 0.7 ppm, acute high risk LOCs were exceeded for 17% of the species tested.

TFM RQ values for the various developmental stages of fish were calculated for predicted treatment concentrations of 0.7 ppm and 2.2 ppm. Acute high risk LOCs are exceeded for 17% of the developmental stages at treatment concentrations of 0.7 ppm and all of the developmental stages at a treatment concentration of 2.2 ppm. Green eggs and eyed eggs were the most sensitive developmental stages based on RQ.

TFM RQ values were examined over a range of pH (6.5 - 9.5) for rainbow trout, and were based on predicted treatment concentrations for each of the pH levels. Predicted treatment concentrations ranged from a low of 0.2 ppm at pH 6.5 to a high of 9 ppm at pH 9.5. RQ values were

relatively consistent (range 0.16 to 0.39) for minimum target concentrations and underscore how treatment levels are adjusted relative to pH to reflect changes in toxicity. At maximum projected treatment concentrations (range 0.6 - 9 ppm), RQ values range from 0.36 to 1.2; acute high risk, restricted use and endangered species LOCs are exceeded at pH values less than 8.1. At minimum predicted application rates ranging from 0.2 to 1.6 ppm, restricted use and endangered species LOCs are exceeded for rainbow trout at all pH levels.

For niclosamide, RQ values based on 96-hr LC₅₀ values and predicted treatment levels of 25 ppb and 35 ppb exceeded acute high risk levels of concern. Acute high risk LOCs were exceeded for sea lamprey and rainbow trout at a treatment level of 25 ppb; at 35 ppb, acute high risk LOCs were exceeded for the majority (60%) of the species tested. The following table summarizes risk quotients for freshwater fish tested.

Table 10: Summary of risk quotients to fresh water fish species based on predicted treatment levels of niclosamide at 25 and 35 ppb.

Species Flow-through or Static	EEC (ppm)	96-hour LC ₅₀ (ppm)	RQ	EEC (ppm)	RQ
Rainbow trout	0.025	0.03	0.83*	0.035	1.3*
Bluegill sunfish	0.025	0.094	0.27**	0.035	0.37**
Sea lamprey	0.025	0.049	0.5*	0.035	0.71*
Carp (<i>Cyprinus carpio</i>)	0.025	0.120	0.21**	0.035	0.29**
Green sunfish (<i>Lepomis cyanellus</i>)	0.025	0.170	0.15***	0.035	0.50*

* Acute high risk, acute restricted use and endangered species LOCs exceeded.

** Acute restricted use and endangered species LOCs exceeded.

*** Endangered species LOCs exceeded

Niclosamide RQ values were examined over a range of pH (6.5 - 9.5) for rainbow trout and were based on treatment concentrations of 25 and 35 ppb. The data indicate that as water becomes more acidic, the risk to fish increases by roughly a factor of 10.

RQ values for the mixture of TFM/niclosamide (98:2 by weight), based on predicted treatment concentration of 0.7 ppm and 2.2 ppm and niclosamide of 25 to 35 ppb indicate that acute high risk LOCs are exceeded. It should be noted however, that niclosamide is typically added to TFM to reduce the amount of TFM needed. Thus, predicted TFM treatment concentrations of 0.7 to 2.2 ppm for water with pH 7.2 to 7.6 would be considered high.

(2) Chronic Fish

No chronic toxicity data for TFM or niclosamide were available for fish. Since little is known about the persistence of these compounds, it is not possible to predict the likelihood of fish being exposed to toxic levels. Given the dilution potential with the volume of water in the lakes, there is little

concern about toxic levels in the Great Lakes themselves. However, due to the uncertainty regarding persistence, there may be chronic concerns for organisms downstream from the application site prior to dilution in the lake.

(3) Acute Aquatic Invertebrates

Aquatic acute high risk, acute restricted use, and endangered species LOCs are exceeded for aquatic invertebrates at the typical use rates of TFM. Acute restricted use and endangered species LOCs are exceeded for 67% of the aquatic invertebrates at the predicted minimum concentration in water pH 7.2 - 7.6. At the maximum predicted treatment concentration, acute restricted use and endangered species LOCs are exceeded for 83% of the aquatic invertebrates tested.

For niclosamide, acute high risk LOCs are exceeded for aquatic earthworms and flatworms. Aquatic acute high risk, acute restricted use, and endangered species LOCs are exceeded for aquatic invertebrates at the typical use rates of niclosamide.

Aquatic invertebrate RQ values for the mixture of TFM and niclosamide at the minimum predicted concentration of 0.7 ppm TFM, range from 0.03 to 0.46, while RQ values for the maximum predicted treatment concentration of 2.2 ppm TFM range from 0.08 to 1.47. Acute restricted use and endangered species LOCs are exceeded for aquatic invertebrates at minimum predicted treatment concentrations for waters of pH 7.2 - 7.6. The data indicate that of the species tested, flatworms are at the greatest risk from the use of mixture of TFM and niclosamide to control the sea lamprey. Data suggest that aquatic invertebrates feeding on bottom sediments are more likely to be at risk to TFM/niclosamide treatments and exposures may be a result of ingestion of TFM/niclosamide bound to detritus.

The TFM/niclosamide mixture results in higher toxicity to aquatic invertebrates; however, the increase in toxicity is not proportional to that of the lamprey. In other words, lampreys undergo a marked increase in toxicity to the TFM/niclosamide compared to the relatively small increase in sensitivity exhibited by aquatic invertebrates. This differential toxicity between sea lamprey larvae and nontarget aquatic invertebrates as a result of using the TFM/niclosamide mix is exploited to enhance mortality of sea lamprey larvae while reducing effects on nontargets (pers. comm. Terry Bills, Fishery Biologist, U.S. Geological Survey 1999).

e. Plants

For TFM, the RQ values for aquatic plants, at the minimum treatment level of 0.7 ppm, range from <0.2 to 0.58, while the RQ values for the maximum treatment level of 2.2 ppm range from < 0.15 to 1.83. Acute high risk and endangered species LOCs are exceeded for aquatic plants at the typical use rates of TFM.

No acute levels of concern were exceeded for the aquatic plant species tested with niclosamide. At the typical maximum treatment rate of 35 ppb for niclosamide, green algae were the most sensitive with an RQ of 0.85.

f. Endangered Species

Freshwater fish and aquatic invertebrate endangered species LOCs are exceeded for TFM and niclosamide and aquatic plant endangered species LOCs are exceeded for TFM. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect endangered species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice.

The U.S. Fish and Wildlife Service's lamprey control program routinely engages in Section 7 consultations when endangered/threatened species are suspected to be present in treatment areas. In studies conducted on lake sturgeon (*Acipenser fulvescens*), concentrations of TFM approximately 1.3 times the LC₅₀ of sea lamprey larvae were not lethal to juvenile lake sturgeons (Johnson *et al.* 1999). If endangered or threatened species were known to inhabit projected treatment sites, treatment concentrations of the lampricides would be adjusted to minimize impact to these species. Adjustments would include the use of TFM/niclosamide mix to broaden the differential toxicity of these compounds, and thus increase toxicity to sea lamprey larvae while holding the toxicity to nontarget species relatively constant (personal communication, Terry Bills, Fishery Biologist, U.S. Geological Survey Biological Resource Division 1999; Bills *et al.* 1985). According to the U.S. Fish and Wildlife Service (personal communication, Terry Morse, Treatment Supervisor, U.S. Fish and Wildlife Service 1999), if treatment concentrations could not be adjusted to minimize impact to sensitive nontarget species, then the identified habitats would not be subjected to lampricide use.

I. Environmental Risk Characterization for TFM and Niclosamide

TFM is both chemically and biologically stable and without evidence to the contrary is expected to remain toxic for long periods of time. However, mitigation of its effects at the treatment site is likely to occur as a result of the flushing action of the stream/river. TFM is a phenolic compound and behaves as a weak acid; its neutral form (free phenol) is more likely to cross cell lipid membranes, and thus its uptake and toxicity are strongly dependent on pH (Bills *et al.* 1988); however, at the pH of most natural streams/ivers, the majority of the compound will be in the ionized form. Un-ionized TFM was more readily adsorbed than the ionized (phenolate) form; however, the adsorption process was readily reversible.

Decisions regarding application rates and times are based on both abiotic and biotic factors including pH, stream discharge, time of day, temperature, in-field bioassays and population assessment data. Spreadsheet-based flow models have been developed to assist in determining application rates, flowtimes, and dilution factors. Models are developed only for streams with complex treatment scenarios, including marked diurnal fluctuations in pH or physical/chemical changes. These models permit greater latitude in explaining possible effects of input factors on treatment concentrations and start times of applications. Predicted treatment concentrations for specific locations, based on physico-chemical data or in-stream toxicity tests, are intended to result in a concentration greater than the $LC_{99.9}$ for sea lamprey while being substantially less than the LC_{25} for brown trout. This improves treatment effectiveness for sea lampreys, yet minimizes the effect on nontarget species. Predicted treatment concentrations based on physico-chemical data may be modified on the basis of data produced by on-site flow-through toxicity tests. In Lake Superior and upper Lake Michigan, streams tend to have soft water with pH less than 8.2 and thus require lower application rates, *i.e.*, less than 6 ppm. In the lower tier of the Great Lake, tributaries harboring lamprey may exhibit hardnesses exceeding 200 ppm with a pH range 8.1 - 8.7. Care must be taken in selecting application rates for streams with large diurnal pH fluctuations. Typically, initial target concentrations remain primarily based on the lower observed pH values because of the increased toxicity potential of TFM at lower pH. TFM target concentrations in hard water streams may range from 1 to 6 ppm. While application rates as high as 12 ppm have been reported, the cost effectiveness of TFM at this concentration would be better offset by applying TFM/niclosamide mix (99:1) and as such, applications of TFM at greater than 9 ppm would rarely occur (personal communication, Dorance Brege, U.S. Fish and Wildlife Service Treatment Supervisor 1999).

Estimated environmental TFM concentrations used in this evaluation (range 0.7 - 2.2 ppm) are projected treatment concentrations derived from a nomograph developed by U.S. Fish and Wildlife Service reflecting toxicity over ranges in both pH and alkalinity that were representative of the conditions under which most of the toxicity data were reported, *i.e.*, pH range 7.2 - 7.6 and water hardness 44 mg/L as $CaCO_3$. Estimated environmental concentrations of niclosamide used in this evaluation (25 to 35 ppb) were based on typical concentrations reported by the Fish and Wildlife Service. At the predicted treatment levels, acute high risk, acute restricted use, and endangered species LOCs are exceeded for aquatic animals. Use of the TFM/niclosamide mixture results in larger exceedences of the LOCs; however, the mixture tends to exhibit a marked increase in toxicity to sea lamprey larvae while nontarget organisms exhibit only a moderate increase. Although TFM is likely to have an immediate effect on the aquatic community, the data suggest that most organisms recover quickly and the treatment area community structure returns to pre-treatment conditions within approximately 6 months (Kolton et al., 1986). Additionally, a genuine effort is made to document where sensitive populations reside and steps are undertaken to avoid treatments at concentrations known to be toxic to these organisms. The long-term effects to more sensitive species, such as indigenous lampreys, and to aquatic communities downstream from the treatment sites where chronic effects may be more likely, remain uncertain.

Because of the nature of the use of TFM and niclosamide, *i.e.*, applied to flowing water, it is difficult to characterize the magnitude of the ecological effects associated with use of the chemical. Aquatic organisms in the treatment area are expected to be impacted to some extent during the proposed 12-hr treatments. Impacts to aquatic communities in terms of food-web structure are unknown. The two

Special Local Needs labels for niclosamide are for application to ponds in which ornamental fish are grown; these fish ponds are contained, an NPDES permit is required for water release and there should be very low exposure to nontargets from this use. Therefore, the risks associated with this use of niclosamide are expected to be negligible.

In the environment, the sorption and degradation of TFM by sediments is expected to occur primarily in the lakes and not in the tributary streams. Most of the TFM will be quickly flushed into the lakes. The amount removed by sorption to the stream sediments is unknown, but is likely to be minimal. In the lake environment, degradation of TFM and niclosamide must occur in a primarily sediment-free system, given the high ratio of water to sediment and the lack of sediments containing appreciable amounts of organic material (Thingvold, 1975). As such, TFM is expected to remain in solution in the lake system and persist for long periods of time at low concentrations.

In addition to dilution and dispersion, sorption to sediments and suspended particulates and possibly photodegradation (in clear shallow waters), are the major routes of dissipation of niclosamide. Neither hydrolysis nor volatilization from soil or water surfaces should be major fate processes for this compound. In most aquatic environments, niclosamide will adsorb to suspended solids and sediment. Though niclosamide does tend to bind to sediments, the binding is by no means irreversible, thus nontarget species and benthic organisms in particular, will be exposed to niclosamide for extended periods of time. It is unclear what role, if any, aerobic and anaerobic microbial degradation plays in the dissipation of niclosamide in the aquatic environment.

Although TFM and niclosamide are not expected to bioaccumulate in aquatic organisms, two potential exposure scenarios exist. Aquatic animals may be directly exposed to lampricide in the water as the chemical block moves through during roughly a 24-hr period. Additionally, predatory animals may be exposed through the consumption of prey incapacitated by lampricide treatments. However, in a study of the lampricide niclosamide, it was estimated that the common tern (*Sterna hirundo*), a shore bird which is a state-listed endangered species in Michigan, would have to consume roughly 16.8 times its body weight in contaminated sea lamprey larvae to approach toxic levels (Hubert *et al.* 1999).

While TFM and niclosamide treatments will likely impact stream/river community structure in the short term, data suggest that most organisms recover quickly and the treatment area community structure returns to pre-treatment conditions within approximately 6 months (Kolton *et al.*, 1986). This recovery is site specific and may take much longer in certain environments and certain species may be significantly impacted, most notably the indigenous lamprey species that may populate treatment areas. In general, however, native lamprey species have tended to populate the upper reaches of tributary streams whereas the sea lamprey is more likely to inhabit lower reaches of the stream. Thus, nontarget species that may have been affected in the treatment area are repopulated through downstream migration from untreated areas. Furthermore, retreatment of the stream will not occur for at least 3 to 5 years.

It is believed that, given the current application rates, the effects of TFM and niclosamide are mitigated solely by the flushing action of the stream through the treatment site. Effects on the aquatic environment downstream from the treatment site are unknown and would depend heavily on the

stream/river discharge rate, water temperature, pH and alkalinity and the proximity of sensitive nontarget organisms. While treatment areas have demonstrated a capacity to recover, the downstream acute and chronic effects, where TFM is most likely to be deposited, remain uncertain.

Exposure to TFM during embryonic development increased the frequency of abnormalities that lead to increased mortalities and stream treatments with lampricides have resulted in a shift in sex ratios among lampreys over a 16-yr period. TFM treatments have been associated with induction of hepatic mixed function oxygenase activity and altered levels of circulating steroids in fish and induced hepatic vitellogenesis in primary cultures of rainbow trout hepatocytes. As such, TFM acts as an estradiol agonist and has a demonstrated endocrine disrupting effect. The potential for TFM to result in endocrine disrupting effects on fish populations in treatment areas has been considered remote based on the fact that streams are treated at most once every 3 to 5 years, exposure duration is less than 24 hours and TFM has not been demonstrated to persist in treatment areas (Hewitt et al. 1998). However, the duration of exposure to fish downstream of the application site has not been adequately characterized and thus the potential for an endocrine disrupting effect cannot be dismissed.

1. Terrestrial

TFM and niclosamide are only registered for use on aquatic sites. However, because numerous avian, (waterfowl and shorebirds) and mammalian species (muskrats, beavers, raccoons and numerous other small mammals) typically utilize aquatic environments as nesting and/or feeding habitats, and may be exposed to TFM and niclosamide via contaminated water, there is some potential for exposure to terrestrial species. Additionally, the aerial application of the niclosamide 3.2% granular formulation may serve as a route of exposure to nontarget terrestrial organisms.

Based on the available toxicity data there is very little risk from either acute oral, acute dermal or subacute dietary exposure to mammals or birds. Acute RQs for both birds and mammals (< 0.01) show that there is minimal risk from the concentrations likely even at a maximum treatment concentrations. In addition, during the nearly forty years of TFM use to control the sea lamprey, there are no actual field reports documenting any acute mortality to avian or mammalian species.

There are no available chronic toxicity data for TFM or niclosamide for avian species. However, because of the very low levels of exposure and the relatively short time that terrestrial species will be exposed, chronic risk to terrestrial species is expected to be very low.

2. Aquatic

TFM and niclosamide are applied directly to water and maintained at a desired concentration for a specified period of time, *i.e.*, generally 12 hours. A number of environmental factors influence the toxicity of TFM; these factors include stream/river discharge rate, pH, and temperature. Of all of the water quality parameters investigated, pH had the greatest influence on the toxicity of TFM to aquatic organisms as pH affects the availability and uptake of TFM by aquatic organisms. In general, the lower the pH, the greater the uptake and thus, the greater the toxicity.

TFM ranged in toxicity from slightly to highly toxic to freshwater fish. Based on 1-hr LC_{50} values, acute high risk, acute restricted use and endangered species LOCs were exceeded for 33% of the species tested while acute restricted use and endangered species LOCs were exceeded for all of the species at predicted maximum treatment concentrations of 2.2 ppm. At the minimum predicted treatment concentration of 0.7 ppm and based on 96-hr LC_{50} values, acute high risk, acute restricted use and endangered species LOCs were exceeded for all of the species tested.

Studies described in NRCC (1985) have suggested that native lamprey (*Ichthyomyzon* spp. and *Lampetra* spp.) are less sensitive (9-hr $LC_{99.9}$ 2.0 and 2.5 mg/L), than the sea lamprey (9-hr $LC_{99.9}$ 1.4 mg/L) and that this differential sensitivity may lessen the impact to native species.

TFM was slightly to moderately toxic to freshwater invertebrates; acute restricted use and endangered species LOCs are exceeded for 67% of the aquatic invertebrates at the predicted minimum concentration of 0.7 ppm in water pH 7.2 - 7.6. At the maximum treatment concentration of 2.2 ppm for these waters, acute restricted use and endangered species LOCs were exceeded for 83% of the aquatic invertebrates tested. Tricopterans appeared to be particularly sensitive to the effects of TFM. Their sensitivity to the lampricide is consistent with the observation that bottom dwelling organisms that feed on detritus may have increased exposure to the lampricide by ingestion of TFM-bound sediments (pers. comm. Terry Bills, Fishery Biologist, U.S. Geological Survey Biological Resource Division 1999). Since 1981, the U.S. Fish and Wildlife Service has examined the effect of lampricide applications on more than 200 aquatic macroinvertebrates. Based on the data, it is estimated that greater than 95% of the nontarget macroinvertebrates survive exposure to lampricide applications. Recovery of the 6 sensitive nontarget organisms that were identified (*Hexagenia*, *Litobranchia*, *Chimarra*, *Dolophilodes*, *Glossosoma*, and *Simuljum*) often begins within days or weeks after exposure, and the short- and long-term diversity and health of the aquatic communities remains stable. The most apparent effect of TFM based on field observations was an immediate reduction in macroinvertebrate density that was attributed to increased downstream drift and mortality of sensitive organisms (NRCC 1985). Particulate feeding macroinvertebrates were the most sensitive to the effects of TFM and may reflect increased uptake of TFM by ingestion of TFM bound to particulate matter.

The effects of niclosamide on non-target aquatic invertebrates from sea lamprey control operations have been reported (Gilderhus, 1979). Although niclosamide treatment reduced the total number of aquatic invertebrates by 56% in the first 7 days after treatment, this effect was transitory.

TFM was toxic to aquatic plants and resulted in the inhibition of growth; at concentrations of greater than 35 ppm, TFM was herbicidal. Acute high risk and endangered species LOCs were exceeded in 20% of the plants evaluated at 2.2 ppm TFM. There are limited data on the effects of niclosamide on aquatic plants.

Since 1994, a broad range of nontarget mortality has been reported following application of both TFM and niclosamide (document reference numbers 1008982-001 and 1008983). Nontarget mortality affected 32 species of fish, 4 species of amphibians, and 4 groups of invertebrates (Table 11) during application of lampricides in tributaries of the Great Lakes, Lake Champlain, and Finger Lakes during

1994 - 1998. The most notable fish kills have occurred following the aerial application of the 5% granular formulation of niclosamide and resulted in approximately 169,000 fish killed. During September 1994, application of niclosamide to the Ausable River system, a tributary of Lake Champlain, killed approximately 33,000 indigenous American brook lamprey (*Lampetra appendix*) and silver lamprey (*Ichthyomyzon unicuspis*) combined. As recently as May 1999, nontarget fish mortality (log perch; *Percina caprodes*) was reported following TFM applications and resulted from a downward shift in pH in poorly buffered (low alkalinity) waters that increased the toxicity of TFM. These data indicate that despite efforts to minimize impact to nontarget species, there are occasional situations where nontarget mortality occurs. The incident reports on Lake Champlain suggest that nontarget mortality was enhanced following aerial application of the 5% granular formulation of niclosamide. The magnitude of nontarget mortality following this application verifies EPA's concern that aerial application of niclosamide is the least controlled application method and as such is the most susceptible to nontarget mortality.

Table 11: List of nontarget species or taxa experiencing mortality during application of lampricide in streams and deltas of streams tributary to the Great Lakes, Lake Champlain and the Finger Lakes of the U. S. during 1994-1998.

Invertebrates			
annelids	Phylum Annelida (segmented worms: earthworms, aquatic worms, and leeches)	burrowing mayflies	Family Ephemeridae (burrowing mayflies)
Hexagenia	<i>Hexagenia</i> spp.	Mayflies	Order Ephemeroptera (mayflies)
Amphibians			
frogs	Family Ranidae (frogs)	salamanders	Order Caudata (salamanders)
Northern two-lined salamander	<i>Eurycea bislineata</i>	red-spotted newt	<i>Notophthalmus viridescens viridescens</i>
Fishes			
American brook lamprey	<i>Lampetra appendix</i>	banded killifish	<i>Fundulus diaphanus</i>
blackchin shiner	<i>Notropis heterodon</i>	blacknose dace	<i>Rhinichthys atratulus</i>
bluegill	<i>Lepomis macrochirus</i>	brown bullhead	<i>Ameiurus nebulosus</i>
bullheads	<i>Ameiurus</i> spp.	common carp	<i>Cyprinus carpio</i>
common shiner	<i>Lusilus cornutus</i>	creek chub	<i>Semotilus atromaculatus</i>
emerald shiner	<i>Notropis atherinoides</i>	hornyhead chub	<i>Nocomis biguttatus</i>
johnny darter	<i>Etheostoma nigrum</i>	largemouth bass	<i>Micropterus salmoides</i>
logperch	<i>Percina caprodes</i>	longnose dace	<i>Rhinichthys cataractae</i>
mimic shiner	<i>Notropis volucellus</i>	minnows	Family Cyprinidae (carps and minnows)
Northern hog sucker	<i>Hypentelium nigricans</i>	perches	Family Percidae (perches)
redhorses	<i>Moxostoma</i> spp.	rock bass	<i>Ambloplites repestris</i>
silver lamprey	<i>Ichthyomyzon unicuspis</i>	smallmouth bass	<i>Micropterus dolomieu</i>
spottail shiner	<i>Notropis hudsonius</i>	stonecat	<i>Noturus flavus</i>
suckers	Family Catostomidae (suckers)	tadpole madtom	<i>Noturus gyrinus</i>
tessellated darter	<i>Etheostoma olmstedii</i>	trout perch	<i>Percopsis omiscomaycus</i>
white sucker	<i>Catostomus commersoni</i>	fishes	Osteichthyes (boney fish)

Although adverse effects to certain species and/or taxa have been observed, the evidence suggests that these effects are only transitory and do not threaten any populations of aquatic species.

Although there have been some cases where recolonization of affected populations have taken up to 6 or 7 months, most streams recovered to pretreatment levels in a matter of days or weeks. Recolonization of the treated areas usually occurs from untreated, upstream portions of the tributary although some recolonization may also occur from sediments that were too deep to be exposed.

3. Uncertainties

The environmental fate and ecological effects of TFM and niclosamide characterized in this document are restricted to the specific treatment site and focus on the acute toxicity of the lampricides given projected treatment levels selected to achieve a sea lamprey LC_{99.9} with little nontarget mortality.

Given the persistence of TFM and niclosamide, mitigation of their effects relies predominately on the flushing action of the stream/river tributaries and eventual deposition and dilution in the Great Lakes. Initial assessments of the ecological effects assumed that both TFM and niclosamide would not be persistent in the treatment area and that the eventual dilution of both compounds in the Great Lakes would render chronic-effect studies unnecessary. However, the Agency is uncertain to the degree to which treatment site concentrations of TFM and niclosamide are rendered ineffective, meaning that the potential for chronic effects is uncertain particularly in the mixing zones at the confluence of tributaries with the Great Lakes. While the data suggest that treatment areas recover to pre-treatment community structure, certain species are sensitive to the effects of TFM and niclosamide. Although the direct effects of lampricide treatments have been partially characterized, the secondary effects on food chains and the ability of nontarget species to feed during the recovery period is uncertain. Although the ecological data gaps identified in this document may address uncertainties over potential chronic effects, the environmental fate of TFM and niclosamide downstream of application sites, *i.e.*, the stream/river deltas is uncertain without monitoring studies to quantify TFM and niclosamide concentrations in the mixing zones.

Also, chemical-specific uncertainties are that the potential effects of TFM as an endocrine disruptor are difficult to characterize. Additionally, the newer formulations of niclosamide (3.2% granular) that result in its slow release along the stream/river bottom pose an unknown risk in terms of both acute and chronic toxicity to nontarget sediment-dwelling organisms.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing TFM and niclosamide as active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing TFM and niclosamide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of TFM and niclosamide, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of TFM and the lampricide uses of niclosamide, and to determine that TFM and niclosamide can be used as low volume, restricted use compounds, as specified in this document, without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing TFM and niclosamide as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed for lampricide uses in Section V of this document.

The Agency made its reregistration eligibility determination based upon the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that all uses of TFM and niclosamide are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing TFM and niclosamide, if new information comes to the Agency's attention or if the data requirements for registration or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients TFM and niclosamide, the Agency has sufficient information on the health effects of TFM and niclosamide and on its potential for causing adverse effects in fish and wildlife and the environment. Although the current database is limited, this finding of sufficient information is based on the limited use pattern, stringent use restrictions mandated by the USFWS and the PPE required on current labels. The Agency has determined that TFM and niclosamide products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency concludes that products containing TFM and niclosamide for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of TFM and niclosamide for control of Sea Lamprey are eligible for reregistration under the conditions specified in this RED.

The niclosamide Special Local Needs labels for use in ornamental fish ponds should result in minimum exposure to humans and non-target organisms and are eligible for reregistration under the conditions specified in this RED assuming monitoring programs similar to those conducted by the U.S. Fish and Wildlife Service (USFWS) are instituted for these uses. These monitoring programs include medical monitoring for applicators, a routine industrial hygiene program, an incident reporting system, and comprehensive use records.

The Agency has determined that the molluscicide use of niclosamide for human health purposes is not eligible for reregistration due to lack of data on the use and potential non-occupational exposure of humans to niclosamide. According to the Public Health Service at the Centers for Disease Control and Prevention, there are currently no public health uses for niclosamide in the United States. The currently labeled public health use is the use of Bayluscide 70% Wettable Powder (EPA Registration Number 6704-87) in Puerto Rico against fresh water snails serving as the vector for schistosomiasis. Niclosamide has not been used in Puerto Rico since 1980. This use is ineligible for reregistration at this time. In order for this use to be eligible for reregistration, a minimum of use information, application methods summary, and a 21-28 day dermal toxicity study (OPPTS 870.3200) are required.

The USFWS has submitted a voluntary cancellation letter for Bayluscide 5% Granular (EPA Registration Number 6704-90) which was used to kill snails serving as the vector for swimmer's itch in MI, WI, and MN.

C. Regulatory Position

The Agency recognizes the efforts of the USFWS and the Great Lakes Fisheries Commission to lessen the risks posed by TFM and niclosamide, by the use of extensive monitoring, IPM measures, public notification and worker training. In order to support these efforts EPA is requiring the following clarification measures for TFM and niclosamide containing products.

- The manual for application must be cited on the label and must be available to all workers.
- The required PPE must be clearly stated on the label.
- The label must prohibit aerial applications.

There are currently two Special Local Needs (SLN) labels issued for niclosamide; both labels are for the Bayluscide 70% Wettable Powder formulation. These labels are for the use of Bayluscide in ornamental fish ponds in Florida (SLN FL94000100) and Arkansas (SLN AR99000700). This use is to kill fresh water snails which infect the fish. The empty pond is treated with Bayluscide at 1 lb formulated product per acre of surface area; the pond is then filled with water. Fish are usually added to the pond in four to seven days. The labels require an NPDES permit for discharging the water from the

pond, but in practical terms, the water is rarely released without treatment. There have been no fish toxicity incidents reported from this use.

The risk assessment calculations reported for risks to humans were made with the following assumptions:

- (1) The manual developed for the use of TFM and niclosamide by the USFWS will be adopted by any user of these compounds (i.e., add it as a requirement on all labeling). *Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey Control Program including Standard Operating Procedures* (1993).
- (2) The USFWS administers a comprehensive medical monitoring program for their employees engaged in any activities involving the use of TFM and niclosamide.
- (3) A routine industrial hygiene monitoring program is conducted to quantify exposures for those occupationally exposed to TFM and niclosamide (in lieu of completing a comprehensive pesticide guideline exposure study)
- (4) The USFWS will maintain an incident reporting system.
- (5) A record keeping system to document the use of TFM and niclosamide will also be maintained by the USFWS. Such a system should be able to document chemical use, locations, dates, site-specific data (e.g., water concentrations and amount used), efficacy, incidents, and any postapplication follow-up required. This system could be used to assess a relationship between the use of TFM and niclosamide and incidents and illnesses should they occur.

The purpose of these monitoring and reporting systems is to verify that EPA's assumptions of low exposure are correct and to ensure that potentially exposed populations are adequately protected.

The following is a summary of the Agency's regulatory position and rationale for managing risks associated with the use of TFM/niclosamide. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

The Agency has determined that there is no reasonable expectation of humans being exposed to TFM or niclosamide residues in the diet via water, fish, irrigated crops, and livestock due to the low use volume, the infrequency of use and the tight control USFWS has over the use of TFM and niclosamide including 24-hr irrigation and potable water intake restrictions. There are no established tolerances for TFM or niclosamide.

There are no residential uses and residential exposure is expected to be negligible.

If the Agency determines, as a result of later implementation process of FQPA, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

b. Endocrine Disruptor Effects

TFM treatments have been associated with induction of hepatic mixed function oxygenase activity and altered levels of circulating steroids in fish and induced hepatic vitellogenesis in primary cultures of rainbow trout hepatocytes (Hewitt et al. 1998). As such, TFM acts as an estradiol agonist and has a demonstrated endocrine disrupting effect.

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. EPA may require further testing of TFM active ingredient and end use products for endocrine disruptor effects when this program is in place.

2. Tolerance Reassessment

TFM has been classified as a low-volume and nonfood use chemical based on the quantity used, the method of application, and the rapid dissipation of any possible residues in fish and water. Therefore, a dietary risk assessment is not required for TFM and there are no tolerances.

3. Benefits from Use of TFM/Niclosamide

Although no formal benefits analysis was conducted for TFM and niclosamide, an informal analysis was provided by the USFWS. Sea Lampreys were introduced to the Great Lakes when the Welland Canal opened in 1829. These parasitic organisms are very destructive to commercial and sport

fish species in the Great Lakes. A variety of IPM measures including traps, weirs and a sterilized male program are in place to try to control the adult sea lamprey population; however, these measures are only partially successful. The TFM/niclosamide treatment program managed by the Great Lakes Fisheries Commission is necessary to protect commercial and sport fish populations in the Great Lakes.

4. Human Health Risk Mitigation

Worker Mitigation

Risk From Handler Exposure: Based on two worker exposure scenarios for TFM, workers are not at unreasonable risk from TFM use. The exposure assessments indicate that workers are primarily at risk to dermal, rather than inhalation exposure. The exposure scenarios were calculated using application information from 41 applications made in tributaries to the Great Lakes in 1997. The backpack application scenarios were calculated assuming that 1% of the total applied could be applied by backpack spray. The margins of exposure (MOE) were calculated taking into account the PPE required in the Fish and Wildlife Services Manual for Pesticide Application which is a double layer of clothing, rubber boots, chemical resistant gloves for TFM, and a respirator. However, respirators are only required in poorly ventilated areas and are not required for general (open air) applications. MOEs calculated with double layers of clothing, rubber boots and chemical resistant gloves, but with no respirators are still above 100 except for three large application scenarios which have MOEs of 66, 68, and 96. These applications would not be made by one person during one day; therefore, the Agency has determined that the MOEs for TFM are above the level of concerns and a respirator is not required for workers handling or applying TFM.

The TFM and niclosamide labels must be updated to clarify the double layer clothing and to ensure that the labels are consistent with the Manual for Lampicide Applications.

No risk assessment was conducted for niclosamide based on the low volume of use; therefore, the Agency is recommending to retain the PPE and use restrictions which are currently on the niclosamide labels.

Table 12 outlines the handler PPE required on the various TFM and niclosamide labels. No engineering controls are required. Although EPA has no data to specifically assess the exposure reduction to mixers/loaders afforded by a chemical-resistant apron, the Agency is persuaded that the exposure reduction would be significant for this chemical. Available data indicate that the preponderance of non-hand exposure to mixers/loaders/applicators and other handlers is to the front torso. Therefore, for mixers/loaders/applicators and other handlers the use of a chemical-resistant apron is probably approximately equivalent to double-layer body protection.

Table 12. Summary of Worker Protection Requirements for TFM and Niclosamide	
Exposure Scenario	PPE Required
TFM	
Mixing/Loading	face shield, double layer of clothing, rubber boots, and chemical resistant gloves
Applying with metered pump.	face shield, double layer of clothing, rubber boots, and chemical resistant gloves
Applying with backpack sprayer	face shield, double layer of clothing, rubber boots, and chemical resistant gloves.
Niclosamide	
Mixing/Loading/Applying 70% Wettable Powder Formulation	face shield, double layer of clothing, rubber boots, chemical resistant gloves, NIOSH approved PF-10 respirator
Mixing/Loading/Applying 3.2% Granular applications	face shield, double layer of clothing, rubber boots, chemical resistant gloves, NIOSH approved PF-10 respirator.

Other Risks: No residential exposures or occupational post-application exposures are expected from the approved registered uses of TFM and niclosamide given compliance with the USFWS regulations.

5. Ecological Risk Mitigation

Mammalian and Avian Mitigation

Aerial applications are to be prohibited on all new labels in order to lessen chances of exposures to nontarget terrestrial animals. Several of the fish kills reported to the Agency were the result of aerial applications of the product which is being voluntarily canceled.

There should be very limited exposure to terrestrial animals and, therefore, low risk to most birds and mammals. The USFWS limits applications in order to avoid disturbing nesting osprey. No further mitigation is necessary for terrestrial systems.

Aquatic Species Mitigation

Although application rates are carefully monitored and adjusted to minimize impact to nontarget aquatic organisms, the analysis of the environmental fate and ecotoxicity indicates that current application rates will impact non-target aquatic organisms. When the combination of TFM and niclosamide are applied, the toxic effects of TFM are potentiated. The extent or degree of adverse effects in the treatment area depends on stream/river discharge rate, pH, hardness and water temperature. Although TFM is likely to have an immediate effect on the aquatic community in the treatment area, the data suggest that most organisms recover quickly and the treatment area community structure returns to pre-

treatment conditions within approximately 6 months (Kolton et al., 1986). Additionally, a genuine effort is made to document where sensitive populations reside and steps are undertaken to avoid treatments at concentrations known to be toxic to these organisms. Some areas are not treated because of the sensitive or endangered species concerns. The long-term effects to more sensitive species, *e. g.*, indigenous lampreys, lake sturgeon and Mayflies, and to aquatic communities downstream from the treatment sites where chronic effects are more likely, remain uncertain.

The goal of The Great Lakes Fishery Commission is to control the sea lamprey populations and not to eradicate the sea lamprey. The Commission has targeted that the reliance on lampricides be reduced by 50%. Through a combination of physical barriers, sterile male release and fine tuning of lampricide applications, lampricide use has been reduced by 35% compared to levels used in the 1980's. To further reduce chemical reliance while controlling the lamprey populations, the Commission has recommended that additional research be conducted on the use of pheromones to serve as attractants to traps and treatment areas, the use of TFM/niclosamide mix, and the use of lampricide formulations that better direct treatments to habitats favored by larval sea lamprey.

6. Labeling Rationale

a. Occupational Risk Mitigation

The Worker Protection Standard (WPS)

At this time none of the registered uses of TFM and niclosamide are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

(1) Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.
2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or certain other adverse effects, such as allergic effects or systemic effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

The Agency concurs with the PPE requirements for TFM and niclosamide which are currently specified in the USFWS manual for application. For TFM, the requirements are two layers of clothing, rubber boots, and chemical resistant gloves. For niclosamide, the requirements are two layers of clothing, rubber boots, chemical resistant gloves, a face shield and an approved organic vapor resistant respirator. Although EPA has no data to specifically assess the exposure reduction to mixers/loaders afforded by a chemical-resistant apron, the Agency is persuaded that the exposure reduction would be significant for this chemical. Available data indicate that the preponderance of non-hand exposure to mixers/loaders/applicators and other handlers is to the front torso. Therefore, for mixers/loaders/applicators and other handlers the use of a chemical-resistant apron is probably approximately equivalent to double-layer body protection.

b. Occupational-Use Products

NonWPS Uses: EPA's evaluation of the dermal and inhalation toxicity of TFM indicates that significant toxicity from either route of exposure is unlikely with the PPE specified by the USFWS manual for application of lampricides. Only very large applications (greater than 1500 kg/treatment) yielded MOEs less than 100; and it is unlikely these large applications would be made by one applicator during one day.

No toxicity endpoints were chosen for niclosamide based on the low volume of use; therefore, so no worker risk assessment was done. The Agency concurs with the PPE currently required on the niclosamide labels.

4. Post-Application/Entry Restrictions

a. Occupational-Use Products

Restricted-Entry Interval: Due to the nature of the TFM and niclosamide use patterns, no significant occupational postapplication exposure scenarios are thought to exist. There are no specified worker re-entry intervals.

b. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing TFM/niclosamide. For the specific labeling statements, refer to Section V of this document.

c. **Endangered Species Statement**

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. **ACTIONS REQUIRED OF REGISTRANTS**

This section specifies the data requirements, responses and labeling changes necessary for the reregistration of both manufacturing-use and end-use products.

A. **Manufacturing-Use Products**

1. **Additional Generic Data Requirements**

The generic data base supporting the reregistration of TFM and niclosamide for the eligible uses has been reviewed and determined to be complete enough to make an assessment for the limited use pattern and low volume usage of these restricted use compounds. The following data gaps remain and these confirmatory data are still required:

Table 13: Data gaps for TFM and Niclosamide.			
	New Guideline #	Old Guideline #	Description
TFM	835-2240	161-2	Photodegradation in water.
Niclosamide	835-2240	161-2	Photodegradation in water.
	835-4300	162-4	Aerobic aquatic metabolism
	835-4400	162-3	Anaerobic aquatic metabolism

The chronic ecotoxicity data requirements listed below are data gaps, but the requirements are being held in reserve pending the results of a currently ongoing monitoring study which the USFWS is conducting.

Table 14: Data requirements held in reserve for TFM and Niclosamide.

	New Guideline #	Old Guideline #	Description
TFM	850.1300	72-4b	Aquatic invertebrate life cycle
	850.1500	72-5	Fish full life cycle
Niclosamide	850-1790	—	Chronic sediment toxicity testing
TFM/Niclosamide mixture	850.1500	72-5	Fish full life cycle
	850.1300	72-4b	Aquatic invertebrate life cycle

Additionally, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects when the endocrine disruptor test program is in place.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained in the table at the end of this section.

In addition, one of the following statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.

"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

If included, this statement should be placed in the Directions for Use section of the label.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Label changes are necessary to implement mitigation measures outlined in Section IV above. Specific language to implement these changes is specified in the following table.

C. Required Labeling Changes Table Summary (Following Page)

Table 15: Summary of Required Labeling Changes for TFM

Description	Required Labeling	Placement on Label
End Use Products Intended for Occupational Use (Non-WPS))		
Restricted Use Pesticide is Triggered by Active Ingredient	<p>"RESTRICTED USE PESTICIDE due to acute hazards to the eye, nontarget aquatic organisms, and to the need for highly specialized applicator training."</p> <p>"Only for sale to and application by certified applicators of the U.S. Fish and Wildlife Service, Fisheries and Oceans Canada, and Provincial and State fish and game employees or persons under their direct supervision."</p>	Top of Front Panel and enclosed in a box.
	"RESTRICTED USE PESTICIDE"	Immediately under the heading Directions for Use.
PPE Requirements Established by the RED Based on the Active Ingredient.	<p>"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category (insert A,B,C,D,E,F,G,or H) on an EPA chemical-resistance category selection chart."</p> <p>"Mixers, loaders, applicators and other handlers must wear:</p> <p>Long sleeved shirt and long pants Rubber boots and socks Chemical resistant gloves such as (registrant inserts correct glove type) Chemical Resistant aprons or coveralls Face shield."</p>	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 15: Summary of Required Labeling Changes for TFM

Description	Required Labeling	Placement on Label
User Safety Recommendations	<p>"User Safety Recommendations"</p> <p>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."</p> <p>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."</p> <p>"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards	<p>"Environmental Hazards"</p> <p>"This chemical is toxic to fish and aquatic invertebrates. Nontarget aquatic organisms may be killed at rates recommended on this label."</p> <p>"Directions for Use must be strictly followed to minimize hazards to nontarget organisms. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."</p> <p>"Local, State, and Provincial Fish and Game Agencies must be contacted before product is applied. Municipalities that use streams requiring treatment as potable water sources must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators that use streams requiring treatment as a source of irrigation water must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators must turn off their irrigation systems for a 24-hour period during and after treatment."</p> <p>"May not be used by unauthorized personnel."</p>	<p>Precautionary Statements under Environmental Hazards</p>
Application Restrictions	<p>"Do not apply this product in a way that will contact workers or other persons, either directly or through drift"</p>	<p>Directions for Use</p>
Other Use/Application Restrictions	<p>"Applicators must follow the instructions provided in the "Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey (<i>Petromyzon marinus</i>) Control Program" for correct rates of application. Prior to and during the application of this chemical, take all appropriate actions to notify public water users including notification actions specified in this manual."</p>	<p>Directions for Use under Application Instructions and/or General Precautions and Restrictions</p>

Table 15: Summary of Required Labeling Changes for TFM		
Description	Required Labeling	Placement on Label
Other Use/Application Restrictions	"Aerial applications of this product are prohibited."	Directions for Use under Application Instructions and/or General Precautions and Restrictions

PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Table 16: Summary of Required Labeling Changes for Niclosamide		
Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into a lampricide for use in tributaries to the Great Lakes, Lake Champlain or the Finger Lakes or into a molluscicide for use against fresh water snails.	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This chemical is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
End Use Products Intended for Occupational Use (Non-WPS)		
Restricted Use Pesticide is Triggered by Active Ingredient	"RESTRICTED USE PESTICIDE due to:" <i>For Bayluscide 70% WP insert: "acute inhalation toxicity, aquatic organism toxicity and to the need for highly specialized applicator training."</i> <i>For Bayluscide 3.2% Granular: "to acute hazards to the eye, nontarget aquatic organisms, and to the need for highly specialized applicator training."</i>	Top of Front Panel and enclosed in a box.
	"RESTRICTED USE PESTICIDE"	

Table 16: Summary of Required Labeling Changes for Niclosamide

Description	Required Labeling	Placement on Label
<p>PPE Requirements Established by the RED Based on the Active Ingredient.¹</p>	<p>"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart."</p> <p>"Mixers, loaders, applicators and other handlers must wear:</p> <p>Long sleeved shirt and long pants Rubber boots & socks Chemical resistant gloves such as (registrant inserts correct glove type) Chemical resistant aprons or coveralls Face shield NIOSH approved respirator with: <ul style="list-style-type: none"> - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or - a canister with any N,R,P or HE prefilter NIOSH approved organic vapor resistant respirator." </p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry."</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

Table 16: Summary of Required Labeling Changes for Niclosamide

Description	Required Labeling	Placement on Label
User Safety Recommendations	<p>"User Safety Recommendations"</p> <p>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."</p> <p>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."</p> <p>"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards	<p>"Environmental Hazards"</p> <p>"This chemical is toxic to fish and aquatic invertebrates. Nontarget aquatic organisms may be killed at rates recommended on this label."</p> <p>"Directions for use must be strictly followed to minimize hazards to non-target organisms. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."</p> <p>"Local, State, and Provincial Fish and Game Agencies must be contacted before product is applied. Municipalities that use streams requiring treatment as potable water sources must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators that use streams requiring treatment as a source of irrigation water must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators must turn off their irrigation systems for a 24-hour period during and after treatment."</p> <p>"May not be used by unauthorized personnel."</p>	<p>Precautionary Statements under Environmental Hazards</p>
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift"	Directions for Use
Other Use/Application Restrictions	"Applicators must follow the instructions provided in the "Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey (<i>Petromyzon marinus</i>) Control Program" for correct rates of application. Prior to and during the application of this chemical, take all appropriate actions to notify public water users including notification actions specified in this manual."	Directions for Use under Application Instructions and/or General Precautions and Restrictions

Table 16: Summary of Required Labeling Changes for Niclosamide		
Description	Required Labeling	Placement on Label
Other Use/Application Restrictions	"Aerial applications of this product are prohibited."	Directions for Use under Application Instructions and/or General Precautions and Restrictions

¹ PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

In accordance with the above policy, the Agency has determined that registrants may distribute and sell TFM and niclosamide products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 3082 [Lamprecide (*)] Chemical 036201 [a,a,a-Trifluoro-4-nitro-meta-cresol]

LGDRHD

Notes: Uses Eligible or ineligible for Re registration, Food/Feed or Non Food/Non Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose (AI unless noted otherwise) : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (day) : Minimum Interval between Applications (days)
Re Entry Interv. : Reentry Interval
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Other

FORMULATION CODES

IMPR : IMPREGNATED MATERIAL
SC/L : SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

AR : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, burst, cake, can, canister, capsule, coil, collar, container, dispenser, drop, ear tag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, ...

APPLICATION RATE

OCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 3082 [Lamprecide (*)] Chemical 036201 [a,a,a-Trifluoro-4-nitro-meta-cresol]

APPLICATION RATE (CONT.)

wt : Hundred Weight

mg-xx : xx times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

CW1 : Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.

CW2 : This pesticide is toxic to aquatic invertebrates.

CW3 : Do not contaminate water, food, or feed by storage or disposal.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

SELECTED PRODUCTS

006704-00045

006704-00086

APPENDIX A REPORT

Case 2455 [Niclosamide] Chemical 077401 [2-Aminoethanol salt of 2',5-dichloro-4'-nitrosalicylanilide]

SITE Application Type, Application Timing, Application Equipment -- Surface Type (Antimicrobial only) & efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (At un- less noted otherwise)	Max. Appl. Rate (At Yex. g Max. Rate unless noted otherwise) Dose cycle	Soil Max. # Apps Max. Dose (At Max. Rate unless noted otherwise) /crop /year unless noted otherwise	Max. Re- Interv Entry (days) Intv.	Geographic Limitations Allowed Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES

LAKES/PONDS/RESERVOIRS (WITH HUMAN OR WILDLIFE USE)

Use Group: AQUATIC FOOD CROP

Water treatment, Not on label, Not on label	G	NA	5 lb A	* NS NS NS	NS 1 NS	MI, NN, W1	
	G	NA	5 lb A	* NS NS NS	NS NS NS NS 013		CAL, CHD, CWH, CMJ, CML
						Geo.013: Lake Champlain and the waters of the Great Lakes Basin.	
Water treatment, When needed, Pump	WP	NA	UC	* NS NS NS	NS AN NS PR		C40, C62, CAL, CAT, CWC, CHH, CMJ, CML

NON-FOOD/NOH-FEED

ORNAMENTAL PONDS/AQUARIA

Use Group: AQUATIC NON-FOOD RESIDENTIAL

Spray, When needed, Sprayer	WP	NA	.7 lb A	* NS 1/1 yr	NS NS NS NS FL		C23, C40, CAL, CAT, CHD, CHH, CMJ, CML
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STREAMS/RIVERS/CHANNELLED WATER

Use Group: AQUATIC NON-FOOD OUTDOOR

Water treatment, Not on label, Metering pump	WP	NA	UC	* NS NS NS	NS AN NS PR		C40, C62, CAL, CAT, CWC, CHH, CMJ, CML
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APPENDIX A REPORT

Case 2455 [Nicosamide] Chemical 077401 [2-Aminoethanol salt of 2',5-dichloro-4'-nitrosalicylanilide]

LEGEND

SOIL : Uses Eligible or Ineligible for Re-registration, Food/Food or Non Food/Non-Food Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate/Unit/Amount, Minimum Application Rate

HEADLINE ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Antimicrobial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tox. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Damage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "1 applications per 1 year" is expressed as "1/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Re-Entry Intv. : Reentry Intervals
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

G : GRANULAR
NP : NETTABLE POWDER

ABBREVIATIONS

AR : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, burst, cake, can, canister, capsule, cartridge, coil, collar, container, dispenser, drop, castag, grains, lure, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pump, sec, sac burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towellette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume

APPENDIX A REPORT

Case 2455 [Niclosamide] Chemical 077401 [2-Aminoethanol salt of 2',5-dichloro-4'-nitrosalicylanilide]

APPLICATION RATE (CONT.)

cwt : Hundred Weight
nnt:xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C23 : HPD85 license restriction.
C40 : Do not apply by aircraft.
C62 : Do not use on surfaces that may contact food, feed, potable water, livestock or dairy animals.
CA1 : Do not contaminate water, food or feed.
CAT : Do not place in locations accessible to children, pets or domestic animals.
CWC : Shrimp and crab may be killed at application rates recommended on this label. Do not apply where these are important resources.
CWB : Shrimp and crab will be killed at application rates recommended on this label. Do not apply where these are important resources.
CWI : Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.
CWI : This pesticide is toxic to aquatic invertebrates.
CWL : Do not contaminate water, food, or feed by storage or disposal.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

011 : Other
FL : Florida
MI : Michigan
MN : Minnesota
PR : Puerto Rico
WI : Wisconsin

UNIT DESCRIPTIONS

A : acre
lb : pound

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within case 3082 (TFM) and case 2455 (Niclosamide) covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to TFM and Niclosamide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 605-6000.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B-TFM

Data Supporting Guideline Requirements for the Reregistration of TFM.

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
61-1 Chemical Identity	ALL	41507102
61-2A Start. Mat. & Mufg. Process	ALL	41507102
61-2B Formation of Impurities	ALL	41507102
62-1 Preliminary Analysis	ALL	41507102
62-2 Certification of limits	ALL	41507102
62-3 Analytical Method	ALL	41507101, 93135002
63-2 Color	ALL	41507102
63-3 Physical State	ALL	41507102
63-4 Odor	ALL	41507102
63-5 Melting Point	ALL	41507102
63-6 Boiling Point	ALL	41507102
63-7 Density	ALL	41507102
63-8 Solubility	ALL	41507102
63-9 Vapor Pressure	ALL	41507102
63-10 Dissociation Constant	ALL	41507102
63-12 pH	ALL	41507102
63-13 Stability	ALL	41507102
63-14 Oxidizing/Reducing Action	ALL	41507102
63-15 Flammability	ALL	41507102

Data Supporting Guideline Requirements for the Reregistration of TFM.

REQUIREMENT		USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>			
71-1A	Acute Avian Oral - Quail/Duck	E	43677702
71-2A	Avian Dietary - Quail	E	00067314,931 35005
71-2B	Avian Dietary - Duck	E	Heath et al, 1972.
71-3	Wild Mammal Toxicity		40999204, 41898102
72-1A	Fish Toxicity Bluegill	E	44186901, Bills and Marking, 1976
72-1C	Fish Toxicity Rainbow Trout	E	44186902 Bills and Marking, 1976
72-2A	Invertebrate Toxicity	E	40094602 Maki et al, 1975.
72-4A	Early Life Stage Fish	E	00070314
72-4B	Life Cycle Invertebrate	E	Reserved
72-5	Life Cycle Fish	E	Reserved
122-1B	Vegetative Vigor		00070732
122-2	Aquatic Plant Growth		Maki et al, 1975
<u>TOXICOLOGY</u>			
81-1	Acute Oral Toxicity - Rat	ALL	40999204,41898102
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	40999205, 41898103
81-4	Primary Eye Irritation - Rabbit	ALL	40999207, 41898104
81-5	Primary Dermal Irritation - Rabbit	ALL	40999206,41898105
81-6	Dermal Sensitization - Guinea Pig	ALL	41898106

Data Supporting Guideline Requirements for the Reregistration of TFM.

REQUIREMENT		USE PATTERN		CITATION(S)
82-1A	90-Day Feeding - Rodent	ALL	00112726, 00112727	
82-1B	90-Day Feeding - Non-rodent	ALL	00112725 ^a	
83-1A	Chronic Feeding Toxicity - Rodent	ALL	00081184 ^b	
83-3A	Developmental Toxicity - Rat	ALL	00131201	
84-2A	Gene Mutation (Ames Test)	ALL	42551801	
84-2B	Structural Chromosomal Aberration	ALL	40999201	
84-4	Other Genotoxic Effects	ALL	42187101, 40999202	
<u>ENVIRONMENTAL FATE</u>				
161-1	Hydrolysis	ALL	44429501	
161-2	Photodegradation - Water	E	data gap	
162-3	Anaerobic Aquatic Metabolism	E	43887601	
162-4	Aerobic Aquatic Metabolism	E	43781801	
163-1	Leaching/Adsorption/Desorption	E	Dawson, 1986 Carey, Fox, and Schleen, 1988	
165-4	Bioaccumulation in Fish		44666501	

- a. No 90-day feeding study was available for non-rodents. A 6-month feeding study for dogs was substituted.
- b. No study was required, but study was submitted, if it is upgraded, this study could substitute for subchronic study.

APPENDIX B–NICLOSAMIDE

Data Supporting Guideline Requirements for the Reregistration of NICLOSAMIDE.

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	43667101
61-2A	Start. Mat. & Mufg. Process	ALL	43667101
61-2B	Formation of Impurities	ALL	43667101
62-1	Preliminary Analysis	ALL	43667102
62-2	Certification of limits	ALL	43667101
62-3	Analytical Method	ALL	43667102, 41616301
63-2	Color	ALL	43667103
63-3	Physical State	ALL	43667103
63-4	Odor	ALL	43667103
63-5	Melting Point	ALL	43667103
63-6	Boiling Point	ALL	43667103
63-7	Density	ALL	43667103
63-8	Solubility	ALL	43667103
63-9	Vapor Pressure	ALL	43667103
63-10	Dissociation Constant	ALL	43044901
63-11	Octanol/Water Partition	ALL	43667103
63-12	pH	ALL	43667103
63-13	Stability	ALL	41616302

Data Supporting Guideline Requirements for the Reregistration of NICLOSAMIDE.

REQUIREMENT		USE PATTERN	CITATION(S)
<u>ECOLOGICAL EFFECTS</u>			
71-1A	Acute Avian Oral - Quail/Duck	E	43677701, 43677702, 44180301,
71-2A	Avian Dietary - Quail	E	44180302
71-2B	Avian Dietary - Duck	E	44180303
71-3	Wild Mammal Toxicity		42552301
72-1A	Fish Toxicity Bluegill	E	43679302
72-1C	Fish Toxicity Rainbow Trout	E	44206101
72-2A	Invertebrate Toxicity	E	44174804
72-4A	Early Life Stage Fish	E	reserved
72-4B	Life Cycle Invertebrate	E	reserved
72-5	Life Cycle Fish		reserved
72-7B	Actual Field - Aquatic Organisms		42552317
122-2	Aquatic Plant Growth		43679310 ^a
<u>TOXICOLOGY</u>			
81-1	Acute Oral Toxicity - Rat	ALL	425522301 ^a
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	42552301 ^a
81-4	Primary Eye Irritation - Rabbit	ALL	42552305 ^a
81-5	Primary Dermal Irritation - Rabbit	ALL	42552301
81-6	Dermal Sensitization - Guinea Pig	ALL	42552306
82-1A	90-Day Feeding - Rodent	ALL	42552307 ^a , 42552308 ^a
82-1B	90-Day Feeding - Non-rodent	ALL	42552309 ^a

Data Supporting Guideline Requirements for the Reregistration of NICLOSAMIDE.

REQUIREMENT		USE PATTERN	CITATION(S)
83-1A	Chronic Feeding Toxicity - Rodent	ALL	42698001 ^a
83-3B	Developmental Toxicity - Rabbit	ALL	42552310 ^a
84-2B	Structural Chromosomal Aberration	ALL	43677901, 43677902,
<u>ENVIRONMENTAL FATE</u>			
161-1	Hydrolysis	ALL	42552313
161-2	Photodegradation - Water	E	data gap
162-3	Anaerobic Aquatic Metabolism	E	data gap
162-4	Aerobic Aquatic Metabolism		data gap
163-1	Leaching/Adsorption/Desorption	E	42552315, 42552316, 42552317
164-2	Aquatic Field Dissipation	E	42552317
165-4	Bioaccumulation in Fish		44128201, 42552317

a: The submitted study did not fulfill guidelines, but provided some information for the assessment of Niclosamide. No new data are required.

**Appendix C. CITATIONS CONSIDERED TO BE PART OF THE DATA
BASE SUPPORTING THE REREGISTRATION DECISION
(BIBLIOGRAPHY)**

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable

laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

- b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID CITATION

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Heath, R. G., J.W. Spann, E.F. Hill, and J Kreitzer. 1972. Comparative dietary toxicities of Pesticides to birds. U.S. Fish and Wildlife Service, Special Scientific Report-- Wildlife No. 152. 57.

Henrich, J.W., J.G. Weise and B.R. Smith. 1979. Changes in biological characteristics of the sea lamprey (*Petromyzon marinus*) as related to lamprey abundance, prey abundance, and sea lamprey control. Canadian Journal of Fisheries and Aquatic Science 27: 1861-1871.

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Appendix D. COMBINED GENERIC AND PRODUCT SPECIFIC DATA
CALL-IN

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the

generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You are Receiving this Notice
- Section II - Data Required by this Notice
- Section III - Compliance with Requirements of this Notice
- Section IV - Consequences of Failure to Comply with this Notice
- Section V - Registrants' Obligation to Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries and Responses to this Notice

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Generic Data Call-In and Product Specific Data Call-In Response Forms (Insert A) with Instructions
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms (Insert B) (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B).

The Data Call-In Response Forms (Insert A) must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms (Insert B) also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms (Insert A) and the Requirements Status and Registrant's Response Forms (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in

the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

- (i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;
- (ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- (iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form (Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert A). Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form (Insert B) and item 6b on the Data Call-In Response Form (Insert A). If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) also must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms (Insert B). If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form (Insert B) and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form (Insert A). Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form (Insert B). If you choose this option, you must submit the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B) as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form (Insert A) that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form (Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified timeframe (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)

- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and ungradable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency guidelines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form (Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34). In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by

submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3, *Raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both documents available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA".

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be

upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA."

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert B) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified time-frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.1, Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), and in the generic data requirements section (III.C.1.), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume/minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume/minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume/minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

- (i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.
- (ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.
- (iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your

product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form (Insert B). Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
 - a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B).
 - b. Fulfill the commitment to develop and submit the data as required by this Notice; or
 - c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

- 1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
- 2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
- 3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Insert A) and completed Requirements Status and Registrant's Response Forms (Insert B), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice

1. Chemical Status Sheets

TFM AND NICLOSAMIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing TFM or Niclosamide.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of cases 3082 and 2455. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), and (5) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the databases for TFM and Niclosamide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on TFM and Niclosamide are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible TFM and Niclosamide products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Bonnie Adler at (703) 308-8523.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Bonnie Adler
Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: TFM AND NICLOSAMIDE

TFM AND NICLOSAMIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing TFM or Niclosamide.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of TFM and Niclosamide. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), and (4) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for TFM and Niclosamide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on TFM and Niclosamide are needed. These data are needed to fully complete the reregistration of all eligible TFM and Niclosamide products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Laura Parsons at (703) 305-5776.

All responses to this Notice for the generic data requirements should be submitted to:

Laura Parsons, Chemical Review Manager
Special Review Branch
Special Review and Registration Division (H7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: TFM and Niclosamide

2. Combined Generic and Product Specific DCI Response Forms (Insert A)
Plus Instructions

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" (Insert A) and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." (Insert A) Only registrants responsible for generic data have been sent the generic data response form. The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
(INSERT A)

Generic and Product Specific Data Call-In

- Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
- Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
- Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms (Insert B)
- Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
(INSERT B)

Generic and Product Specific Data Call-In

- Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form (Insert B) that indicates how you will satisfy those requirements.

NOTE: Item 6a and 6b are not applicable for Product Specific Data.

- Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

- Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: Item 7a and 7b are not applicable for Generic Data.

- Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.
- Item 9. **ON BOTH FORMS:** Enter the date of signature.
- Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Insert Generic and Product Specific DCI Sample page here—4 pages

page 2 of 4

page 3 of 4

page 4 of 4

3. Generic and Product Specific Requirements Status and Registrants' Response Forms (Insert B) and Instructions

Instructions For Completing The "Requirements Status and Registrant's Response Forms"
(Insert B) For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6.

ON BOTH FORMS: This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Item 7.

ON BOTH FORMS: This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ____%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

- Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

- Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

- Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.
- Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

- Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

- Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.
- Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
- Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available ONLY for acute toxicity or certain efficacy data and ONLY if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" (Insert B) for generic data.

- Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.
- Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
- Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" (Insert B) for product specific data.

- Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

- Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.
- Item 11. **ON BOTH FORMS:** Enter the date of signature.
- Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.
- Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

Insert Generic and Product Specific "Requirements Status and registrants" response Forms Here,
including footnotes and definitions—page 1 of 10

page 2 of 10

page 3 of 10

page 4 of 10

page 5 of 10

page 6 of 10

page 7 of 10

page 8 of 10

page 9 of 10

page 10 of 10

4. EPA's Batching of TFM and Niclosamide Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing TFM or Niclosamide as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a

registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Two products were found which contain TFM as the active ingredient. These products have been placed into two batches. Five products were found to contain Niclosamide as the active ingredient and these products have been placed in three batches in accordance with the active and inert ingredients and type of formulation.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

EPA'S BATCHING OF TFM PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing TFM as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit, or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration

Number. If more than one Confidential Statement of Formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1); Submitting an Existing Study (Option 4); Upgrading an Existing Study (Option 5); or, Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2); Offers to Cost Share (Option 3); or, Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5, or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Two products were found which contain TFM as the active ingredient. These products have been placed into two batches, in accordance with the active and inert ingredients and type of formulation. Based on the existing acute toxicity data available to the Agency, and based on the differences between the formulation types of the two batches, the Agency is requiring that data for each batch be submitted separately.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	6704-45	38.8	liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	6704-86	23.0	solid block

EPA'S BATCHING OF NICLOSAMIDE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing NICLOSAMIDE as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar," since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit, or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data are generated or existing data are referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one Confidential Statement of Formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In (DCI) Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1); Submitting an Existing Study (Option 4); Upgrading an Existing Study (Option 5); or, Citing an Existing Study (Option 6). If a

registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2); Offers to Cost Share (Option 3); or, Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5, or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Five products were found which contain NICLOSAMIDE as the active ingredient. These products have been placed into three batches, in accordance with the active and inert ingredients and type of formulation.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient on most-recent label	Formulation Type
1	6704-88	96%	technical; solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	6704-87	70%	wettable powder
	6704-89	70%	wettable powder

Batch	EPA Reg. No.	% Active Ingredient on most-recent label	Formulation Type
3	6704-90	5%	granular
	6704-91	3.2%	granular

5. List of All Registrants Sent This Data Call-In Notice

page 1 of 1--Insert list of registrants here

**Appendix E. LIST OF AVAILABLE RELATED DOCUMENTS AND
ELECTRONICALLY AVAILABLE FORMS**

Pesticide Registration Forms are available at the following EPA internet site:

<http://www.epa.gov/opprd001/forms/>

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf

8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chernigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

- f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
- g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

- a. Health and Environmental Effects Science Chapters.
- b. Detailed Label Usage Information System (LUIS) Report.

**Montana Fish,
Wildlife & Parks**

1400 So. 19th
Bozeman, MT 59718

July 27, 2001

TO: Governor's Office, Todd O'Hair, Rm. 204, State Capitol, Box 200801, Helena, MT 59620-0801
Environmental Quality Council, Capitol Building, Room 106, P.O. Box 201704, Helena, MT 59620
Dept. Environmental Quality, Metcalf Building, P.O. Box 200901, Helena, MT 59620-0901
Montana Fish, Wildlife & Parks:

Director's Office

Wildlife Division

Legal Unit

MT Historical Society, Historic

MT State Parks Association, P.

MT State Library, 1515 E. Sixth

James Jensen, Montana Environ

Janet Ellis, Montana Audubon Council, P.O. Box 595, Helena, MT 59624

George Ochenski, P.O. Box 689, Helena, MT 59624

Gallatin County Commissioners, Ga

Jerry DiMarco, P.O. Box 1571, Boz

Wildlife Federation, P.O. Box 1175,

Wayne Hurst, P.O. Box 728, Libby,

Glen Hockett, 745 Doane Road, Boze

Jack Atcheson, State Land Coalition,

John Bloomquist, MT Stockgrowers A

Bob Gilbert, Montana Woolgrowers Assn., P.O. Box 1693, Helena, MT 59624

Tom Sather, Headwaters Fish & Game Assoc., P.O. Box 1941, Bozeman, MT 59771-1941

Perry Backus, 65 Redtail, Dillon, MT 59725

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ox 201202 Helena, MT 59620-1202

103

Helena, MT 59620

P.O. Box 1184, Helena, MT 59624

MT 59624

West Main, Bozeman, MT 59715

9701

Box 1185, Helena, MT 59624

Ladies and Gentlemen:

Attached are decision notices for two Environmental Assessments (EA) related to proposals to conduct a control action on New Zealand mud snails (NZMS) and construct a footbridge over Darlington ditch/spring creek at Cobblestone Fishing Access Site on the Madison River. Both measures aim to reduce the likelihood of New Zealand mud snails being introduced into the Madison River at this location. The public comment period ended on June 4, 2001.

It is my decision to proceed with the proposed actions; namely, construct a footbridge across Darlington Ditch/spring creek to facilitate access to the Madison River (Alternative A), and eradicate New Zealand mud snails in Darlington Ditch using the molluscicide Bayluscide (Alternative 1). In addition, I will seek a temporary fishing closure for the area of the New Zealand mud snail infestation in the Darlington Ditch. This closure would be proposed until a successful molluscicide treatment is completed, as determined by

FWP. The proposed fishing closure would be subject to the approval of the Montana Fish, Wildlife & Parks Commission.

Questions regarding this decision notice should be directed to me at Montana Fish, Wildlife & Parks, Region Three, 1400 So. 19th Avenue, Bozeman, MT 59718, telephone 406-994-4042, or at pflowers@montana.edu.

Sincerely,

Patrick J. Flowers
Regional Supervisor

Enclosures

**COBBLESTONE FISHING ACCESS SITE FOOTBRIDGE
DECISION NOTICE**

**MONTANA FISH, WILDLIFE & PARKS
REGION THREE, BOZEMAN
JULY 27, 2001**

Proposed Action

Construct a footbridge and install fencing to prevent wading in Darlington Ditch where New Zealand Mud Snails (NZMS) have been discovered in the past year. Post signing to inform site users of the presence of NZMS and to encourage a variety of precautions to prevent spread of the NZMS into the Madison River at this location.

Montana Environmental Policy Act

Montana Fish, Wildlife & Parks (FWP) assess impacts of its proposals to the human and natural environments. The Cobblestone Fishing Access Site (FAS) footbridge construction proposal and its effects were discussed in the May 4, 2001, Draft Environmental Assessment (EA) to comply with the requirements of the Montana Environmental Policy Act (MEPA).

A 31-day comment period was open from May 4 through June 4, 2001, and public meetings were held in Three Forks and Bozeman on May 21 and 24, respectively. Public notification of the proposed action was facilitated with the distribution of a news release to all southwestern Montana newspapers on May 7, 2001.

Issues raised during the public comment period on the Draft EA are addressed in the Comment section of this Decision Notice.

Summary of Public Comment

Comments on the proposed construction of a footbridge over Darlington Ditch, in order to keep site users from wading through the ditch on their way to the Madison River, were received from 20 individuals and organizations. In addition, a petition was received with 15 signatures. These included written comment from 15 parties, one petition, and oral comment from 7 parties, with 2 parties submitting both oral and written comment. Thirteen (13) commentors supported the proposed action (footbridge construction) as did the 15 people listed on the petition, 6 opposed footbridge construction, and 1 mentioned management and enforcement concerns unrelated to footbridge construction. It should be noted that site management, law enforcement, and access concerns were identified by many of the commentors who made a definitive statement concerning the proposed action.

Comments were categorized into 4 major issues. Those issue categories are listed below. Responses to the comments follow.

Public Comment Issues

Issue 1 – Design and location of footbridge and associated fencing

Issue 2 – Jurisdiction and authority to construct footbridge

Issue 3 – General access to fishing access site

Issue 4 – Site management and law enforcement

Issue 1. Design and location of footbridge and associated fencing

A number of comments were received concerning the design of the footbridge and the placement of fencing. FWP will modify the footbridge design and location of fencing as follows and include this language in the final EA:

FWP Response:

The proposed footbridge would be constructed with 3 approximately 30-foot long untreated pole stringers placed on simple timber or concrete abutments to span the ditch/spring creek. The stringers would be decked with planks 5 feet in width. The bridge would be elevated to a height (approximately 3 feet above the high water mark) that would permit high ditch flows to pass under the bridge without obstruction. The bridge would serve as a pedestrian footbridge; no motorized vehicles would be permitted. Approximately 400 yards of 4-strand smooth wire fencing attached to wood fence posts would be utilized to fence the stream bank of Darlington Ditch throughout the length of the ditch that the NZMS are known to inhabit within Cobblestone FAS. Jack-leg fencing would be utilized across the ditch at the southern extreme of NZMS infestation to prevent wading. All fencing would be placed adjacent to the ditch. No fencing would encroach upon the dike.

Issue 2. Jurisdiction and authority to construct footbridge

A question was raised at the Three Forks public hearing as to whether FWP could construct the proposed footbridge without the Corps of Engineers permission and permitting process.

A person in attendance at the Bozeman public hearing asked, "What does (the Cobblestone FAS) deed say for jurisdiction over the ditch?"

FWP Response:

Corps representatives Doug McDonald and Alan Steinle indicated to FWP that after review of the EA they found that the proposed footbridge construction project will not require a 404 permit, nor will the Corps assume jurisdiction over the dike.

FWP's deed for the Cobblestone FAS property does not mention that any entity has jurisdiction on or over the ditch. The deed does grant the Madison Dike and Drain District the authority to

enter a portion of the FAS to repair, maintain and patrol the Madison River Rural Flood Protection Project (dike).

Issue 3. General access to fishing access site

Many comments (19) were received concerning public access to Cobblestone FAS. Eleven (11) commentors wanted the site opened at the earliest possible time and reiterated the value of Cobblestone FAS for access to the lower Madison River. Eight (8) commentors advocated keeping Cobblestone FAS closed so additional research on NZMS could be conducted and to reduce the potential spread of the NZMS. Many of these commentors pointed out the availability of other FASs on the Madison River.

FWP Response:

FWP recognizes both the value of Cobblestone FAS as an access point to the Madison River and the potential negative impact NZMS might have on the valuable fishery resource in Darlington Ditch/spring creek and the Madison River. The potential impacts of an expanding NZMS population is described in a separate EA. A decision on reopening Cobblestone FAS to public use or continuing the closure must balance these two factors.

Issue 4. Site management and law enforcement

Landowners adjacent to and in the vicinity of Cobblestone FAS expressed concern about a variety of site management and law enforcement issues that affect the FAS as well as neighboring property. Frustration and dismay were expressed that FWP would propose building a footbridge and, to a large extent, depend on voluntary visitor compliance to stay out of Darlington Ditch as a primary method to limit the potential spread on NZMS to the Madison River and other adjoining properties. They point out a number of continuing regulation violations (firearm discharge and overnight camping), vandalism, inappropriate behaviors (late night partying and drunkenness), and trespass onto adjacent private properties as evidence that depending on voluntary compliance by the public is a risky proposition. They also decried the perceived lack of law enforcement presence (by both FWP wardens and county sheriff deputies) at the FAS, the lack of prompt response when neighbors report violations and the seeming inability of FWP to control the criminal element at the FAS. Most commentors citing these problems felt it was best to keep the FAS closed until substantial progress can be made to improve site management and regulation enforcement, and a thorough NZMS eradication program can be implemented and proven successful.

FWP Response:

FWP is committed to improve managerial control and regulation enforcement at Cobblestone FAS. The site will continue to be operated as day use only; no overnight camping is permitted. FWP wardens will continue to patrol and respond to complaints related to the FAS administrative rules, as posted. FWP will continue to work closely with the Gallatin County Sheriff to provide additional FAS patrols as budgets and workloads permit. FWP will seek a temporary fishing closure on Darlington Ditch to help limit the potential spread of NZMS.

**Modifications to the Draft Environmental Assessment for the Cobblestone Fishing Access
Site Footbridge construction proposal**

Replace the existing language in the last paragraph of section 9 of the EA entitled, "Narrative Summary of the Proposed Action" (page 3) with the bolded paragraph listed above under Issue 1.

The Draft EA and this Decision Notice with the above listed modifications to the Draft EA will serve as the final document.

DECISION

Based on the information in the Draft EA and public comment, it is my decision to proceed with the proposed action (Alternative A). This includes construction of a footbridge across the Darlington Ditch, erection of fencing to discourage wading in the ditch where NZMS are known to exist, posting of signs informing users of the NZMS presence/precautions, and the reopening of Cobblestone FAS to public use when these improvements are in place.

In addition, I will seek a temporary fishing closure for the area of the NZMS infestation in the Darlington Ditch. This closure would be proposed until a successful molluscicide treatment is completed as determined by FWP. This closure will further limit the likelihood of a fisherman inadvertently transporting NZMS from the Ditch to the Madison River. This proposed fishing closure would be subject to the approval of the FWP Commission.

Based on the analysis in the Environmental Assessment and the applicable laws, regulations and policies, I have determined that this action will not have a significant effect on the natural or human environment. Therefore, an Environmental Impact Statement will not be prepared.

This construction project is subject to appeal, which must be submitted to the FWP Director in writing and postmarked within 30 days of the date on this decision notice. The appeal must specifically describe the basis for the appeal, explain how the appellant has previously commented to the department or participated in the decision-making process, and lay out how FWP may address the concerns in the appeal.

If you have questions regarding this decision notice, please contact Pat Flowers, Region Three Supervisor at (406) 994-4042, 1400 S. 19th Avenue, Bozeman, MT 59718 or at pflowers@montana.edu.

Patrick J. Flowers
Regional Supervisor
Bozeman, MT
July 27, 2001

**DARLINTON DITCH NEW ZEALAND MUDSNAIL CONTROL PROJECT
DECISION NOTICE**

**MONTANA FISH, WILDLIFE, & PARKS
REGION 3, BOZEMAN
JULY 27, 2001**

Proposal

Removal of an invasive non-native snail from a section of Darlington Ditch using the molluscicide Bayluscide (nicosamide).

Montana Environmental Policy Act

Montana Fish, Wildlife & Parks assesses impacts of its proposals on the human and physical environments. The Darlington Ditch New Zealand Mud Snail Control proposal and its effects were discussed in the May 4, 2001, Draft Environmental Assessment to satisfy the requirements of the Montana Environmental Policy Act (MEPA).

A 31-day comment period was open from May 4 - June 4, 2001, and public meetings were held in Three Forks and Bozeman on May 21 and 24, respectively. Public notification of the proposed action was completed through a published news release distributed to all southwest Montana newspapers on May 7, 2001.

Issues raised during the public comment period on the Draft EA are addressed in the Comment section of this Decision Notice. Modifications to the Draft EA are listed at the end of this Decision Notice. The Draft EA and this Decision Notice with the listed modifications to the Draft EA will serve as the final document.

Issues Raised in the Environmental Assessment

The EA lists the issues in detail. These include:

- Effects of conducting the proposed project and potential consequences if the project is not conducted.
- Biology of the New Zealand Mud Snail (NZMS) and potential impacts to other aquatic invertebrates and fish food availability.
- Potential nutritive impacts on fish caused by potential NZMS population expansion.
- Health and environmental information of the selected toxicant.

Summary of Public Comment

Comments on the proposed chemical treatment were received from 36 individuals and organizations. These included written comment from 28 parties and oral comment from 11 parties, with one party submitting both oral and written comment. Twenty commentators favored the proposed chemical treatment, including 15 names submitted on a petition, four were neutral or undecided, and 11 opposed the chemical treatment.

Comments were categorized into five major issues. Responses to the comments follow, as well as a list of commentators and identifying number.

Issue 1. The chemical treatment may not be a permanent solution to the problem; this is an experiment; the snails will re-invade the Ditch as they progress down the Madison River; fish outside the treatment area will reintroduce NZMS into the Ditch via passage through their digestive system; not known if Bayluscide is effective against NZMS; address the problem throughout all infested waters, not just Darlington Ditch; lack of review of infestations in other areas.

Commentors: 1, 3, 4, 7, 10, 11, 12, 17

FWP Response:

As with any chemical treatment of a pest, the results are not guaranteed to be successful. Other systems in the Greater Yellowstone Area known to be infested with NZMS, except Darlington Ditch, are far too large to attempt eradication. It is important to attempt treatment in any infested waters that are small enough that success may be achieved, not only to reduce the threat of spreading the NZMS, but also for the sake of the fishery in those waters.

As stated in the draft EA, the current distribution of the NZMS in the Madison drainage is upstream of Reynolds Pass Bridge, near Quake Lake. The rate at which NZMS will move downstream to the site of the Darlington Ditch headgate is not known – 5 years or 25? FWP is committed to addressing invasive species problems, which are becoming more prevalent.

FWP pointed out in the draft EA that surviving fish may reintroduce NZMS into the ditch via passage through their digestive system, and discussed this in Alternatives 7 and 8. If public concern grows to the point that these alternatives become more acceptable, FWP will consider their implementation.

Bayluscide was originally developed as a molluscicide to eliminate snails that serve as an intermediate host of human parasites. As stated in the draft EA, FWP will conduct bioassays prior to implementing treatment to determine Bayluscide effectiveness against NZMS, effective concentration, and neutralization techniques. Bayluscide is currently used for snail control in Florida and Arkansas ponds and, along with TFM, for control of larval sea lamprey in tributaries to the Great Lakes and Finger Lakes, but there are no active attempts to neutralize it.

FWP consulted with researchers who are working on NZMS infestations locally and all over the world. In addition, FWP consulted with the agencies listed on page 9 of the EA.

Issue 2. Environmental effects of Bayluscide; effects on non-target organisms – humans, trout; terrestrial and other aquatic animals; too much unknown about the chemical; impacts of treatment to recreational fishery; water quality concerns,

including groundwater used for domestic purposes; inconsistent reporting of impacts on micro invertebrates.

Commentors: 1, 4, 5, 18, 19, 20

FWP Response:

Scientifically thorough data on environmental and health effects of Bayluscide are presented in Appendix B2 of the draft EA, as well as in other appendices and in the text of the draft EA.

Any impact on recreational angling in Darlington Ditch due to mortality of game fish in the treatment area should be temporary. Fish outside the treatment area will fill any void left by mortality in the treatment area. FWP will not stock fish in Darlington Ditch after the treatment.

Among other inactivation routes, Bayluscide binds with stream sediments and suspended solids. Maximum movement through the soil is estimated at less than 25 cm.

In the EA, FWP reported two families of caddis fly are positively correlated with NZMS infestations, while in the slide presentation FWP reported that another family of caddis flies was negatively correlated. The explanation for this apparent discrepancy lies in the fact that different families of caddis fly appear to have different interactions with NZMS. The locations for the testing may also explain the differences.

Issue 3. Persistence of Bayluscide in the water; movement beyond the target area.

Commentors: 18, 20

FWP Response:

Bayluscide is non-persistent in flowing waters, rapidly decreasing in concentration. Appendix B2 of the draft EA describes several degradation routes.

As stated in the draft EA and at the public meetings, bioassays will be conducted prior to conducting any treatment to determine the necessary concentration to kill NZMS, effective treatment time, and neutralization techniques. Travel time can be determined by using dye tablets to determine the distance stream water flows over a given period of time. If left un-neutralized below the treatment area, Bayluscide may persist at detectible but non-lethal concentration until diluted upon entering the Madison River below Three Forks.

Issue 4. Time of year for conducting the treatment.

Commentors: 8, 12

FWP Response:

As stated on the Bayluscide label in Appendix A1 and in the text of the draft EA, federal law and label instructions prohibit the application of Bayluscide in waters used for irrigation or domestic supply. Unless there is a break during the irrigation season, this means treatments would be conducted prior to or after irrigation season. Water temperature may become a factor in allowing a treatment to be conducted. Generally, water temperatures below 50°F are undesirable for conducting treatments.

Issue 5. Public education of the issue, re-introduction of the NZMS from recreationists' equipment.

Commentors: 1, 19

FWP Response:

Educating the public to the consequences of invasive species introductions is becoming a greater priority for FWP. However, it is difficult to reach the general public to inform them unless they have a personal interest in an issue. Signing at specific locations is presently the only viable option available to educate recreationists to clean their equipment and reduce the probability of unintentional introductions.

FWP is exploring the use of Traveler Information Systems (TIS) to offer the public information on invasive species issues. A TIS is a local radio broadcast station often set up along a roadway. It broadcasts a short-recorded message that travelers may tune into to learn about specific issues. These can be adapted to broadcast messages relevant to a specific area, such as the Madison River.

Modifications to the Draft Environmental Assessment for the Darlington Ditch New Zealand Mud Snail Control Project

Errors in the draft EA are:

- Appendix B2 is out of sequence – as distributed, it is the last Appendix of the document. It should be between Appendix B1 and Appendix C.
- Appendix E – the title page and the single text page (Montana Department of Agriculture Application for Special Local Need) of the Appendix are reversed. The title page should precede the text page.

DECISION

Utilizing the draft EA and public comment, FWP must render a decision that addresses the concerns and issues identified for the proposed project.

Based on the information in the draft EA and public comment, it is my decision to proceed with Alternative 1 of the EA, to eradicate New Zealand mud snails in Darlington Ditch using

the molluscicide Bayluscide. This decision is provisional pending the results of bioassays as described in the EA and in this Decision Notice, and the availability of a crew to conduct the treatment with the necessary equipment from the Upper Midwest Environmental Services Center (UMESC) in LaCrosse, Wisconsin. Presently, the UMESC crew is unavailable until 2002.

I find there to be no significant long-term impact associated with this action. I therefore conclude that an Environmental Impact Statement is not necessary. The completed EA and response to comments included in this Decision Notice are an appropriate level of analysis.

Patrick J. Flowers
Regional Supervisor
Bozeman, MT
July 27, 2001

**LIST OF COMMENTORS FOR THE DARLINTON DITCH NEW ZEALAND MUD SNAIL
CONTROL PROJECT**

Commentor	Name	City	State	Oral/Written	Support/Oppose
1	Don Doig	Manhattan	MT	W	O
2	Jay Hankin	Three Forks	MT	O	Neutral
3	Leland Rice	Three Forks	MT	O	O
4	Doug Broling	Bozeman	MT	O	O
5	Jack Rea	Three Forks	MT	O	O
6	Gene Townsend	Three Forks	MT	W	S
7	Larry Wilcox	Three Forks	MT	O	O
8	Steve McDonnell	Three Forks	MT	O	Neutral
9	Larry Michnevich	Bozeman	MT	O	Neutral
10	Bill Munro	Bozeman	MT	O	Neutral
11	Bob Gibson	Bozeman	MT	OW	Neutral
12	Greater Yellowstone Coalition	Bozeman	MT	W	S
13	Ray Noble	Three Forks	MT	W	S
14	Bill Swartz	Bozeman	MT	W	S
15	Jack Jones	Butte	MT	W	O
16	Jack Atcheson, Sr.	Butte	MT	W	O
17	Larry Cronenwett	Bozeman	MT	W	O
18	Donna Rice Faison	Las Cruces	NM	W	O
19	Linda Rice Lorenzetti	Three Forks	MT	W	O
20	Daniel Lorenzetti	Three Forks	MT	W	O
21	Public Lands Access Association	Billings	MT	W	S
22	Joe Chapman	Belgrade	MT	W	S
23	Dave Parker	Bozeman	MT	W	S
24		Bozeman	MT	W	S
25	Erin Noreen	Belgrade	MT	W	S
26		Bozeman	MT	W	S
27	Charles Rogers	Belgrade	MT	W	S
28		Belgrade	MT	W	S
29	Susan Dickson	Belgrade	MT	W	S
30		Bozeman	MT	W	S
31		Bozeman	MT	W	S
32		Bozeman	MT	W	S
33		Bozeman	MT	W	S
34	Scot Mundt	Belgrade	MT	W	S
35	Mike	Gallatin Gateway	MT	W	S
36	Brian Ramsey	Bozeman	MT	W	S