

THE 2003 PROPOSED FOREST PROTECTION PROGRAM

AGAINST HEMLOCK LOOPER

USING THE AERIALLY APPLIED INSECTICIDE

MIMIC[®] (tebufenozide)

Submission to:

**Department of Environment
Environmental Assessment Division**

by:

**Department of Forest Resources and Agrifoods
FOREST SERVICE**

April 2003

NAME AND ADDRESS OF PROPOSER

This application is submitted on behalf of

**THE DEPARTMENT OF FOREST RESOURCES & AGRIFOODS
FOREST SERVICE
ST. JOHN'S, NL**

Chief Executive Officer:

Mr. Allan Masters

Deputy Minister

729-4720

St. John's

Contact Person:

Mr. Hubert Crummey

Supervisor, Forest Insect and Disease Control

637-2424

Corner Brook

THE UNDERTAKING:

In fulfilment of the mandate and commitment of the Department of Forest Resources and Agrifoods to protect the forest resource and limit damage from infestations of significant pests, with due regard for human health and non-target environmental effects, the following undertaking is proposed.

NATURE OF PROPOSED PESTICIDE APPLICATION

The insecticide Mimic[®] (tebufenozide) is proposed to be applied aerially to selected forest areas forecast to receive mainly moderate to severe hemlock looper defoliation in 2003. This program is a smaller component of the overall control program for hemlock looper using the biological insecticide, B.t.k.

PURPOSE OF PROPOSED PESTICIDE APPLICATION

The purpose of this control program is to reduce larval populations of the hemlock looper to minimize feeding pressure on infested trees and thereby:

- (a) prevent additional tree mortality;
- (b) promote growth in younger stands to aid in offsetting projected future wood deficits;
- (c) protect seed supplies for natural regeneration and potential production areas;
- (d) protect existing and/or proposed silvicultural treatment areas;

Background:

Coniferous defoliators are natural elements in the forests of Newfoundland and Labrador. The need to protect the forest resource against insects

has been evident from past outbreaks of hemlock looper and spruce budworm. The potential impact of unchecked forest pest outbreaks cannot be ignored. In the 1970s, a major infestation of spruce budworm occurred. Due to the lack of early intervention to control the budworm, (full scale, adequate programs were only initiated in 1978 and 1981 which were very late in the outbreak), it is estimated that the Province suffered tree mortality of up to 50 million m³ of balsam fir and black spruce. This equates to about a 25 year wood supply for the entire forest industry based on current demand.

The 1980 Royal Commission on Forest Protection and Management confirmed the magnitude of the existing budworm problem and recommended that Government adopt a long-term policy on protection, particularly related to investment in expensive silvicultural practice aimed at renewing the forest resource. This recommendation, along with many others, was adopted by Government and provided the basis for forest spraying policy within the Province. Control programs since 1980 have become an integral part of forest management, with particular emphasis being placed on protecting silviculture areas. To date, the position of the Department is that the forest resource will be protected against insect pests, using the most effective federally registered pesticides which have the least impact on the environment. It is imperative that a variety of control tools / methods be available to allow for the efficient and effective control of pest infestations as the situation arises. No particular tool / method works well in all situations. In addition, the Department is committed to actively seek more acceptable

solutions to pest problems, such as: biological insecticides, enhancing natural control measures, or any other practical methods of pest management. All pesticide usage is subject to annual environmental assessment and/or review processes within the Province, as deemed necessary. Annually, Government decides on the nature and extent of a program based on all available information and recommendations.

Without such a policy, the Royal Commission recommended that silvicultural prescriptions not be undertaken. As silviculture efforts continue to increase, the need to protect these substantial investments in forest management against losses to insects and diseases becomes more apparent. A future wood supply for the forest industry is dependent on a vigorous, healthy, growing stock, which can reach rotation age relatively free from significant insect and disease infestations. Also a healthy forest is equally important for ecosystem management, biodiversity and environmental health.

The Province has been reasonably successful in the past in dealing with the spruce budworm and the hemlock looper where treatment was adequate. Previous control programs have limited the potential impacts of insect infestations by minimizing extensive tree mortality and saving as much foliage as possible. The current, on-going hemlock looper infestation is of concern and must be addressed. In valuable stands and in areas where weather is a significant factor influencing pest management operations, it is necessary to utilize those tools which will more adequately provide effective insect control under such

conditions. Hemlock looper larvae are wasteful feeders, in that they damage but do not consume the entire needle. After hatching, larvae initially feed on the current year's growth and then move to feed on the older needles. Once damaged, needles usually die. In high numbers, looper larvae can cause tree mortality in one season. Because of the seriousness of a looper infestation, immediate control action is required. The Department has been addressing hemlock looper infestations for several years by treating high value stands on a priority basis, with the biological insecticide, B.t.k., to keep trees alive. As in 2001 and 2002, an additional control tool is being proposed for 2003 to deal with the current hemlock looper infestation in an integrated pest management approach. As indicated, although B.t.k. has been reasonably successful where treatment could be carried out on time, weather often interferes with the appropriate timing of insecticide application and how long the product is effective. The use of the registered insecticide Mimic® will allow a time frame to provide essential control and maximize protection of tree foliage. Mimic® can be applied just prior to or at larval hatch and therefore will be present at the initial onset of feeding. B.t.k. must be applied after most of the larvae have hatched and are actively feeding since B.t.k. is effective for a shorter period of time (days). Mimic® is less susceptible to weather conditions (rain) and breakdown from sunlight (UV light). This insecticide also remains on the foliage for a longer period compared with B.t.k. which is subject to rain and sunlight degradation after several days. Mimic® was used on a limited basis but on very high looper population areas in 2001, and on approximately 20,000 hectares (ha) in 2002. The product was successful in reducing looper

population levels and preventing expected levels of tree defoliation.

Current situation:

The pest management program that has been developed will address the current infestation. The total proposed looper program for 2003 involves control intervention on the Northern Peninsula, in western, and central Newfoundland using two insecticides, 1) the biological insecticide, B.t.k. for the larger part of the program and, 2) the subject of this submission, the insect growth regulator, Mimic ® (tebufenozide). B.t.k. will be used on infested stands not treated with Mimic ® and in other areas located on the Island. In terms of this submission, Mimic ® is proposed to be used on up to approximately 30,000 ha, with the general locations being identified on maps in this document. The purpose of this program is to reduce insect population levels as early as possible in areas with expected high larval counts and those of high priority. Early control, during the early larval feeding stages in treated areas will minimize the loss of foliage, the loss of tree growth and the prevention of tree mortality.

Control options:

As indicated, two control options are being considered for use in 2003 to combat the looper. Both the biological insecticide, B.t.k. and Mimic ® (tebufenozide) [PCP # 24502], an insect growth regulator, are registered for use against the hemlock looper and several other forest insect pests such as the spruce budworm, tussock moth and jack pine budworm. In fact, data from experimental trials carried out in Newfoundland on the hemlock looper supported the registration of the

products for looper control.

Both B.t.k. and Mimic ® must be present on the needles and eaten by the larvae to be effective. With B.t.k., larvae must have hatched from the eggs and be actively feeding during the limited time (days) the product is effective on the foliage. When spray weather is suitable, larvae are actively feeding, and post-spray weather favours larval feeding and product retention on the needles, B.t.k. is very effective. Often when weather causes spray delays or unfavourable post-spray weather causes deterioration of the product or inhibits larval feeding, B.t.k. is less effective and the degree of program success is affected.

Proposed Control Product - Mimic ®:

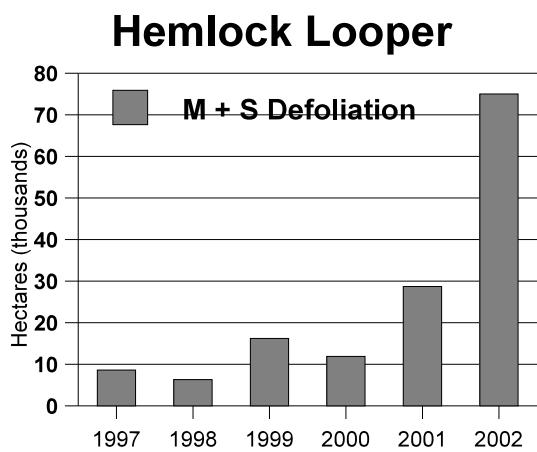
Mimic ® (tebufenozide), a growth regulator, is an aqueous flowable formulation whose mode of action mimics the action of the insect molting hormone, ecdysone, in larval Lepidoptera (caterpillars). This initiates an unsuccessful (lethal) molt in the larvae. Mimic has very little effect on the environment and non-target species. When used under operational spraying and according to the label directions with appropriate buffers and the correct dosage, Mimic ® does not adversely affect bees, birds, fish mammals, shrimp, oysters, green algae or earthworms. It also does not affect beneficial insects such as predatory mites, beetles, wasps, and spiders,. Mimic ® has advantages in that it has a wider window of application and appears to weather better on the foliage. Because it is active for a longer time (weeks) it can be applied at or just prior to larval hatch and still be effective against later hatching larvae.

In order to use a pesticide, the federal registration process requires that the product must be able to control the insect on the host (tree) being attacked without harmful effects to the tree, and without significant impacts on non-target organisms.

DESCRIPTION OF UNDERTAKING

Insect Population Levels

A hemlock looper infestation has been ongoing on the Northern Peninsula in the past few years and building up particularly in western and central Newfoundland, with additional pockets occurring elsewhere in eastern Newfoundland. The following figure summarizes the actual levels of defoliation from 1997 to 2002 only.

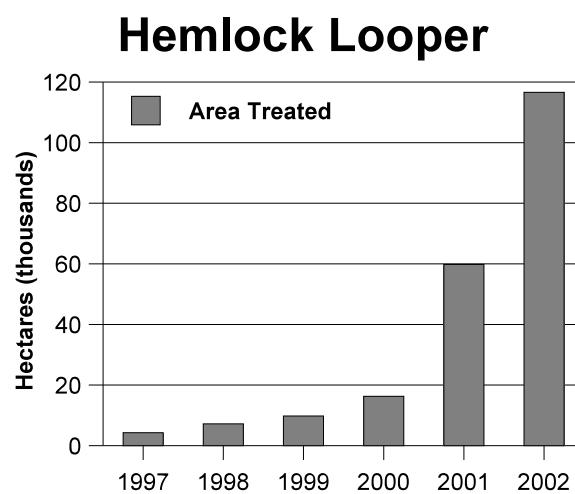


As illustrated, in 2002 the hemlock looper caused moderate and severe defoliation on approximately 75,000 hectares (the 2002 forecast was for approximately 190,000 ha to be affected; also a significant looper control program was conducted on specific areas in 2002 - see below).

Areas affected in 2002 were basically within the predicted forecast, but most of the defoliation occurred outside of designated treatment areas.

Affected areas were located on the Northern Peninsula from St. Barbe-Round Lake north and northeast towards St. Anthony Airport and eastwards towards Main Brook. Scattered pockets occurred elsewhere. In western NF, basically from Little Grand Lake area northward to the Main River vicinity, with pockets scattered throughout. In central NF, from Victoria Lake northeastward to the eastern part of Noel Pauls Brook. Scattered pockets occurred in Bay d'Espoir. In eastern NF defoliation occurred around Shoal Harbour-Clarenville, along South West Arm in the Hatchet Cove - Caplin Cove areas, and on the Bonavista Peninsula.

The following figure shows the level of protection carried out over the last 6 years.



In 2002, the Department carried out a control program on approximately 117,000 ha on the Northern Peninsula, in western NF, central NF, and Bay d'Espoir (B.t.k. only). Mimic® was used on approximately 19,300 ha on the Northern Peninsula, in western NF and central NF. B.t.k. was used on the remainder of these areas, as well as in Bay

d'Espoir.

Observations during the program and fall surveys showed that most of the defoliation was limited to the current years growth which occurred prior to treatment or was in areas which had been significantly defoliated for one or more previous seasons. In Bay d'Espoir and western NF, defoliation was mapped in areas where both looper and balsam fir sawfly were feeding and both combinations caused the observed damage. B.t.k. is not effective against sawflies. As well, in some areas there was defoliation caused by the rusty tussock moth.

The hemlock looper forecast for 2003 (based on the egg survey in the fall of 2002) is for a total area of 223,000 ha to receive moderate and severe defoliation [see Appendix A]. This is slightly more than the level of infestation forecast for 2002. However, the locations of the predicted infestation indicate a significant increase in infestation particularly in western and central NF.

The forecast on the Northern Peninsula is located from north of Ten Mile Lake in the Green Island Brook-Gaultons Steady area, east of Round Lake with scattered pockets across the central part of the Peninsula towards Roddickton. A significant area is predicted from Coles Pond, northward to the general Main Brook vicinity and on the north side of Hare Bay from the St. Anthony Airport to north of St. Anthony.

In western Newfoundland, scattered pockets of moderate & severe defoliation are forecast in the Crooked Lake-Landowns Pond area,

in the Serpentine Lake-Stag Lake-Cooks Brook area, Blue Pond-Pinchgut Lake vicinity, Little Grand Lake-Lewaseechjeech Brook north to Corner Brook and northeast to Deer Lake-Glide Lake. Pockets are predicted from Bay of Islands northward to Goose Arm and north and east to North Lake, from North Arm Mountain east to Cormack and north and northeast to Bonne Bay Little Pond. Moderate and severe defoliation is also predicted along the west side of Adies Pond to Silver Mountain-Upper Humber River and northward to Main River and Jackson's Arm.

In central Newfoundland, the infestation is predicted from Victoria Lake east and northeastward to Diversion Lake, with pockets around Red Indian Lake, near the Gaff Topsails and near Birchy Lake-Sandy Lake vicinity.

In eastern Newfoundland, the forecast is located near Shoal Harbour-Clarenville, from Come By Chance northward to Hillview and along both sides of South West Arm eastward to the Hatchet Cove and Caplin Cove areas. On the Bonavista Peninsula, the infestation is predicted east of Ocean Pond and towards the tip near Upper Amherst Cove-Newmans Cove. On the Avalon Peninsula, the infestation is predicted near Chapel Arm, Placentia Junction, near Fitzgerald Pond and along the Salmonier Line.

The locations of the **insect infestations** (**damage**) predicted for 2003 and general locations being proposed for control activity using Mimic® are as indicated on the accompanying maps. **These areas are not finalized treatment area boundaries. Spray blocks will be identified**

within and adjacent to these areas later, subject to the necessary “no-spray” buffer zones and other stipulations, as dictated by the Department of Environment.

It is anticipated that Mimic ® will be applied to selected sites within the forecast by single engine spray aircraft working out of the airstrip(s) at Main Brook, Stephenville, Deer Lake and Buchans, as applicable. At this time, it is proposed to treat up to approximately 30,000 ha with one early application of Mimic ® at 70 g a.i. per hectare. If necessary, to achieve maximum control, these areas may receive a follow-up application of B.t.k. depending on remaining insect population levels.

Treatment is expected to start in late June, however, it could be in mid June (depending on weather affecting insect hatching and development) and continue into early August. Final aircraft type to be used will depend on aircraft availability, operational parameters, economics, logistics, and final spray block sizes. The Department uses the most up-to-date technology to ensure the best delivery of the program.

UNDERTAKING PARAMETERS

SPRAY PROCEDURES

Since 1977, the Forest Protection Division of the Newfoundland Department of Forestry & Agriculture (now the Forest Engineering & Industry Services Division of the Department of Forest Resources & Agrifoods) assumed responsibility for any control programs conducted against forest insect and disease pests and to date have planned and supervised major insect control programs. The insect population forecast, now carried out by

Departmental staff, predicts infestation levels for the following summer. This is used to determine if there is a need for control intervention and, if so, provides the outline to identify proposed treatment areas. The Department has carried out all other aspects of the operational aerial programs (apart from the actual aircraft application of the insecticide and aircraft maintenance), including the transportation, handling, mixing, loading and decontamination of equipment and containers, up to and including the loading of aircraft, i.e. ground operations. The Department also oversees the actual spraying by the contractor to ensure that the proper areas are treated under the appropriate weather conditions, and that all Licence stipulations, including buffer zones, are followed. The Department monitors insect and host tree shoot development and larval numbers from early in the season, to determine the ideal application date(s) and priorities of areas to be treated. Monitoring to determine insecticide efficacy continues throughout the spray program, and the final assessment is made after insect feeding has ended. All necessary ground, communication and sampling equipment is supplied and owned by the Department.

The Department utilizes currently available equipment and technology. It complies with existing regulatory guidelines. In earlier programs, navigation of spray aircraft was provided by utilizing qualified and licenced Departmental personnel. Usually a supervisor, in a helicopter, led spray aircraft along pre-determined flight lines, and a supervisor, in a fixed-wing aircraft or a helicopter, determined the accuracy of the navigation and performance of the spray aircraft, and initiated corrective action, as necessary. The supervisor also

assessed the favourability of weather parameters before and during spray missions. For the past 6 years, because of the buffer zones stipulated in the provincial Operators Licence, the Department of Forest Resources & Agrifoods has required the aircraft contractor to use Differential Global Positioning System (DGPS). This system of navigation enabled the spray aircraft pilots and aerial supervisors to better anticipate identified buffer zones during spray missions and also to facilitate the actual flight along the pre-determined flight lines. The system has worked reasonably well. This technology is the best available at this time for operational programs. This system is proposed to be used again in 2003. The aerial supervisor is still monitoring and directing the treatment as well as assessing the accuracy of the application and the suitability of the weather as before.

Spray bases have been provided with appropriate equipment to ensure environmental safety by using approved containment dyking and currently acceptable safety and emergency equipment and materials.

WORKER SAFETY

The Department has well-established safety guidelines for workers involved in insect control activity. Staff have a lot of experience and an enviable safety record. To protect workers involved with the programs, personnel handling the insecticide (each mixer/loader) will be required to wear hooded rubber suits, rubber gloves, rubber boots, goggles and appropriate respirators during the mixing of the insecticide formulation, the filling of loading and holding tanks and aircraft, and during the decontamination of insecticide drums (as per

current occupational health and safety standards and product label instructions). Pilots and navigators/supervisors are not permitted to be involved in the handling of insecticides.

In addition, approved safety precautions and established rules and guidelines will be adhered to concerning personal hygiene of all mixer/loader personnel working with insecticides and what to do if contact with an insecticide occurs or if symptoms of illness occur during or after handling of any insecticide or mix. Hospital and emergency telephone numbers will also be posted in a conspicuous place to be used in the event of accident.

Applicable contingency measures will be available to personnel in the event of an accident.

PUBLIC HEALTH CONSIDERATIONS

To minimize the risk of exposure of people to insecticide spray, "no-treatment" buffer zones will be left around known places of permanent human habitation and around areas such as cabin development and park camp and day use areas. In 2003, spraying near habitation will be subject to terms and conditions of the Operator's Licence from the Department of Environment in consultation with the appropriate Health and Community Services personnel. Cabins will be adequately buffered in relation to the product being applied. In addition, a 1.6 km buffer zone is left around identifiable intakes to known community water supplies; however, it may be desirable to decrease buffers in specific cases. These are dealt with in consultation with the provincial Department of Environment on an

individual basis as and when identified. If, during the course of a spray mission, unauthorized personnel are detected in or near a treatment area, the aerial supervisor will instruct the spray aircraft pilot(s) to provide extra buffers or to terminate the mission, as applicable in the circumstance. Local hospitals and regional public health officials in the vicinity of the proposed spray areas are notified in advance of the program concerning which product(s) are to be used, general areas of treatment blocks, timing of spray season, etc. This action is to ensure full notification and preparation should an incident occur which would require medical assistance.

ENVIRONMENTAL SAFETY

In terms of environmental safety, all stipulations in the licence issued by the provincial Department of Environment are followed. These include the reporting of any incidents, such as spills, to the appropriate authorities. In connection with this, the Department of Forest Resources and Agrifoods has a contingency plan which is annually reviewed and approved prior to receiving of an Operator's Licence. The plan outlines procedures for spill reporting, emergency first aid for exposure, insecticide spill only, aircraft crash in bush, aircraft accident on or near the airport, jettisoned aircraft load, drum decontamination and disposal, and other general regulations and instructions as necessary.

PUBLIC NOTIFICATION

As part of the program, the public and media in the vicinity of the proposed treatment areas are notified, prior to commencement of the program, through ads or news releases, or through appropriate contact if required, with information of

which product is being used, general areas of treatment blocks, timing of application, contact numbers, etc. Access roads to the general areas are posted with signs indicating treatment, product, dates, and phone numbers for more information. A phone-in information line will be set up and the general public can call to find out the status of areas receiving treatment. Since 1977, daily messages have been sent to the news media with information indicating what areas are ready to be treated as well as the status of areas which have been treated since the last update.

Regional offices of the Department of Forest Resources & Agrifoods and the Department of Environment, as applicable, will be provided with maps showing spray blocks. These maps are available for viewing by the general public during regular office hours. District offices of the Department will be made aware of treatment blocks in their area and are provided with applicable detailed maps so they can inform the public on specific local blocks, when requested.

POTENTIAL SPRAY CONFLICTS:

There are always potential conflicts with insect control programs. Such factors as proximity to habitation, cabin development areas, individual cabins, water supply areas, recreational uses (fishing and camping, berry picking), potential impacts on wildlife. However, in approving a product at the federal registration level, and in granting a licence at the provincial level, mitigating measures are identified which eliminate or significantly reduce the potential for conflicts. These mitigating measures are outlined on the product label as approved by the PMRA-Health Canada and in terms

of buffer zones stipulated in the Operator's Licence [see attachments to this document]. In addition, the proponent is also required to post signs and advise the public about the program to lessen accidental exposure.

ALTERNATE OPTIONS FOR LOOPER CONTROL

Integrated Pest Management Approach

The Department prefers, and has been actively encouraging and participating in research focussed on the identification and development of, biological solutions to insect problems, and in particular, a significant amount of work has been done on the hemlock looper by the Canadian Forest Service. In fact, the biological insecticide, B.t.k. was tested against looper in Newfoundland and the successful results enabled the manufacturers to apply and receive registration from PMRA. In addition, Mimic® was also tested in Newfoundland and this information was used to support registration. Integrated pest Management work will continue.

Also, in attempting to improve control measures and techniques, the Canadian Forest Service, in cooperation with the Department and the Forest Industry, will continue to identify methods of dealing with pest outbreaks. Experimental programs are an integral part of operational programs and essential to better manage pest problems in an effective and efficient manner.

The Department of Forest Resources & Agrifoods will continue to explore control options for insect pests to determine cost effective, efficient control methods with regard to minimizing human health risks and environmental impacts.

APPROVAL OF THE UNDERTAKING

Aerial (and ground) application of insecticides falls under both federal and provincial legislation. The approval of product use (operationally or experimentally) has first to be given by the federal government. This mandate rests with the Pest Management Regulatory Agency of Health Canada.

In Canada, before they are registered for use, pesticides must have undergone extensive assessments for both environmental impacts and human health risks, when used according to label directions under appropriate weather conditions.

In Newfoundland, pesticide application has to be carried out under an Operators Licence, issued by the Department of Environment, and under the direction of qualified and licenced Applicators.

The Federal Government, pesticide manufacturers, universities and colleges are also involved in pesticide research. Decisions, made by government after all of the research has been reviewed, are made with wide safety margins.

Any manufacturer who wishes to sell a pesticide in Canada must first register that pesticide under the *Pest Control Products (PCP) Act*. To receive registration, the manufacturer must follow the registration process administered by the Pest Management Regulatory Agency (PMRA) of Health Canada. Registration involves the submission of an application by the manufacturer. Before this is possible, the company must carry out specific studies on the product, as required by PMRA. The

application must be supported by a very thorough data package documenting the effects of the pesticide on users, bystanders and the environment

The scientific testing may take years, as the study includes long and short term health effects of the user, exposure to bystanders, residues in food, ground water contamination, effects on wildlife and environmental fate. A scientific evaluation of the product is then performed by Health Canada. A registration will be granted only if the pesticide's safety, merit and value for the proposed use are found to be acceptable. If problems with the product are identified, registration will not be granted. All products are subject to re-evaluation, with provision for suspension or cancellation.

Once the federal government approves a registration, the provincial governments become more involved. Each province has legislation dealing specifically with pesticide use in that province. In Newfoundland and Labrador pesticide use is regulated under the *Environmental Protection Act*. This legislation requires all organizations and companies using pesticides to apply for and receive a Pesticide Operator Licence. This licence regulates aspects of an operation not covered by federal legislation and requirements. As with federal regulations, the Pesticide Operator License is designed to minimize risks to human health and the environment. Aspects of a pesticide operation like buffer zones, spill response, public information and notification programs, monitoring requirements, weather conditions, etc are all specified in the license as they relate to a particular spray program.

Provincial legislation also requires

individuals to be trained in the safe use of pesticides. Only individuals that successfully pass the provincial pesticide applicator exam (administered by the Department of Environment - Pesticides Control Section) are granted an applicator license and authorized to handle pesticides. Compliance and enforcement activities are also carried out by the Pesticides Control Section.

As with all commercial pesticide operations, the 2003 insecticide program will be regulated by the Pesticides Control Section of the Department of Environment [**see attachments to this document**]. The Federal registration system combined with the provincial licensing and regulatory system ensures that any pesticide that is used in Canada has passed a comprehensive environment/health evaluation.

SCHEDULE

The insects will emerge, and the best time for application of control, is expected to be late June to early August, but weather dependent. Because of the logistics and acquisition of supplies and services, it is essential that approval be given at the earliest.

Original signed by

April 3, 2003

Date

Allan Masters

Deputy Minister

ATTACHMENTS

**MAPS OF INFESTED AREAS PREDICTED FOR
2003 AND WHERE MIMIC IS PROPOSED**
see Appendix A

**COPY OF 2002 OPERATORS LICENCE
(TERMS AND CONDITIONS) FROM THE
DEPARTMENT OF ENVIRONMENT**
APPLICABLE TO FOREST INSECTICIDE USE

see Appendix B

HEALTH CANADA - PMRA

DOCUMENT ON MIMIC

Appendix C

NOTE: This was an **initial (1996)** Health Canada Discussion Document prepared by PMRA public comment. **Subsequent to this document, PMRA granted a registration for the product with stipulations on the label to address any concerns identified. These stipulations incorporated levels of protection for non-target exposure.** The label provided in Appendix D is the current label in use.

MIMIC® PRODUCT LABEL

Appendix D

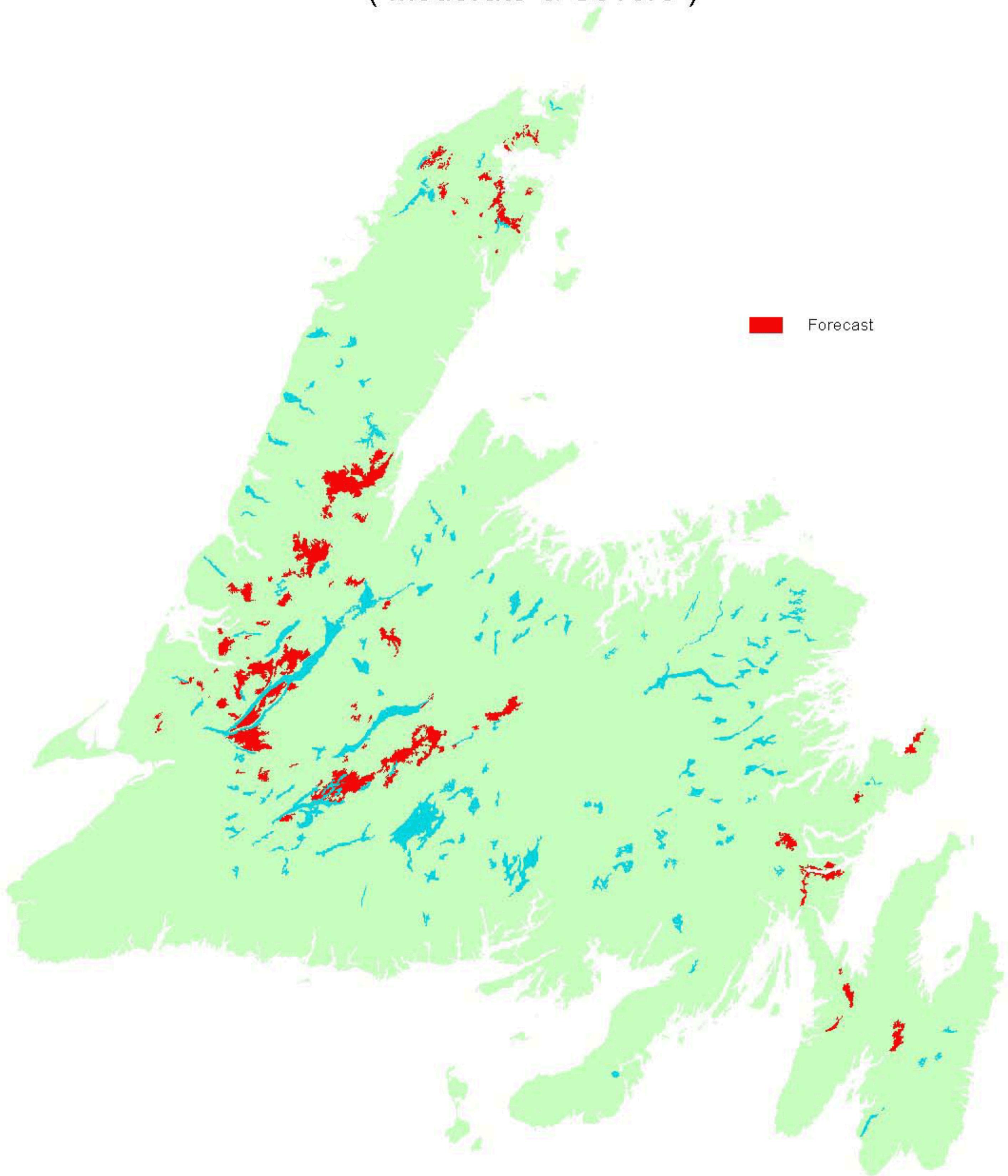
Appendix A

- 1) Map of insular Newfoundland showing general hemlock looper infestation areas forecast for 2003
- 2) Maps of **Infested areas Predicted** for 2003 where Mimic ® is being proposed.

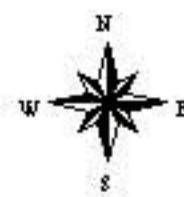
NOTE:

The areas outlined on the following maps indicate where the hemlock looper populations and expected defoliation / damage will occur in 2003. And where control activity will be focussed. They are not final treatment areas. Treatment blocks will be established within and adjacent to these boundaries once the terms and conditions and buffer zone (no-treatment areas) are determined by the provincial Department of Environment under the approval and licensing process.

2003 Hemlock Looper Defoliation Forecast (Moderate & Severe)



20 0 20 40 60 80 100 Kilometers



HEMLOCK LOOPER

POTENTIAL MIMIC
TREATMENT AREAS IN 2003
(within and adjacent to the forecast
boundaries)

Any treatment areas selected within these
boundaries are subject to configuration into
spray blocks with applicable buffer zones around
sensitive areas such as designated water bodies,
habitation, water supplies, etc.

NOTE: Minimum buffer zones established by
Federal Regulators; additional buffers can be
imposed by Provincial Department of
Environment

Hare Bay

 **HEMLOCK
LOOPER**
AREAS FORECAST TO
RECEIVE MODERATE
AND SEVERE
DEFOLIATION IN 2003

Main Brook

Croque

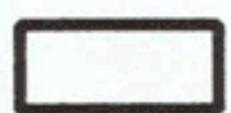
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Scale 1:225,000



HEMLOCK LOOPER

AREAS FORECAST TO RECEIVE MODERATE AND SEVERE DEFOLIATION IN 2003

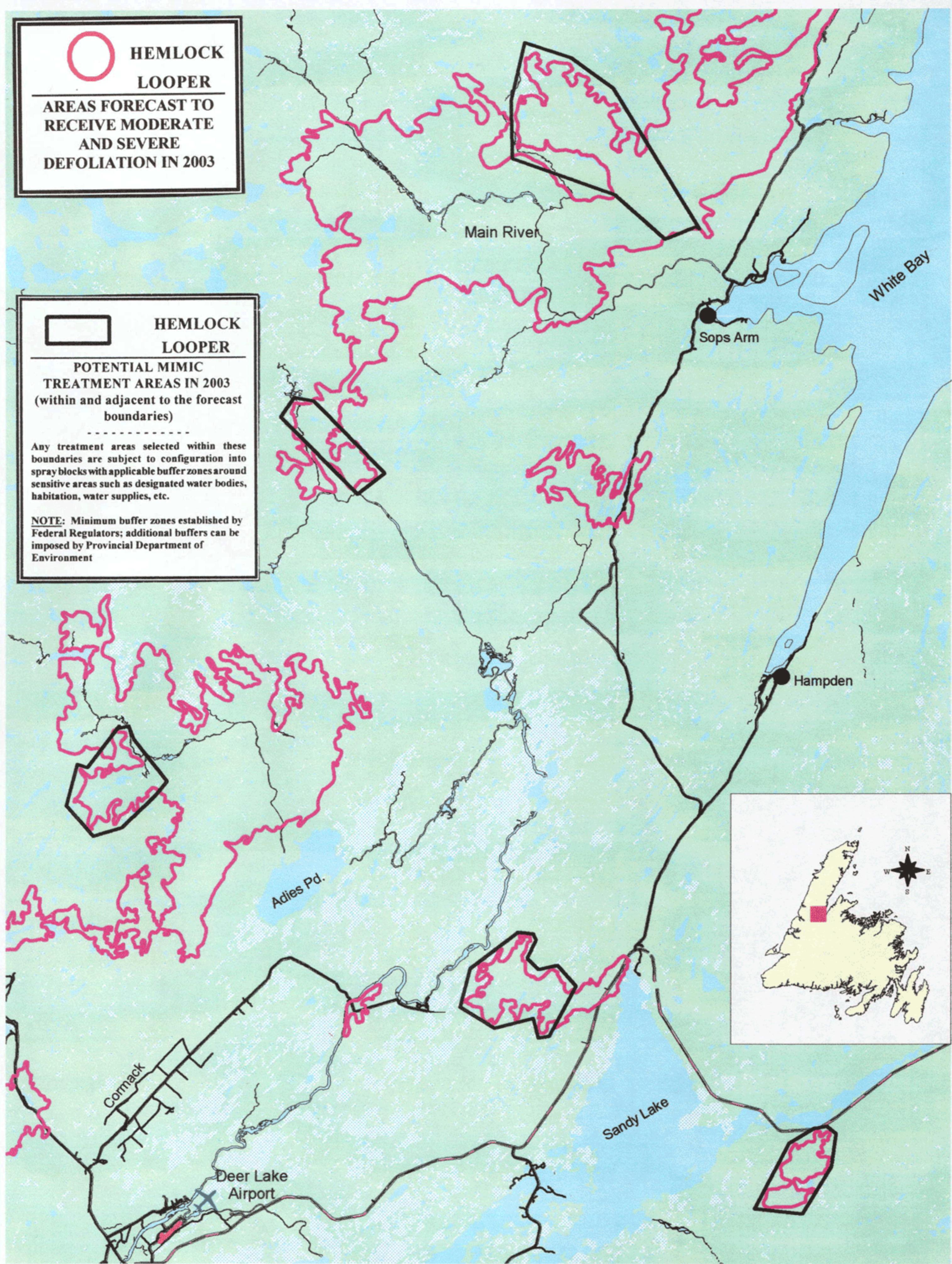


HEMLOCK LOOPER

POTENTIAL MIMIC TREATMENT AREAS IN 2003
(within and adjacent to the forecast boundaries)

Any treatment areas selected within these boundaries are subject to configuration into spray blocks with applicable buffer zones around sensitive areas such as designated water bodies, habitation, water supplies, etc.

NOTE: Minimum buffer zones established by Federal Regulators; additional buffers can be imposed by Provincial Department of Environment

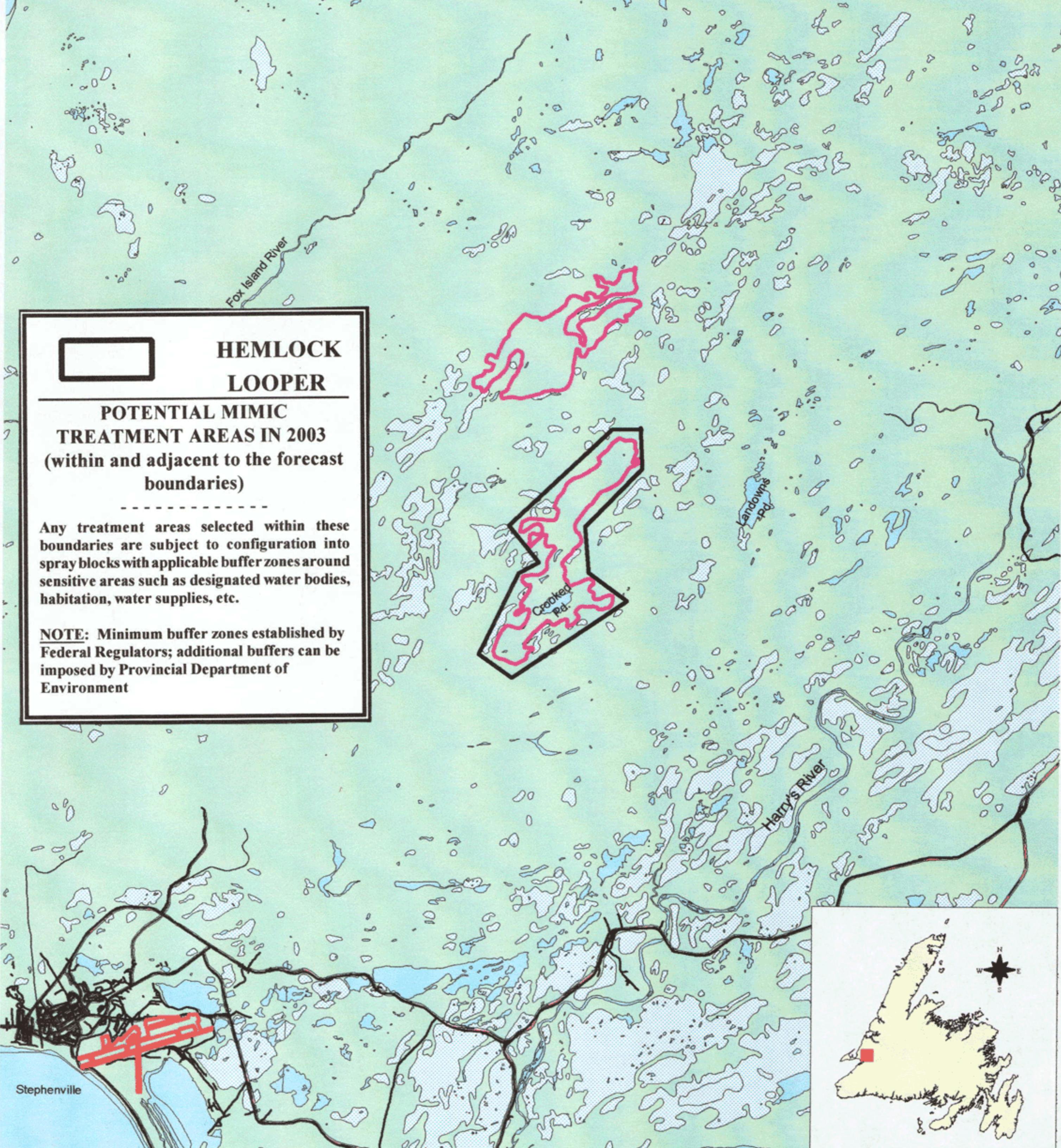


 **HEMLOCK
LOOPER**
AREAS FORECAST TO
RECEIVE MODERATE
AND SEVERE
DEFOLIATION IN 2003

 **HEMLOCK
LOOPER**
**POTENTIAL MIMIC
TREATMENT AREAS IN 2003**
(within and adjacent to the forecast
boundaries)

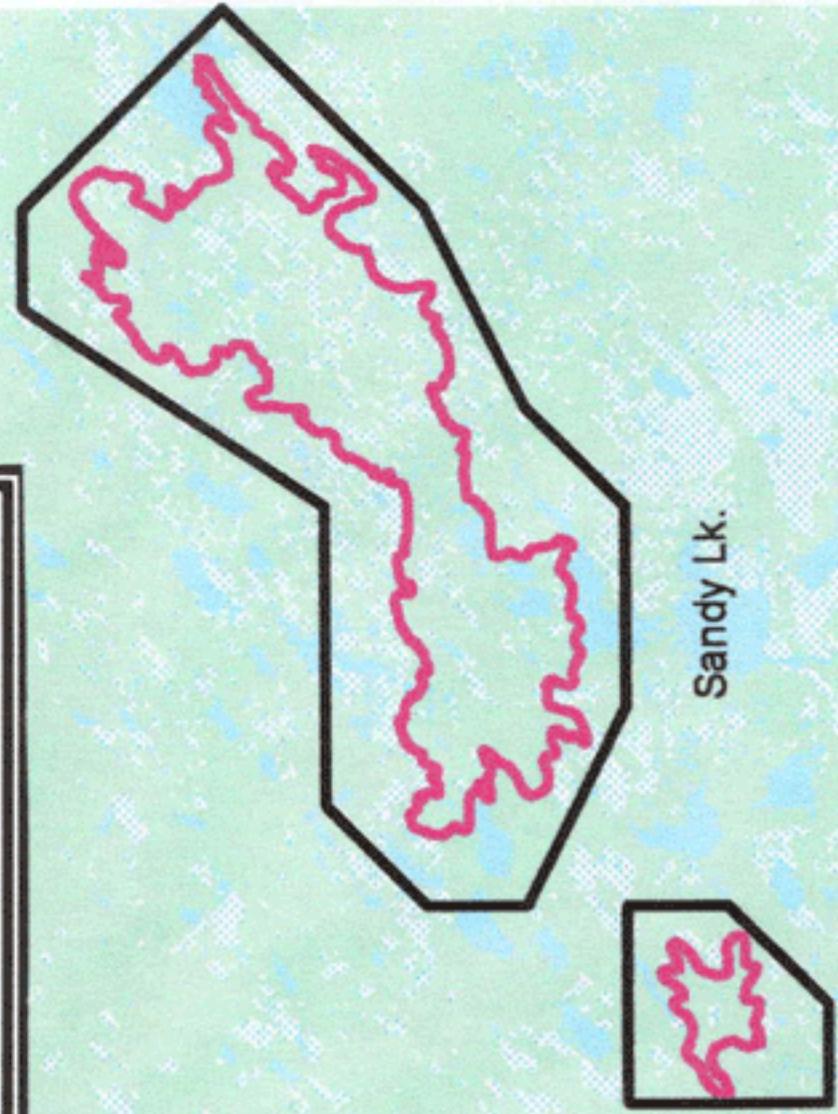
Any treatment areas selected within these boundaries are subject to configuration into spray blocks with applicable buffer zones around sensitive areas such as designated water bodies, habitation, water supplies, etc.

NOTE: Minimum buffer zones established by Federal Regulators; additional buffers can be imposed by Provincial Department of Environment



Scale 1:150,000

**HEMLOCK
LOOPER**
AREAS FORECAST TO
RECEIVE MODERATE
AND SEVERE
DEFOLIATION IN 2003



Sandy Lk.



Millertown



Buchans

Hinds Lk.

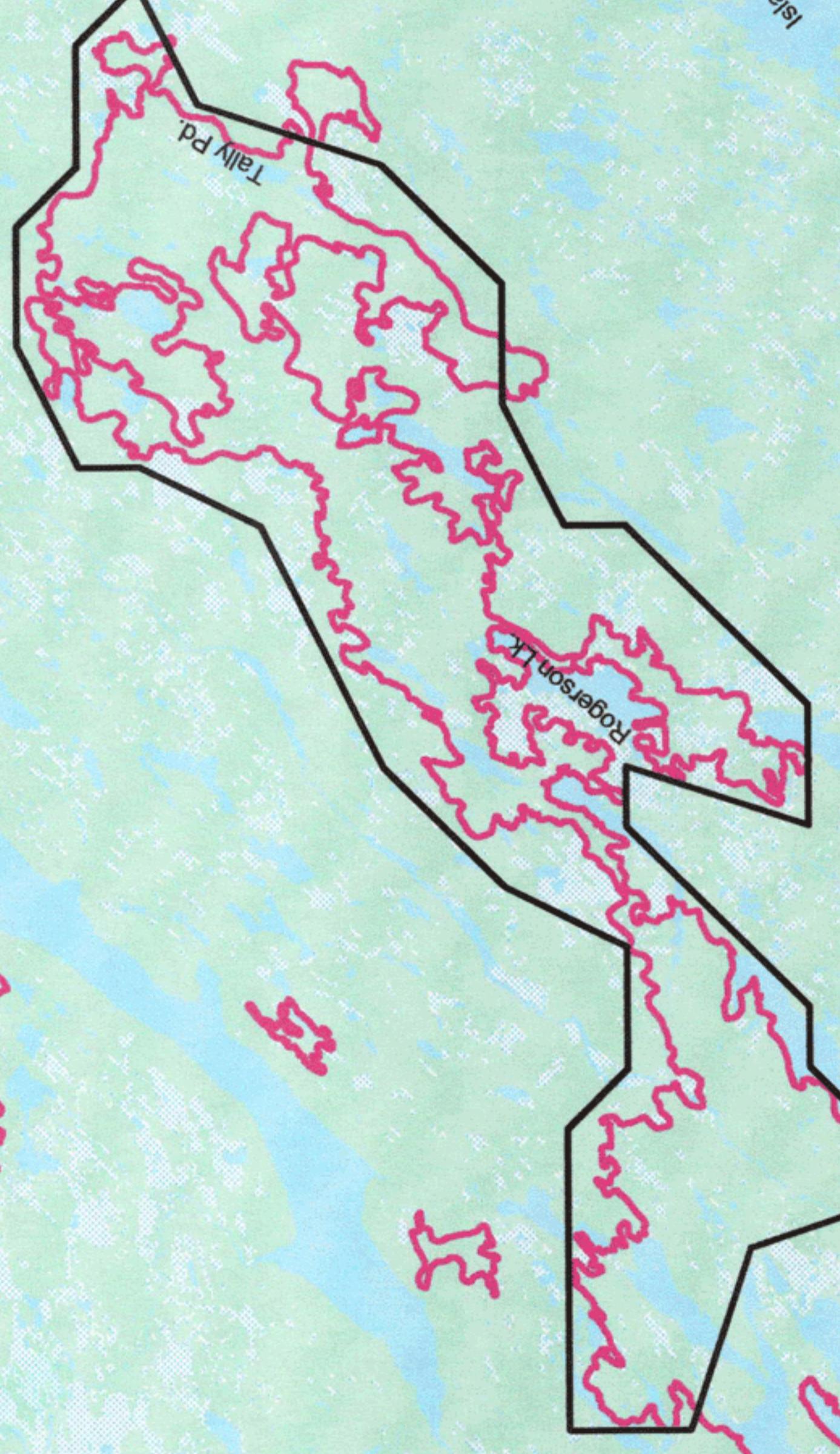
Red Indian Lake

HEMLOCK LOOPER

POTENTIAL MIMIC TREATMENT AREAS IN 2003

(within and adjacent to the forecast boundaries)
Any treatment areas selected within these boundaries are subject to configuration into spray blocks with applicable buffer zones around sensitive areas such as water bodies, habitation, water supplies, etc.

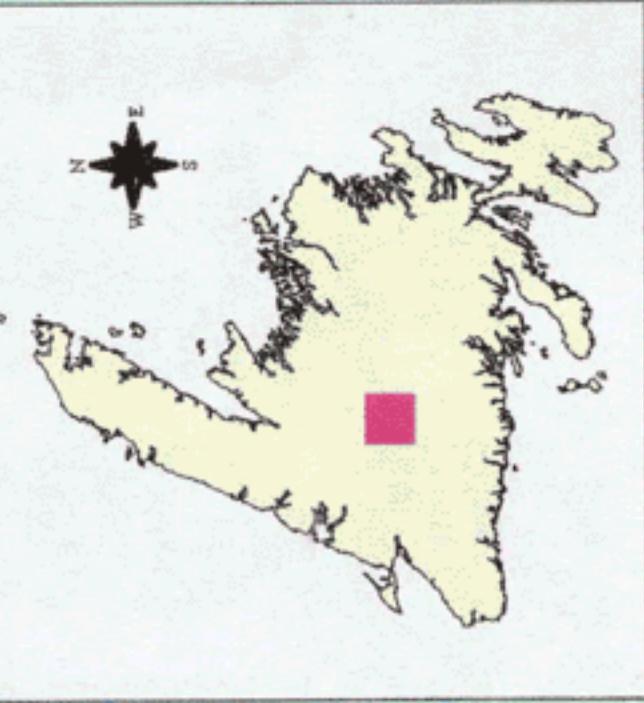
NOTE: Minimum buffer zones established by Federal Regulators; additional buffers can be imposed by Provincial Department of Environment



Tally Rd.

Rogerston Lk.

Victoria Lk.



N
E
S
W

Scale 1:400,000

APPENDIX B

Copy of 2002 Pesticide Operators Licence (modified to show only the applicable sections pertaining to forest insecticide application)



GOVERNMENT OF
NEWFOUNDLAND AND LABRADOR

**Department of
Environment**

Pesticides Control Section

PESTICIDE OPERATOR LICENCE

TERMS AND CONDITIONS

DEPARTMENT OF FOREST RESOURCES AND AGRIFOODS

June 2002

1. **Definitions**

Waterbody: means any surface (high water mark) or subterranean source of fresh or salt water within the province, whether such course usually contains water or not, and includes coastal water within the jurisdiction of the province and includes water above the bed of the sea that is within the jurisdiction of the province, any river, stream, brook, creek, water course, lake, pond, spring, lagoon, ravine, gully, canal and any other flowing or standing water and the land usually or at the time covered by any such body of water.

Well: means an artificial opening in the ground from which water is obtained or that is made for the purpose of exploring for or obtaining water.

Human habitation: means every structure in which a person or persons resides on either a part-time or full time basis.

2. For the purpose of this licence, all definitions and regulations as indicated in the Environmental Protection Act, SNL 2002, cE-14.2 and the Pesticides Control Regulations, 1166/96 shall apply.
3. All applications shall be conducted in strict compliance with the label registered under the authority of the Pest Control Products Act (Canada).
4. The operator shall be limited to using only those pesticides and applicators as indicated on its Pesticide Operators License Application dated June 14, 2002. Any changes in the program outlined in the application must receive written approval of the Manager, Pesticides Control Section, prior to their implementation.
5. The operator shall review these terms and conditions with each applicator prior to the start of each season, and a copy of the terms and conditions shall be provided to each applicator.
6. A copy of the operators licence and these terms and conditions shall be available at each site during the application of a pesticide. In addition, the operator shall ensure that all applicators have their applicators license in their possession while applying pesticides.
7. Upon completion of the pesticide program for the year, the operator shall submit to the Pesticides Control Section details regarding the type and quantity of each pesticide used and the name of the vendor(s) from whom the pesticide was purchased. This information shall be submitted no later than December 31 of each year. Licenses for the following season will not be processed until this information is received.
8. Empty pesticide containers which have been triple rinsed, cleaned and rendered unusable may be disposed off at an Approved waste disposal site. Contaminated material shall be disposed off in accordance with the manufacturer's directions and in consultation with the Pesticides Control Section.
9. All spills involving greater than 10 liters of mixed pesticide or the equivalent of unmixed formulation shall be reported immediately. All spills involving mixed or unmixed pesticide into a water body or within 100 m of a water body, well or area frequented by people shall be reported immediately. Spills involving less than 10 liters of mixed pesticide or equivalent amount of unmixed formulation in areas not frequented by people, or remote from water bodies or wells shall be duly recorded by the Operations Supervisor. Records of all such incidents (spills) shall be kept on file by the Operator. Reporting of spill incidents shall be made to the Pesticides Control Section, Newfoundland and Labrador Department of Environment, St. John's (ph. 729-3395) and to Environment Canada, St. John's (ph 772-2083).
10. All vehicles (except spray aircraft) carrying liquid pesticide formulations shall carry a quantity of approved absorbent materials sufficient to contain the amount of product on hand. The vehicle shall

also carry clean-up equipment such as shovels, brooms, bags, etc.

11. All pesticide storage sites shall be in accordance with Section 13 of *The Pesticides Control Regulations*.
12. Pesticides shall be stored in their original container or in a substitute container approved by the manufacturer. Substitute containers shall be labelled appropriately.
13. Concentrated pesticides transported in a vehicle during spray operations shall be contained in a locked box, secure area or compartment which must be locked while unattended. Pesticides shall not be transported in the passenger compartment of any vehicle.
14. The operator shall provide and ensure that all personnel involved in the mixing, loading, and application of pesticides wear appropriate protective equipment in accordance with the pesticide manufacturer's product label and / or Material Safety Data Sheet.
15. All exterior spraying activities are permitted only when wind speeds are between 2 and 15 km/hr; air temperatures are below 25° C; the relative humidity is above 50 % and it is not raining nor is rain anticipated over the next 2-hour period. Exceptions to wind speed conditions may be granted on a case by case basis. Contact the Pesticides Control Section for details.
16. **For pesticide operations involving a total of 750 ha or more**, dyking, security, storage and communications plans shall be provided and approved by the Pesticides Control Section in advance of any spray program for all locations where any pesticide is to be mixed or loaded.

The operator will also be responsible for the development of contingency plans and associated call out notifications to the satisfaction of the Pesticides Control Section in advance of any spray program.

17. **For aerial insect control programs**, requests to treat proposed areas during the next seven calendar days period shall be submitted to the Pesticides Control Section, **ph.: 709-729-3395; Fax: 709-729-6969**; at least **one week** prior to said seven day period. At the end of the seven day period the Pesticides Control Section shall be notified of any future anticipated work in the manner described above.
18. Aerial spraying of pesticides is generally not permitted within Protected Water Supply Areas. The storage, mixing, loading and application of any pesticide within Protected Water Supply Areas requires a separate approval from the Water Resources Management Division of the Department of Environment. The approval request shall provide detailed information on the type and duration of activity, location of activity (to be delineated on 1:50 000 NTS topographical map), name of the pesticide along with its composition and toxicity data, application rate, application method, as well as any other information required.

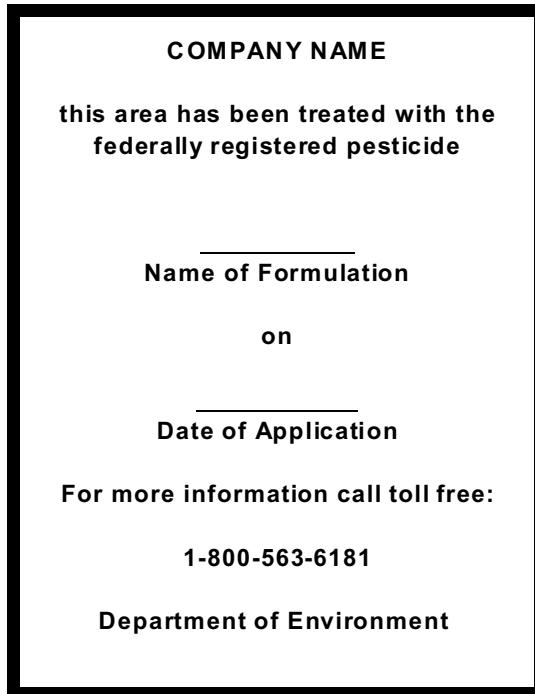
The requirement of obtaining a separate approval from the Water Resources Management Division may be waived provided the above-noted information is provided to the Pesticides Control Section at the time of the submission of the pesticide operator licence application. The Water Resources Management Division will consult appropriate town council(s) before issuing any approval or consent for a pesticide operator license.

The operator assumes liability to provide an alternate source of water to the affected community or communities as a result of the source of water supply being contaminated due to the spray program.

19. For pesticide operations involving treatments of **pesticides applied aerially**, the public shall be advised of the purpose and scope of the project and of the issuance of this licence by means of a notice published in at least one (1) newspaper with circulation in municipalities whose boundaries encompass treatment areas. The newspaper ad will appear in any issue at least one week prior to

commencing the program. The ad will state the area that is proposed for treatment over the next 21 calendar days, at the end of which time another ad is to be placed until the program is completed. The ad will contain the telephone numbers of the Pesticides Control Section, 709-729-3395, and 1-800-563-6181.

20. **For aerial insect control programs**, municipal governments whose boundaries encompass treatment and storage areas shall be notified prior to commencement of the programs. As per provisions of the Urban and Rural Planning Act and the Municipalities Act, any activity within a town boundary requires approval of the town council in question.
21. **For aerial insect control programs**, the public shall be advised of local treatments by the posting of signs in the area. The signs shall be as follows:



The particulars (location, timing, size of sign, etc.) of said posting shall be set by the Pesticides Control Section prior to spray programs.

22. The operator and/or his agent shall make every reasonable attempt to verbally notify adjacent owners, prior to the spray program, who, given the nature of the control operation, might be expected to benefit from said notification. In the event that this cannot be done, the operator shall use written notification to all dwellings to the satisfaction of the Pesticides Control Section.
23. For all programs involving the **aerial application of insecticides**, the operator shall be required to submit the details of public/municipality information programs to the Department of Environment. The details of said public/municipality information programs must be approved in advance by the Department of Environment. The operator may be required to carry out these programs following review by the Department of Environment.
24. In the event that formulations containing B.t.k. are to be used, the brochure **Protecting the Forests with Btk**, is to be distributed to all municipal councils with boundaries that may contain spray blocks. In addition, the brochure is to be made readily available to members of the general public. Additional distribution is encouraged but is done so at the pesticide operator's discretion.
25. A toll-free information line shall be set up one week prior to commencement of the spray program,

for the duration of the spray program, and will remain operational until September 30, 2002. The toll-free number will be advertised prior to the beginning of the spray program.

26. Daily notification through press releases shall be made by the licensed pesticide operator, for the duration of the spray program. Regular updates will be made regarding the status of the program. All updates will identify the toll-free information number.
27. For any pesticide application involving, either directly or indirectly, an aircraft of any sort, the operator shall maintain a **800 metre buffer zone around all occupied osprey and bald eagle nests** during the period May 1 to August 15.
28. Bacillus thuringiensis kurstaki
If approved for aerial application in Protected Public Water Supply Areas, the operator shall provide the following widths of buffer zones, or any other buffer widths as specified by the Water Resources Management Division, along and around water bodies from the high water mark in a designated area:

<u>WATERBODY</u>	<u>WIDTH OF BUFFER ZONE</u>
Intake pond or lake	a minimum of 150 meters
River intake	a minimum of 150 meters for a distance of one (1) km upstream and 100 meters downstream
Main river channel	a minimum of 75 meters
Major tributaries, lakes or ponds	a minimum of 50 meters
Other waterbodies	a minimum of 30 meters

29. **Neemix 4.5 (azadirachtin) Temporary Registration # 26548**
For all aerial applications of Neemix 4.5, the operator shall maintain a minimum buffer of 100 meters from all recognized salmon rivers. The proponent will also maintain a minimum buffer of 50 meters from any body of water identified on a 1:50,000 NTS topographical map, any occupied cabin or other inhabited areas.
30. **Mimic 240 LV (tebufenozide) PCP Act #24502.**
For all aerial applications of Mimic 240LV, the operator shall maintain a minimum buffer of 100 meters from all recognized salmon rivers. The proponent will also maintain a minimum buffer of 50 meters from any body of water identified on a 1:50,000 NTS topographical map, any occupied cabin or other inhabited areas.
31. All pesticide mixing and rinsing sites shall be located a minimum of 100 m from the nearest water body. Loading of equipment with water only prior to the addition of pesticide can be done up to 5 metres from a water body. Addition of pesticide to the water in the equipment shall be performed at least 100 m from the nearest water body.
32. Where water must be pumped directly into the formulation tank, an antibackflow device must be fitted onto the pump and the siting should be that the formulating unit be at least 30 m from the watercourse and that the chemical not be opened for addition to the formulation tank until the equipment has been filled with water and is out of the respective buffer zone.
33. **REVOCATION.**
Failure by an operator, its agent, employee or a licensed pesticide applicator under its control, to adhere to the Environmental Protection Act SNL 2002, cE-14.2, the Pesticides Control Regulations,

1166/96, or the stipulations attached to its operator licence shall authorize the Minister of Environment to suspend, revoke, or cancel the subject licence or prosecute under the Environmental Protection Act SNL 2002, cE14.2.

34. **PENALTY.**

Failure by an operator, its agent, employee or a licenced pesticide applicator under its control to comply with any of the terms and conditions of its licence is guilty of an offence under the Environmental Protection Act SNL 2002, cE-14.2.

APPENDIX C

NOTE: This was an **initial (1996)** Health Canada Discussion Document prepared by PMRA for pre-registration public comment.

Subsequent to this document, PMRA granted a registration for the product with stipulations on the label to address any concerns identified.

These stipulations incorporated levels of protection for non-target exposure and mitigated potential impacts. The label provided in Appendix D is the current label in use.



Consultation Document

Tebufenozide

The active ingredient tebufenozide and formulated product Mimic® 240 LV Forestry Insecticide, for control of larval Lepidoptera, are proposed for registration.

This document provides a summary of data reviewed and the rationales for the proposed regulatory decisions concerning Mimic® 240 LV Forestry Insecticide and the active ingredient tebufenozide.

This document has been prepared in keeping with the ongoing efforts of the Pest Management Regulatory Agency (PMRA) to regulate pest control products in an open and transparent manner.

The PMRA will accept written comments on this proposal up to February 15, 1996 and expects to make a final regulatory decision by March 1, 1996. Please forward all comments to:

Tebufenozide Working Group
Pest Management Regulatory Agency
Health Canada
59 Camelot Drive
Nepean, Ontario
K1A 0Y9

Facsimile: (613) 998-1312

(publié aussi en français)

January 15, 1996

This document is published by the Information Division, Pest Management Regulatory Agency. For further information, please contact:

Pest Management Regulatory Agency
Health Canada
59 Camelot Drive
Nepean, Ontario
K1A 0Y9

Telephone: (613) 952-5330
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Information Service: 1-800-267-6315
(In Canada only)
Internet: PMINFOSERV@EM.AGR.CA

Introduction

Tebufenozide, a new active ingredient, is an Insect Growth Regulator (IGR) in the chemical family benzoic acid hydrazide. An aqueous flowable formulation containing 240 g/L of tebufenozide, Mimic® 240 LV Forestry Insecticide, for use in forests and woodlands, is proposed for registration. Tebufenozide has a novel mode of action in that it mimics the action of the insect molting hormone, ecdysone, in larval Lepidoptera (caterpillars), by initiating an unsuccessful (lethal) molt in the larvae. Larvae stop feeding within hours of ingestion of a toxic dose; death occurs in three to seven days.

Chemistry Assessment

Specifications, methods of analysis, microcontaminant analysis, and quality control data of the pilot plant production were reviewed and were found acceptable. Once full-scale production of tebufenozide is initiated, supplementary chemistry data will be submitted and reviewed.

Health Assessment

Toxicology: In the rat, orally administered (by gavage) single doses (3 or 250 mg/kg bw) of ¹⁴C-tebufenozide (labelled in either the t-butyl, A- or B-ring group) were rapidly absorbed and excreted. The excretion profiles were similar, regardless of the position of the ¹⁴C-label, dose level, sex or whether the rats were pre-treated with 30 ppm dietary non-labelled tebufenozide for two weeks. A mean total of 87-104% of the administered dose was excreted within 48 h of dosing, primarily via the faeces which accounted for >90% of the ¹⁴C-label excreted. Only minor amounts (<1-8% of dose) were excreted in urine and trace amounts (<0.1-0.4% of dose) were eliminated in expired air (as ¹⁴CO₂ and organic volatiles) from rats dosed with [¹⁴C-t-butyl]-tebufenozide. At 3 mg/kg bw, systemic absorption was calculated to be 35-39% of the total dose; 30-34% was excreted in the bile and ~5% in the urine. At 250 mg/kg bw, only about 4% of the administered dose was absorbed and metabolized. Tissue retention of ¹⁴C-radioactivity was very low; <1 and ≤0.01% of the dose were retained at 3 and 250 mg/kg bw, respectively, at 7 days post-dose. The highest concentrations were found in the liver, fat and kidneys. The tissue ¹⁴C-distribution profiles were consistent with the pharmacokinetic data and indicated that the ¹⁴C-radioactivity associated with the A-/B-ring label was cleared more rapidly from the tissues than that associated with the t-butyl label.

¹⁴C-tebufenozide was extensively metabolized in rats. The majority of ¹⁴C-radioactivity excreted in faeces was in the form of unabsorbed (parent) tebufenozide, accounting for ~60 and >90% of the given dose at 3 and 250 mg/kg bw/day, respectively. No unchanged parent compound was detected in the urine. There were no significant qualitative differences in the metabolite profiles between the different ¹⁴C-labelled versions of tebufenozide, the high and low doses, sexes, or rats with or without pre-treatment with dietary tebufenozide (30 ppm) for two weeks. In general, the whole-molecule metabolites identified (total of 13-15) in the urine, faeces and bile were identical. The major route of metabolism of tebufenozide appeared to be the oxidation of benzylic carbons (A-/B-ring) of the molecule to provide a number of oxidized metabolites with various combinations of oxidation state at the three carbon centres

oxidized. One exception was RH-2703 which was produced by oxidation of the non-benzylic carbon, the terminal C on the A-ring ethyl group.

In acute studies, tebufenozide technical was of low oral toxicity ($LD_{50} > 5,000$ mg/kg bw) to rats and mice and low dermal ($LD_{50} > 5,000$ mg/kg bw) and inhalation toxicity ($LC_{50} 4.3$ mg/L) to rats. Tebufenozide technical was found to be non-irritating to the skin and minimally irritating to the eyes of male New Zealand White (NZW) rabbits, and it was not a skin sensitizer in the guinea pig.

In acute studies, tebufenozide 240 LV formulation (Mimic[®] 240 LV containing 24% a.i.) was of low toxicity to rats when given via the oral, dermal or inhalation route. The oral LD_{50} was $> 5,000$ mg/kg bw, the dermal LD_{50} was $> 2,000$ mg/kg bw and the inhalation LC_{50} was > 1.33 mg/L (equivalent to > 0.32 mg a.i./L). Tebufenozide 240 LV formulation was found to be mildly irritating to the skin and to the eyes of NZW rabbits, and it was not a skin sensitizer in the guinea pig.

In acute studies, tebufenozide metabolites (RH-111788, RH-96595, RH-120970, RH-089886 or RH-112651) were of low toxicity to mice when given acutely via the oral route. The oral LD_{50} of these tebufenozide metabolites in mice was $> 5,000$ mg/kg bw.

Repeated short-term oral administration of tebufenozide technical to mice (2-week, 13-week), rats (2-week, 4-week and 13-week) and dogs (2-week, 6-week, 13-week and 52-week) resulted primarily in haematotoxic effects - mild regenerative haemolytic anaemia and compensatory responses from the haematopoietic tissues. Based on haematotoxicity, the No Observable Adverse Effect Level (NOAEL)/No Observable Effect Level (NOEL) was 35.3 mg/kg bw/day for mice (13-week), 13.1 mg/kg bw/day for rats (13-week) and 1.9 mg/kg bw/day for dogs (13-week and 52-week combined). The dog appeared to be the most sensitive species for short-term toxicity.

Repeated short-term (4-week) dermal application of tebufenozide technical to rats resulted in no evidence of treatment-related systemic toxicity at dose levels up to 1,000 mg/kg bw/day. The NOEL was $> 1,000$ mg/kg bw/day for rats.

In long-term rodent dietary studies, the NOEL for chronic systemic toxicity was 7.8 mg/kg bw/day for mice (based on a slightly reduced survival rate and mild regenerative haemolytic anaemia at higher dose levels) and 4.8 mg/kg bw/day for rats (based on decreased body weight and food consumption and mild regenerative haemolytic anaemia at higher dose levels). Tebufenozide technical was not oncogenic in the mouse or the rat under the conditions of the studies.

Tebufenozide technical (and its metabolites) had been adequately tested for mutagenicity and/or genotoxicity in a standard series of in vitro and in vivo assays and the results were negative. It was concluded that tebufenozide technical (and its metabolites) did not demonstrate any genotoxic and/or mutagenic potential under the conditions tested.

In a rat reproduction study (two generation, one litter per generation), the NOEL for parental toxicity was 0.7 mg/kg bw/day based on increased severity of pigment deposition in the spleen (F_0 and F_1 females) at the next higher dose of 9.7 mg/kg bw/day. At the highest dose of 142.2 mg/kg bw/day, additional signs of parental toxicity were reduced mean body weight and food consumption (F_0 and F_1 males only) during pre-mating, and increased splenic extramedullary haematopoiesis (both sexes and generations). Signs of reproductive toxicity were evident at 142.2 mg/kg bw/day: decreased mean number of implantation sites (F_1 females), prolonged gestation period (F_1 females), a slightly higher number of pregnant females with total resorption (both generations) and a small increase in the number of dams (F_1 generation) dying during delivery. The NOEL for reproductive toxicity was 9.7 mg/kg bw/day.

In two rat teratogenicity studies, the NOAEL for maternal toxicity was 1,000 mg/kg bw/day, the highest dose level tested. At 1,000 mg/kg bw/day, there was a slight reduction in mean body weight gain and food consumption at initiation of dosing; the decreases were transient and reversible, and therefore were not considered to be toxicologically significant. There were no treatment-related reproductive or teratogenic effects at any dose level. The NOEL for embryo-fetotoxicity and teratogenicity in the rat was 1,000 mg/kg bw/day, the highest dose level tested in the studies. In two rabbit teratogenicity studies, there were no treatment-related mortalities or clinical signs of maternal toxicity, no adverse effects on reproductive parameters and no evidence of teratogenic potential at any dose level. The NOEL for maternal and embryo-fetal toxicity and teratogenicity in the rabbit was 1,000 mg/kg bw/day, the highest dose level tested in the studies.

In summary, the primary target site of tebufenozide toxicity was the peripheral haematopoietic system and the main toxicological end-point, consistent across all species tested, was mild regenerative haemolytic anaemia with compensatory responses from the haematopoietic tissues. Technical tebufenozide was of low acute toxicity to the mouse via the oral route and to the rat via the oral, dermal or inhalation route. Pharmacokinetic and metabolism studies in the rat revealed that the compound was only partially absorbed, rapidly excreted and that there were no signs of bioaccumulation in any tissue/organ examined. Tebufenozide was not oncogenic in the mouse or in the rat, and it did not demonstrate any mutagenic/genotoxic potential in vitro or in vivo. There was no evidence of any teratogenic potential in the rat or the rabbit and no effect on reproduction except at a high dose level that elicited parental toxicity.

Drinking Water Exposure: No monitoring data were found on residues of tebufenozide in surface, ground or drinking water. Based on the environmental data presented, tebufenozide is not expected to pose a significant health risk through drinking water.

Occupational Exposure: Based on a Health Canada assessment, selected data from surrogate exposure studies were combined with estimates from the Pesticide Handlers Exposure Database (PHED) to yield exposure estimates for airblast and aerial application. The replicates derived from the PHED assessment are considered representative of the proposed

use of Mimic® 240 LV. Aerial application exposure estimates for the mixer/loader and applicator (pilot) were 0.017 and 0.015 mg/kg bw/day, respectively. Exposure estimates were based on workers wearing gloves (except pilot), long pants, and long-sleeved shirts.

Risk Assessment: An acceptable daily intake (ADI) of 0.019 mg tebufenozide/kg bw has been estimated based on the overall NOEL of 1.9 mg/kg bw/day (50 ppm) for haematotoxicity in the 13- and 52-week feeding studies in the dog using a 100-fold safety factor.

An objective concentration for tebufenozide in drinking water, using the estimated ADI of 0.019 mg/kg bw, can be calculated as approximately 0.09 mg/L, assuming an adult consumer with a 10% allocation of drinking water.

The use pattern of tebufenozide indicates a short-term occupational exposure of several days per year. Dermal exposure is regarded as the major route of exposure for airblast and aerial application. Given the likely route and duration of exposure, the 4-week rat dermal toxicity study with a NOEL of 1,000 mg/kg bw/day was considered most appropriate for occupational risk assessment purposes. The risk assessment indicated that, provided Mimic® 240 LV is used according to label directions, the margin of safety (MOS) for occupational exposure would be acceptable.

Environmental Assessment

In laboratory experiments, tebufenozide was relatively non-volatile from moist soil and water surfaces and did not bioaccumulate in fish and mammals tested. Based on laboratory and field studies, the likelihood of deleterious effects on beneficial non-target arthropods, following the use of tebufenozide, is predicted to be minimal. Tebufenozide is unlikely to pose a risk to soil microorganisms, earthworms, birds, wild mammals, fish, amphibians, aquatic plants and most aquatic invertebrates including crayfish, copepods, rotifers, insects and the mysid shrimp.

Tebufenozide was shown to have the potential for residue carryover into the next season in forest soil, forest litter and conifer needles, following application at the proposed maximum label rates. Tebufenozide would be classified as moderately persistent in forest pond water in Ontario and was shown to partition into and accumulate in bottom sediments in a forest pond, and to persist at 393 days after treatment. The potential for tebufenozide residues to continue to accumulate in aquatic sediments following annual applications is unknown. Tebufenozide could present a risk to some aquatic invertebrates, i.e., cladocerans and molluscs, following application at the proposed maximum label rates.

To address the above concerns, and identified data gaps, the applicant has agreed to provide data on the effects of tebufenozide on freshwater and terrestrial species of molluscs, terrestrial plants and honey bee larvae, and additional large-scale forestry dissipation data. Research to determine the potential for residue carryover in foliage to provide a second year of control of forest pests must also be conducted. Additional studies on the effects of tebufenozide on

birds, amphibians and non-target terrestrial insects will be submitted and reviewed on a supplementary basis. In order to establish more scientifically-based buffer zones, empirical drift data from aerial application should be generated.

Based on an assessment of the environmental safety of tebufenozide, a temporary registration of the forestry use is acceptable while supplementary data are being generated and with the required “Environmental Precautions” added to the Mimic® 240 LV label (see Appendix 1).

Value Assessment

Mimic® 240 LV Forestry Insecticide is an effective insecticide that would be an asset in forest pest management programs. Some further work is required to optimize application rates and volumes for operational programs. Therefore, a temporary registration is recommended for those uses meeting a satisfactory assessment. Efficacy data were reviewed and the information established that the product has merit and value for the following uses with appropriate labelling:

- Control of eastern spruce budworm with a maximum application of 70 g a.i./ha applied when the insect is between the third and sixth instar. A second application of 70 g a.i./ha may be required to ensure adequate coverage.
- Control of jack pine budworm with a maximum application of 70 g a.i./ha applied when the insect is between the third and fifth instar. A second application of 70 g a.i./ha may be required to ensure adequate coverage.

Acceptable claims for control are: corrected insect population reduction was greater than or equal to 70%; residual populations did not exceed 2.5 larvae per branch; and defoliation of the treated host tree should not exceed 25% or should be less than 50% of that defoliation caused by an untreated population of similar size.

Proposed Regulatory Decision

The PMRA is recommending a “Restricted” class temporary registration for Mimic® 240 LV Forestry Insecticide. This will allow further environmental and efficacy data to be generated when the product is used under operational conditions. The use pattern will be for use in forests and woodlands to control spruce budworm and jack pine budworm. (see label in Appendix 1). Although maximum rates for both pests have been determined, further work is required to optimize application rates and volumes for operational programs.

Mitigative labelling (Environmental Precautions) is required to provide acceptable margins of safety for the identified environmental risks to aquatic invertebrates and includes the establishment of buffer zones to mitigate possible aquatic impacts. Suggested buffer zones are included in Appendix 2.

Label of Mimic® 240 LV Forestry Insecticide

MIMIC® 240 LV

FORESTRY INSECTICIDE

RESTRICTED

FOR CONTROL OF EASTERN SPRUCE BUDWORM AND JACK PINE BUDWORM
IN FORESTS AND WOODLANDS

READ LABEL BEFORE USING

CAUTION
EYE AND SKIN IRRITANT

GUARANTEE- Tebufenozide..... 240 g/L

REGISTRATION NO. PEST CONTROL PRODUCTS ACT

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS
10 L

ROHM AND HAAS CANADA INC.
2 MANSE ROAD
WEST HILL, ONTARIO
M1E 3T9
1-800-268-4201

Mimic® 240 LV forestry insecticide has a novel mode to action in that it mimics the action of the insect molting hormone, ecdysone, in larval Lepidoptera (caterpillars). Larvae stop feeding within hours of ingestion of a toxic dose of Mimic® 240 LV and soon thereafter begin to undergo an unsuccessful (lethal) molt. Actual mean time to mortality is somewhat dependent on the physiology of the target species and on the local environmental conditions, but is generally three to seven days.

Mimic® 240 LV is effective against larval Lepidoptera.

Mimic® and the flask symbol are trademarks of Rohm and Haas Company, Philadelphia, Pa., registered in Canada under which Rohm and Haas Canada Inc. has been registered as user.

NOTICE TO USER: This control product is to be used only in accordance with the directions on this label. It is an offence under the *Pest Control Products Act* to use a control product under unsafe conditions.

NATURE OF RESTRICTION: This product is to be used only in the manner authorized; contact local pesticide regulatory authorities about use permits that may be required.

RESTRICTED USES

Forestry Use: Ground/Aerial Application for sites greater than 500 ha.

Woodlands Use: Aerial Application for sites 500 ha or less.

DIRECTIONS FOR USE:

Apply Mimic® 240 LV forestry insecticide for the control of eastern spruce budworm and jack pine budworm in conifer forests and woodlots. This product may be applied by air or by ground equipment.

Eastern Spruce Budworm

Apply when the insect larvae are between the third and sixth instar (at bud flush for spruce and/or balsam fir). A second application may be required to ensure adequate coverage.

Jack Pine Budworm

Apply when the insect larvae are in the third to fifth instar (at this time the shoots or candles have elongated and the needles have started to separate). A second application may be required to ensure adequate coverage.

The recommended application rate is 290 millilitres of Mimic® 240 LV per hectare. For aerial application, use a spray volume with enough water as the carrier to provide uniform coverage. Uniform coverage of the foliage is essential to provide maximum protection from defoliation.

Before using this product, consult your local Canadian Forestry Service office or forestry authority and Rohm and Haas Canada Inc. for information on timing, method of application, and concentration of spray mixtures.

PRECAUTIONS:

KEEP OUT OF REACH OF CHILDREN

CAUTION, MAY IRRITATE EYES AND SKIN. WEAR PROTECTIVE CLOTHING (LONG TROUSERS, LONG-SLEEVED SHIRTS), IMPERVIOUS GLOVES AND SPLASH GOGGLES DURING ALL MIXING, LOADING AND APPLICATION. WEAR A CARTRIDGE RESPIRATOR DURING APPLICATION. PROTECTIVE CLOTHING SHOULD BE WASHED BEFORE RE-USE.

ENVIRONMENTAL PRECAUTIONS:

DO NOT CONTAMINATE WATER BY CLEANING OF EQUIPMENT OR DISPOSAL OF WASTES. DO NOT APPLY WHEN WEATHER CONDITIONS FAVOUR DRIFT OR RUN-OFF FROM AREAS TREATED.

DO NOT APPLY DIRECTLY TO AQUATIC SYSTEMS. THIS PRODUCT IS TOXIC TO CERTAIN AQUATIC INVERTEBRATES. TO MITIGATE IMPACT ON THESE ORGANISMS, PROVINCIAL REGULATORY AUTHORITIES SHOULD BE CONSULTED TO ESTABLISH APPROPRIATE BUFFER ZONES BETWEEN TREATMENT BLOCKS AND AQUATIC SYSTEMS.

AQUATIC SYSTEMS INCLUDE ALL RIVERS DESIGNATED AS DOUBLE-SIDED AND ALL LENTIC (STANDING) WATER BODIES, INCLUDING IMPOUNDMENTS, BEAVER PONDS AND BOG PONDS THAT APPEAR ON THE MOST RECENT 1:50,000 TOPOGRAPHIC MAP OF THE AREA TO BE TREATED, OR AS IDENTIFIED BY MORE UP-TO-DATE DATA (E.G., GIS SYSTEMS) IN THE PARTICULAR JURISDICTION AND APPROVED BY PROVINCIAL REGULATORY AUTHORITIES. LENTIC (STANDING) WATER BODIES THAT DO NOT APPEAR ON A 1:50,000 TOPOGRAPHIC MAP OF THE TREATMENT AREA, OR A MORE UP-TO-DATE DATA SYSTEM, BUT ARE VISIBLE FROM THE AIR DURING PRETREATMENT RECONNAISSANCE FLIGHTS SHOULD ALSO BE INCLUDED, WHERE POSSIBLE.

FIRST AID:

IF IN EYES: FLUSH EYES WITH LARGE AMOUNTS OF WATER FOR AT LEAST 15 MINUTES. CONSULT A PHYSICIAN IF IRRITATION PERSISTS.

IF INHALED: MOVE SUBJECT TO FRESH AIR.

IF ON SKIN: WASH AFFECTED SKIN AREAS WITH SOAP AND WATER AND CONSULT PHYSICIAN IF IRRITATION OCCURS. REMOVE CONTAMINATED CLOTHING PROMPTLY AND WASH BEFORE RE-USE.

IF SWALLOWED: DILUTE BY GIVING TWO GLASSES OF WATER TO DRINK AND CALL A PHYSICIAN OR POISON CONTROL CENTRE. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

TOXICOLOGICAL INFORMATION:

IF SWALLOWED EMESIS IS RECOMMENDED.

STORAGE:

STORE IN A COOL, DRY AREA. DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL. AVOID CONTAMINATION OF STREAMS, LAKES AND PONDS. PESTICIDE WASTES ARE TOXIC. IMPROPER DISPOSAL OF EXCESS PESTICIDE, SPRAY MIXTURE OR RINSATE IS PROHIBITED.

PESTICIDE DISPOSAL:

1. RINSE THE EMPTIED CONTAINER THOROUGHLY AND ADD THE RINSINGS TO SPRAY MIXTURE IN THE TANK.
2. FOLLOW PROVINCIAL INSTRUCTIONS FOR ANY REQUIRED ADDITIONAL CLEANING OF CONTAINER PRIOR TO ITS DISPOSAL.
3. MAKE EMPTY CONTAINER UNSUITABLE FOR FURTHER USE.

4. DISPOSE OF CONTAINER IN ACCORDANCE WITH PROVINCIAL REQUIREMENTS.
5. FOR INFORMATION ON THE DISPOSAL OF UNUSED, UNWANTED PRODUCT AND THE CLEANUP OF SPILLS CONTACT THE PROVINCIAL REGULATORY AGENCY OR THE MANUFACTURER.

SPILL AND LEAK PROCEDURES:

DIKE AND CONTAIN SPILL WITH INERT MATERIAL (E.G. SAND, EARTH). TRANSFER LIQUID TO CONTAINERS FOR RECOVERY OR DISPOSAL AND SOIL DIKING MATERIAL TO SEPARATE CONTAINERS FOR DISPOSAL. KEEP SPILLS AND RUNOFF OUT OF MUNICIPAL SEWERS AND OPEN BODIES OF WATER. DO NOT TAKE CONTAMINATED CLOTHING HOME TO BE LAUNDERED.

LIMITATION OF WARRANTY:

SELLER'S GUARANTEE SHALL BE LIMITED TO THE TERMS SET OUT ON THE LABEL AND, SUBJECT THERETO, THE BUYER ASSUMES THE RISK TO PERSONS OR PROPERTY ARISING FROM THE USE OR HANDLING OF THIS PRODUCT AND ACCEPTS THE PRODUCT ON THAT CONDITION.

Suggested buffer zones (in metres) for Mimic® 240 LV when applied aerially to forests using a C188 Agtruck with AU4000 Micronairs

The following table provides some appropriate buffer zones for Mimic® 240 LV application by air. Buffer zones assume the use of a C188 Agtruck with AU4000 Micronairs and vary with windspeed, aircraft height and block width. They were developed by Dr. Robert Mickle of the Atmospheric Environment Service of Environment Canada at Downsview, Ontario, based on the Interdepartmental Task Force on Pesticide Drift (ITFPD) data base. As more data are generated, the buffer zone numbers can be further defined and modified.

	block width (metres)					
	100	250	500	1,000	1,500	2,000
windspeed 6.1 kph aircraft height 31.6 m	buffer zone width (metres)					
one application @ 70 g a.i./ha	0	10	15	25	40	40
two successive applications @ 70 g a.i./ha	50	60	80	110	130	160
windspeed 12.6 kph aircraft height 36.7 m	buffer zone width (metres)					
one application @ 70 g a.i./ha	5	40	80	130	140	150
two successive applications @ 70 g a.i./ha	125	175	220	280	320	350

Appendix D

2001.02.22

MIMIC® 240 LV

FORESTRY INSECTICIDE

RESTRICTED

READ LABEL BEFORE USING

**FOR CONTROL OF EASTERN SPRUCE BUDWORM, JACKPINE BUDWORM,
HEMLOCK LOOPER AND WHITEMARKED TUSSOCK MOTH IN FORESTS
AND WOODLANDS.**

CAUTION
EYE AND SKIN IRRITANT

GUARANTEE: TEBUFENOZIDE 240 g/L

REGISTRATION NO. 24502 PEST CONTROL PRODUCTS ACT

KEEP OUT OF REACH OF CHILDREN

**NET CONTENTS
1,000 L**

ROHM AND HAAS CANADA INC.
2 MANSE ROAD
WEST HILL, ONTARIO
M1E 3T9
1-800-268-4201

*Mimic and the flask symbol are trademarks of Rohm and Haas Company, Philadelphia, Pa., registered in Canada under which Rohm and Haas Canada Inc. has been registered as user.

Made in USA
Product Code 74849
EPA Est. No. 39578-TX-1
15415-R5

Mimic® 240 LV forestry insecticide has a novel mode of action in that it

mimics the action of the insect molting hormone, ecdysone, in larval Lepidoptera (caterpillars). Larvae stop feeding within hours of ingestion of a toxic dose of Mimic 240 LV and soon thereafter begin to undergo an unsuccessful (lethal) molt.

Actual mean time to mortality is somewhat dependent on the physiology of the target species and on the local environmental conditions, but is generally three to seven days.

Mimic 240 LV is effective against larval lepidoptera.

NOTICE TO USER:

This control product is to be used only in accordance with the directions on this label. It is an offense under the Pest Control Products Act to use a control product under unsafe conditions.

NATURE OF RESTRICTION:

This product is to be used only in the manner authorized; contact local pesticide regulatory authorities about use permits that may be required.

RESTRICTED USES

FOREST MANAGEMENT: Ground/Aerial Application for sites greater than 500 ha.
WOODLANDS MANAGEMENT: Aerial Application for sites 500 ha or less.

DIRECTIONS FOR USE:

Apply Mimic 240 LV forestry insecticide for the control of eastern spruce budworm, jackpine budworm and hemlock looper in conifer forests and woodlots. This product may be applied by air or by ground equipment.

Eastern Spruce Budworm

Apply when the insect larvae are between the third and sixth instar (at bud flush for spruce and/or balsam fir). A second application may be required to ensure adequate coverage.

Use of Mimic 240 LV may reduce spruce budworm populations sufficiently to provide a second year of control. Population monitoring should be done to determine whether application in subsequent years is necessary.

Jack Pine Budworm

Apply when the insect larvae are in the third to fifth instar (at this time the shoots or candles have elongated and the needles have started to separate). A second application may be required to ensure adequate coverage.

Hemlock Looper

Apply when the insect larvae are in the first instar. A second application may be required to ensure adequate coverage.

Whitemarked Tussock Moth

Apply at late egg hatch when population densities are high. A second application may be applied to ensure adequate coverage. The application rate is a maximum of 290 millilitres of Mimic 240 LV per hectare. For aerial application, use a spray volume with enough water as the carrier to provide uniform coverage. Uniform coverage of the foliage is essential to provide maximum protection from defoliation.

Before using this product, consult your local Canadian Forestry Service office or forestry authority and Rohm and Haas Canada Inc. for information on timing, method of application, and concentration of spray mixtures.

NON-RESTRICTED USES

WOODLANDS MANAGEMENT: Ground application for sites 500 ha or less For use in Recreation Areas, Cottage and Urban areas, Municipal Parks, Shelter Belts, Rights-of-Way, Farm Woodlots, Christmas Tree Plantations, Tree Nurseries and Ornamental Trees.

DIRECTIONS FOR USE:

Apply Mimic 240 LV forestry insecticide for the control of eastern spruce budworm, jack pine budworm and hemlock looper by ground equipment.

Eastern Spruce Budworm

Apply when the insect larvae are between the third and sixth instar (at bud flush for spruce and/or balsam fir). A second application may be required to ensure adequate coverage.

Use of Mimic 240 LV may reduce spruce budworm populations sufficiently to provide a second year of control. Population monitoring should be done to determine whether application in subsequent years is necessary.

Jack Pine Budworm

Apply when the insect larvae are in the third to fifth instar (at this time the shoots or candles have elongated and the needles have started to separate). A second application may be required to ensure adequate coverage.

Hemlock Looper

Apply when the insect larvae are in the first instar. A second application may be required to ensure adequate coverage.

Whitemarked Tussock Moth

Apply at late egg hatch when population densities are high. A second application may be applied to ensure adequate coverage.

The application rate is a maximum of 290 millilitres of Mimic 240 LV per hectare.

Use a spray volume with enough water as the carrier to provide uniform coverage.

Uniform coverage of the foliage is essential to provide maximum protection from defoliation.

Before using this product, consult your local Canadian Forestry Service office or forestry authority and Rohm and Haas Canada Inc. for information on timing, method of application, and concentration of spray mixtures.

PRECAUTIONS:**KEEP OUT OF REACH OF CHILDREN**

Caution: May irritate eyes and skin. Wear protective clothing (long trousers, long-sleeved shirts), impervious gloves and splash goggles during all mixing, loading and application. Wear a cartridge respirator during application. Protective clothing should be washed before re-use.

ENVIRONMENTAL HAZARDS:**RESTRICTED USES:**

Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favour drift or run-off from areas treated.

Do not apply directly to aquatic systems. This product is toxic to certain aquatic invertebrates and persists in aquatic sediments. To mitigate impact on these organisms, appropriate buffer zones should be established between treatment blocks and aquatic systems.

Aquatic systems include all rivers designated as double-sided and all lentic

(standing) water bodies, including impoundments, beaver ponds and bog ponds that appear on the most recent 1:50,000 topographic map of the area to be treated, or as identified by more up-to-date data (e.g., gis systems) in the particular jurisdiction and approved by provincial regulatory authorities. Lentic (standing) water bodies that do not appear on a 1:50,000 topographic map of the treatment area, or a more up-to-date data system, but are visible from the air during pretreatment reconnaissance flights should also be included, where possible.

NON-RESTRICTED USES:

Do not apply during periods of dead calm, when winds are gusty or when wind speed is greater than 15 km/hr at 2 metres high above ground at the site of application.

For the protection of non-target habitats, overspray or drift to sensitive habitats must be avoided. A buffer zone of 5 metres is required between the downwind edge of the boom/sprayer and sensitive aquatic habitats such as sloughs, ponds, prairie potholes, lakes, rivers, and streams. Do not contaminate these habitats when cleaning and rinsing spray equipment or containers.

FIRST AID:

If in eyes: flush eyes with large amounts of water for at least 15 minutes. Consult a physician if irritation persists.

If inhaled: move subject to fresh air.

If on skin: wash affected skin areas with soap and water and consult physician if irritation occurs. Remove contaminated clothing promptly and wash before re-use.

If swallowed: dilute by giving two glasses of water to drink and call a physician or poison control centre. Never give anything by mouth to an unconscious person.

TOXICOLOGICAL INFORMATION:

If swallowed emesis is recommended.

STORAGE:

Store in a cool, dry area. Do not contaminate water, food or feed by storage or disposal. Avoid contamination of streams, lakes and ponds. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is prohibited.

PESTICIDE DISPOSAL:

1. Rinse the emptied container thoroughly and add the rinsings to spray mixture in the tank.
2. Follow provincial instructions for any required additional cleaning of container prior to its disposal.
3. Make empty container unsuitable for further use.
4. Dispose of container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product and the cleanup of spills contact the provincial regulatory agency or the manufacturer.

SPILL AND LEAK PROCEDURES:

Dike and contain spill with inert material (e.g. sand, earth). Transfer liquid to containers for recovery or disposal and soil diking material to separate containers for disposal. Keep spills and runoffs out of municipal sewers and open bodies of water. Do not take contaminated clothing home to be laundered.

NOTICE TO BUYER:

Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition.

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