



CANADIAN
WILDLIFE HEALTH
COOPERATIVE

REGULATORY CONSIDERATIONS FOR CONTROL OF WILDLIFE DISEASES

**CREATING A WORLD
THAT IS SAFE AND SUSTAINABLE
FOR WILDLIFE AND SOCIETY**



Regulatory Considerations for Control of Wildlife Diseases

Purpose of this report: To describe Canadian legislation relevant to the treatment or management of white-nose syndrome (WNS); equipping biologists and wildlife managers with knowledge to begin planning interventions in the wild.

Background: This report provides an overview of the primary Canadian acts and regulations that can apply when treating bats against WNS or their hibernation environment against *Pseudogymnoascus destructans*. We describe the major regulatory authorities and pathways, using British Columbia, Manitoba, and Ontario to explore provincial issues. This document is not a comprehensive manual to navigating such regulatory pathways but illustrates the complexity of the regulatory environment.

Several federal, territorial, and provincial acts and regulations affect the planning and implementation of wildlife diseases interventions. This legislation aims to protect the treated species, the environment, and human health from direct and indirect adverse effects of the intervention. The main federal agencies administering acts covering wildlife treatment are Environment and Climate Change Canada, the Canadian Food Inspection Agency, and Health Canada. Each province and territory has their own acts, regulations, and permitting processes that apply when catching, researching, treating, and/or releasing wildlife. These are usually administered by Ministries of Environment or Natural Resources or their equivalents. Provincial endangered species legislation can also apply. The regulations and agencies administering these acts vary by province.

Key Findings: The specific acts and regulations that apply depend on the nature of the intervention, the listing status of the species involved, and the land management jurisdiction. A single intervention type can be regulated under multiple laws and by multiple agencies. There is no set process, single entry point, or single contact to guide one through the process of understanding the regulatory pathways, identifying the regulatory agencies involved, or acquiring permits. Decisions on regulatory oversight, authority and permits are made on a case-by-case basis. There is a communication gap between regulatory agencies with inconsistency in the perspective across jurisdictions and agencies.

Recommendations: Researchers planning WNS interventions are best served by starting with two points of contact – one federal and one provincial/territorial – to discuss the proposed treatment product/strategy, method of administration or mitigation approach, target species, and location of application to identify and navigate the appropriate regulatory pathways. Information on the nature of the proposed treatment, possible safety requirements and approval timelines should be part of the discussion. The extent to which federal laws apply on provincial and territorial lands, and when these take precedence over



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provincial laws, needs to be better understood and communicated to ensure an efficient response time to management of emerging wildlife diseases. Improved cross-agency communications and a streamlined process for response approvals will be needed to allow rapid response to emerging wildlife disease problems.



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Bat White-nose Syndrome Treatment Regulations Overview



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Disclaimer:

This report is intended to provide a preliminary overview of the considerations that may be applicable to a white-nose syndrome therapeutic or experimental intervention and contains a summary of possible regulations and policies that may apply to these circumstances. Significant effort was made to be as comprehensive and thorough as possible, including expert and regulatory consultations. This report is not intended as an exhaustive overview of the Canadian legal framework as it applies to wildlife health and disease interventions and should not be relied for those purposes.



List of abbreviations

BC: British Columbia

CCVB: Canadian Centre for Veterinary Biologics

CEPA: Canadian Environmental Protection Act

CFIA: Canadian Food Inspection Agency

Class EA-PPCR: Class Environmental Assessment for Provincial Parks and Conservation Reserves (ON)

Class EA-RSFD: Class Environmental Assessment for MNRF Resource Stewardship and Facility Development Projects (ON)

CWHC: Canadian Wildlife Health Cooperative

EAU: Environmental Assessment Unit

ECCC: Environment and Climate Change Canada

ESC: Experimental Study Certificate

FLNRO: Ministry of Forests, Lands and Natural Resource Operations (BC)

FPT: Federal/ Provincial/ Territorial

HC: Health Canada

MB: Manitoba

MECC: Ministry of the Environment and Climate Change (ON)

MNRF: Ministry of Natural Resources and Forestry (ON)

MOE: Ministry of Environment (BC)

NSNRCP: New Substances Notification Regulations (Chemicals and Polymers) (ON)

NSNRO: New Substances Notification Regulations (Organisms) (ON)

ON: Ontario

PCA: Parks Canada Agency

Pd: *Pseudogymnoascus destructans*

SARA: Species at Risk Act

VBO: Veterinary Biologics Operations

VDD: Veterinary Drugs Directorate

WACC: Wildlife Animal Care Committee (ON)

WNS: white-nose syndrome

WPP: Wildlife Program Plan

WSCA: Wildlife Scientific Collectors Authorization (ON)



1. Introduction

The objective of this review is to provide an overview of the Canadian regulatory framework as it applies to the treatment of animals or the environment for the purposes of controlling the spread of *Pseudogymnoascus destructans* (Pd) or treatment or prevention of white-nose syndrome (WNS).

Background on WNS: Since first identified in New York in 2006, the fungus Pd, the etiology of WNS, spread across eastern North America (Blehert et al 2009), causing death in over 6.7 million hibernating bats (Turner et al 2011; US Fish and Wildlife Service 2012). By 2016, the fungus had spread to Ontario, Quebec, New Brunswick, Nova Scotia, and Prince Edward Island and 30 American states. Despite North American disease management efforts, the geographic area affected by Pd expands approximately 200-250 km each year primarily through bats transmitting it to their conspecifics (COSEWIC 2013; Lorch 2016).

Four bat species have been confirmed with WNS in Canada: little brown myotis (*Myotis lucifugus*), northern myotis (*M. septentrionalis*), tri-colored bat (*Perimyotis subflavus*), and big brown bat (*Eptesicus fuscus*). Due in part to the effects of WNS, little brown myotis, northern myotis, and tri-colored bat were assessed as endangered by the Committee on the Status of Endangered Wildlife in Canada in November 2013 and emergency listed under the Species At Risk Act (SARA) in December 2014 by the Canadian Federal Government (Canadian Wildlife Service 2014; Species at Risk Public Registry 2016).

Many researchers are investigating treatment options for WNS, including gene silencing (Lindner 2016), ultraviolet exposure (Palmer et al. 2016), and the use of chitosan (Vonhof et al. 2016), mycoviruses (Roossinck 2015), and bacteria (Cornelison et al. 2014; Cheng et al. 2016). Practical limitations in applying treatments to free ranging bats, risks of introducing foreign substances and unnatural species or concentrations of microbes into the environment, and regulatory considerations must be assessed before contemplating the application of a given treatment in a field setting. **Wildlife managers or researchers hoping to mitigate the effects of WNS by treating the environment or bats will need to comply with the existing applicable Canadian federal and provincial acts, policies and regulations as they relate to approval of methodologies, initiation of field trials or application of candidate treatments.**

Purpose of this report: to provide an outline of likely regulatory expectations for WNS treatments. This document summarizes acts, regulations, and policies that may apply to a WNS experimental or therapeutic intervention. The review includes applicable federal acts and regulations as well as similar provincial acts and regulations for British Columbia (BC), Manitoba (MB), and Ontario (ON) as case examples for the provincial and territorial jurisdictions. The rationale for selecting these provinces was to include a province with endemic WNS (i.e. ON) as well as two provinces acting to prevent the introduction or emergence of WNS (i.e. BC and MB).

2. Approach to identifying legislation

Federal regulations and acts were identified by searching the websites of Environment and Climate Change Canada (ECCC), the Canadian Food Inspection Agency (CFIA), Parks Canada Agency (PCA), the Veterinary Drugs Directorate (VDD), the Canadian Centre for Veterinary Biologics (CCVB), and the Veterinary Biologics



Operations (VBO). Regulatory experts were identified by consultation with staff of the relevant federal agencies, and they helped to discover and interpret the applicable regulations. Provincial regulations for BC, MB, and ON were found by searching the websites of the provincial governments or ministries of Natural Resources or equivalent. Provincial policy experts were identified through consultation with contacts already in the Canadian Wildlife Health Cooperative (CWHC) bat health network. These experts were subsequently asked to identify any additional provincial acts and/or regulations that might apply to the treatment of bats for WNS or hibernacula for Pd.

3. Results

Regulatory responsibility is assigned based on whether the intervention will be done on lands under federal or provincial jurisdiction so this is the first question that must be addressed for any new treatment application. After jurisdiction is determined, the second consideration involves the type of treatment that will be applied. Currently, there are three types of treatment being investigated in bats with WNS and in hibernacula for environmental control of Pd, and these are:

1. Control or eradication of Pd in the environment.
2. Prevention of WNS in bats using an immunologic mechanism.
3. Treatment of WNS in bats using a chemotherapeutic mechanism.

Recommendations are in place to help reduce the risk of human-assisted spread of Pd, but this does not prevent bat-assisted spread of Pd and recommendations are not equivalent to regulations. Eradication is unlikely at a larger scale, considering the rate of Pd expansion as well as WNS emergence, but may be sought after for a specific habitat (e.g. a cave).

3.1 Federal Acts and Regulations

Overview: Federal acts and regulations apply to federal, provincial, territorial, private and First Nations lands and, in some circumstances, take precedence over any provincial regulations or municipal by-laws.

Figure 1 summarizes relevant federal acts and their respective legal authorities. The three primary federal governmental departments and agencies involved are ECCC, Health Canada (HC), and the CFIA. ECCC and HC have a joint committee which administers the Canadian Environmental Protection Act (CEPA) under the New Substances Program, which applies when proposing to treat the environment for Pd (e.g. a hibernaculum).

Vaccines and drugs: Any chemotherapeutic product, whether applied directly to an animal or its environment, with the intention to treat a bat for WNS is regulated as a veterinary drug. HC administers the Food and Drugs Act under the VDD, which applies to the approach of using chemotherapeutic agents (e.g., antimicrobials or immune-stimulants) to treat bats for WNS. Other products, whether applied directly to an animal or its environment, with the intention to immunize a bat for WNS are regulated as biological compounds. CFIA administers the Health of Animals Act under the CCVB and the VBO, which applies when the treatment approach involves a biological compound operating through an immunological mechanism

¹Control involves reducing the frequency of occurrence of the disease within an individual or a population to an acceptable or tolerable level. This also includes containing the disease to prevent further spread. Eradication involves the complete elimination of the etiological agent from the environment and disease in all individuals and populations. Prevention of the introduction of Pd is only applicable in areas where the fungus currently is not endemic.



(e.g., vaccination of bats).

Targeting Pd in the environment: A treatment that controls or kills the fungus in a hibernaculum environment without an immunologic response from bats or a chemotherapeutic effect in bats would not be a veterinary drug nor biologic but instead be considered as a “substance” regulated under CEPA by ECCC. Note: the Pest Control Products Act does not apply when treating against Pd as this act only applies to Animalian ectoparasites, not pathogenic fungi.

Risk Assessment: Depending on the type of product proposed for treatment, the VDD, CCVB, or CEPA committee may require that an environmental risk assessment is conducted by the Environmental Assessment Unit (EAU) of Health Canada before approving a new product or an Experimental Study Certificate for bats. Prior to initiating a study, researchers should contact the EAU to learn about specific activities that would require this type of assessment. Similarly, based on the product, other relevant departments and agencies may be consulted by the VDD, CCVB, or CEPA committee as necessary. Examples of environmental assessments for this purpose, including that of Rabies Vaccine, Live Adenovirus Vector (AdRG1.3) baits, can be found at: <http://www.inspection.gc.ca/animals/veterinary-biologics/licensed-products/environmental-assessments/eng/1318464704520/1320704752007>.

An environmental assessment would have to be conducted to prove the safety and efficaciousness of any product before it is approved for widespread administration. The investigator must be sufficiently qualified to conduct the study before an Experimental Study Certificate (ESC) is granted through an application process (see under section 3.1.3.). After the ESC has been approved, records are required to document the amount of the product used and the results of the study, including any adverse effects in the treated animals or environment. The investigator is not allowed to sell any left-over compound.

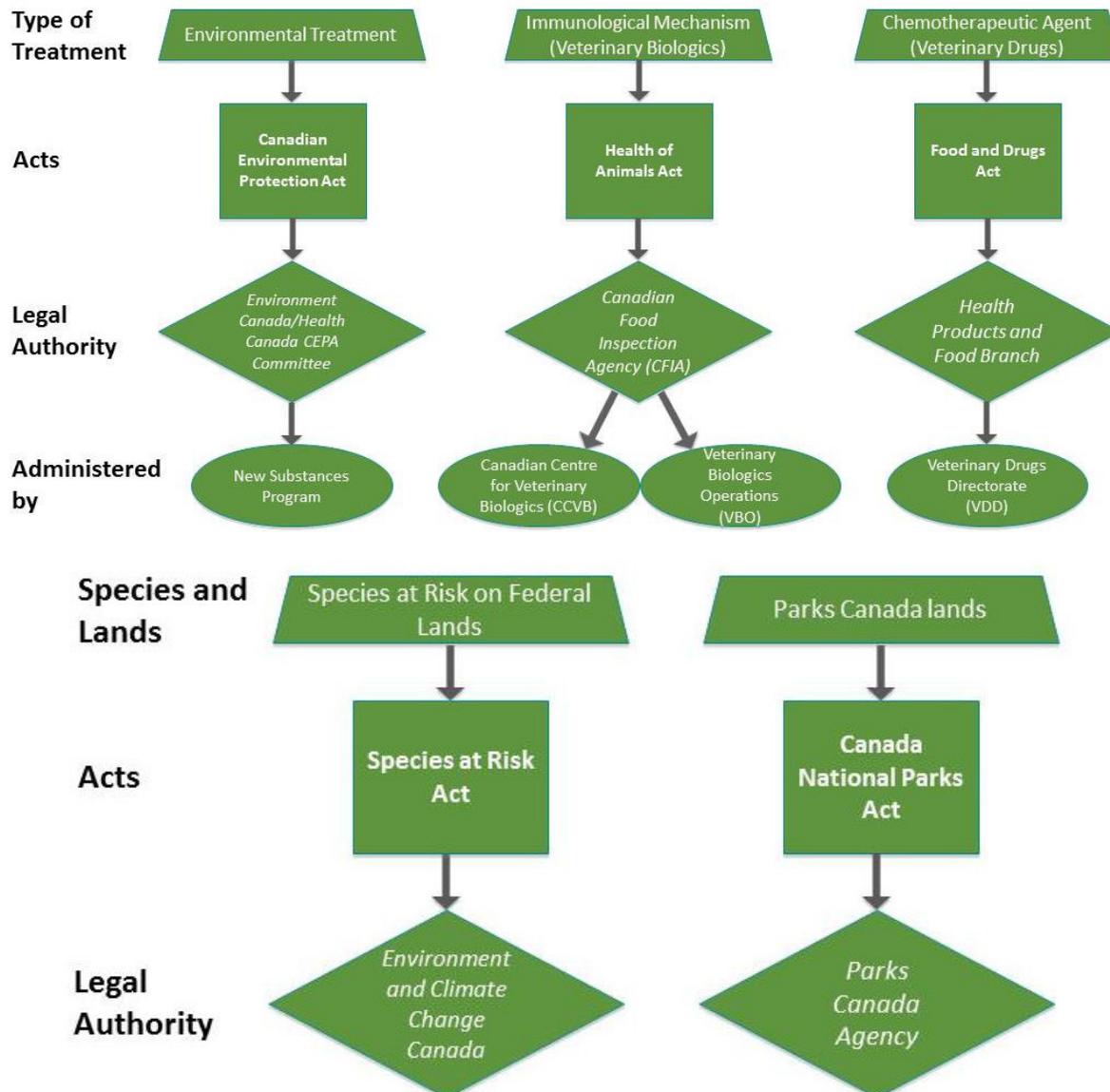


Figure 1: Summary of Canadian federal regulatory acts, including federal authorities and regulatory agencies involved when administering different types of compounds to treat bats for WNS or the environment to control/eradicate Pd. The Species at Risk Act and the Canada National Parks Act can apply in addition to the acts listed above.

3.1.1 The Canadian Environmental Protection Act and Regulations

The Canadian Environmental Protection Act, 1999 (CEPA 1999) was enacted to help prevent pollution and protect the environment and human health and provides the federal government the authority to address pollution issues. The Act takes a preventative approach by requiring that substances be identified and assessed to determine whether they are “toxic” or capable of becoming toxic. CEPA defines toxic substances as those that enter or may enter the environment at levels or conditions that:



- have or may have a harmful effect on the environment;
- are or could be dangerous to the environment that life depends on; or
- are or could be dangerous to human life or health.

The New Substances Notification Regulations (Organisms) (NSNRO, 2017) and the New Substances Notification Regulations (Chemicals and Polymers) (NSNRCP, 2015) are the most applicable to treatment of the environment to control/ eradicate Pd. If a proposed environmental treatment involves a biological control with micro-organisms, a chemical or a polymer, it must undergo a process to determine whether it is subject to NSNRO or NSNRCP. A further outline of how polymers, chemicals and/or micro-organisms are managed under CEPA 1999 can be found in the Chemical Management Plan (see Appendix I for web links). ECC's 'New Substances' website provides information on how new substances and new micro-organisms are assessed and managed.

3.1.2 Health of Animals Act and Regulations

CFIA has legal authority over the Health of Animals Act and Regulations which are intended to protect animals and animal health by controlling diseases and toxic substances that may affect animals or that may be transmitted by animals to people. The CCVB and VBO review veterinary biologics that generate an immune response in animals which include animal health products such as vaccines, antibody products, and in vitro diagnostic test kits that are used for the prevention, treatment, or diagnosis of infectious diseases in animals. The Health of Animals Act defines a veterinary biologic as follows:

- “(a) a helminth, protozoa or micro-organism,
(b) a substance or mixture of substances derived from animals, helminths, protozoa or micro-organisms,
(c) a substance of synthetic origin that is manufactured, sold or represented for use in restoring, correcting or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in animals.”

New veterinary biologics must be shown to be pure, potent, safe, and effective when used in the target species. An experimental veterinary biologic must first be evaluated in containment studies in target animals and found to be safe and efficacious. An environmental assessment must be completed by CCVB and VBO before the release of new veterinary biologics for small scale, controlled studies in the field situation. The data collected from containment and field studies will be considered prior to final approval. Once approved, depending on the type of product, special conditions and restrictions may be imposed on the sale, distribution, release and non-commercial application of a new veterinary biologic. Evaluation of licensing applications is done by CCVB and VBO and is typically completed within 120 days. These Regulations have most often been applied to domestic species as currently the only wildlife vaccine routinely used in Canada is for rabies. See Appendix I for web links.

3.1.3 Food and Drugs Act and Regulations

The Food and Drugs Act and Regulations help protect the health and safety of Canadians with respect to the use and sale of drug products and food. Treatment methods involving chemotherapeutic agents are considered as a veterinary drug and are thus subject to the Food and Drug Act. HC's VDD is responsible



for applying the Food and Drugs Act and Regulations to veterinary drugs. Veterinary drug includes any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in animals, or;
- (b) restoring, correcting, or modifying organic functions in animals

Before a new drug can be authorized for qualified researchers to use for the purpose of conducting clinical evaluations, an ESC issued by VDD is required. The ESC allows researchers to experimentally apply treatments to wildlife populations. Adequate evidence needs to be provided about the safe and effective use of the drug in the target animal to be treated. An ESC will only be issued after the submission of a detailed experimental protocol providing evidence of safe and efficacious application.

Reviews for approval of an ESC typically take about 67 days, with an additional 15 days in the case of a minor information request to the applicant. The minimum review time for approval of a new veterinary drug for any use (experimental use, widespread use, and sale) is 345 days. However, the average review time for approval is 485 days and this process can stretch as long as 750 days if there are problems and delays in any of the steps of the review process. See Appendix I for web links.

Pd inhibiting micro-organisms used for the purposes of a direct treatment (e.g. a probiotic to enhance or change normal micro flora) and not to elicit an immune response are defined as a veterinary drug in the Food and Drugs Act. However, as an autologous biological therapy, they would not be subject to pre-market review by VDD. While there are no specific requirements for post-market use, the VDD would be interested to know the results of this therapy and if there is any adverse effect, including lack of efficacy.

3.1.4 Species at Risk Act and Regulations

SARA's purposes are to prevent wildlife species in Canada from disappearing, to provide recovery of extirpated, threatened, and endangered species, and to manage species of special concern to prevent further population declines. SARA prohibitions currently apply to the endangered little brown myotis, northern myotis, and tri-colored bat, the threatened pallid bat (*Antrozous pallidus*) and special concern spotted bat (*Euderma maculatum*). Bats are not considered federal species; thus, under SARA the need to follow the permitting regulation is only required when undertaking an activity affecting a listed bat species, such as those identified above, and any part of their critical habitat or the residences of individuals residing on federal lands. Federal lands include, but are not limited to, national parks and national historic sites managed by Parks Canada Agency, First Nations reserve land managed by Indigenous and Northern Affairs Canada, and National Defense installations managed by the Department of National Defence. Once a species is federally listed under SARA, in many cases provincial and territorial wildlife authorities will offer a similar degree of protection on lands for which they have authority. A link to a comprehensive list of provincial listing status for all bat species can be found in Appendix I.

Certain activities can be permitted under SARA. Activities benefiting the species or those activities required to enhance its chance of survival in the wild, such as the application of a proven safe treatment against WNS, may be considered as permissible. Scientific research relating to the conservation of the species



(conducted by qualified persons) can be permitted under SARA when three conditions are met:

1. all reasonable alternatives to the activity that would reduce the impact on the species have been considered and the best solution has been adopted;
2. all feasible measures will be taken to minimize the impact of the activity on the species or its critical habitat or the residences of its individuals; and
3. the activity will not jeopardize the survival or recovery of the species.

The proposed SARA recovery strategy for bat species was posted on the Species at Risk Public Registry in December 2015 (final version expected in 2017). Additional conditions may apply regarding experimental treatment of bats or their environment on federal lands. See Appendix I for web links.

3.1.5 Canada National Parks Act and Regulations

The minister responsible for Parks Canada Agency (PCA) has responsibility and authority through the Canada National Parks Act for managing wildlife and activities located within National Park boundaries. This act applies, in addition to other federal acts listed above, if treatment is considered for bats or in their habitat on lands managed by PCA. PCA lands include national parks, national historic sites, and national marine conservation areas. The 'Guiding Principles and Operational Policies' (see Appendix I for web links) include references that would apply to the activities of WNS treatment and Pd mitigation or control/eradication. For example, in Part II – Activity Policies: National Parks Policy in Section 3 'Protecting and Managing Park Ecosystems', Subsection 3.1 'Ecosystem Protection' it is stated:

"3.2.5 Where manipulation is necessary it will be based on scientific research, use techniques that duplicate natural processes as closely as possible, and be carefully monitored."

And Subsection 3.2 "Ecosystem Based Management" it is stated:

"3.2.11 All practical efforts will be made to prevent the introduction of exotic plants and animals into national parks, and to eliminate or contain them where they already exist."

Conducting research or collecting animals from lands managed by PCA requires a Research and Collection Permit issued by the Park superintendent. See Appendix I for web links.

3.2 Select Provincial Acts, Regulations and Policies

Each Canadian province or territory has its own acts, regulations, and permitting processes that apply when catching, researching, treating, and/or releasing wildlife; and for protecting endangered species. The sections below provide an outline of the applicable regulations for British Columbia (BC) and Manitoba (MB) which are in Pd and WNS non-endemic regions and Ontario (ON) which is in a Pd and WNS endemic region. Figure 2 illustrates the Provincial regulatory authorities and applicable acts.

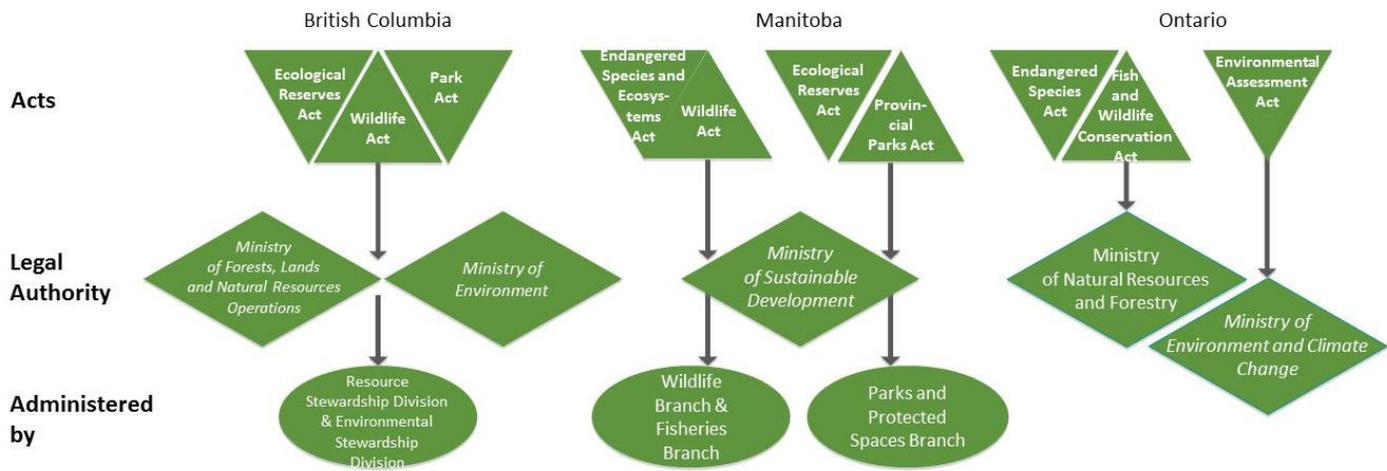


Figure 2: Provincial regulatory authorities and applicable acts for Manitoba, British Columbia, and Ontario.

The relevant acts and regulations differ not only between the three provinces selected for review but also with other provinces and territories. For example:

- 1) Newfoundland and Labrador is similar to MB from a wildlife perspective, but depending on the treatment, an environmental assessment may be required;
- 2) In Alberta, little brown myotis is not listed under the provincial wildlife act;
- 3) Quebec's process is similar to that of ON, however, no bat species is listed under their provincial species at risk legislation; and
- 4) In contrast to ON, BC's and MB's Environmental Assessment Acts review projects based on areas of industrial or commercial development and do not apply to wildlife treatment.

These differences highlight why it would be essential to contact the provincial or territorial wildlife agency in your jurisdiction early in the planning stages of any WNS or Pd environmental treatment or management action to learn what acts and regulations apply and what permits are required. See Appendix I for web links to BC, MA, and ON specific acts and permitting.

3.2.1 British Columbia

BC Wildlife Act and Wildlife Amendment Act

BC's provincial government is responsible for managing wildlife across the province through the Wildlife Program Plan (WPP). The Ministry of Forests, Lands and Natural Resource Operations (FLNRO) is responsible for the Wildlife Act and the Wildlife Amendment Act, which guide the Wildlife Program Plan. Enforcement activities are under the Conservation Officer Service of the Ministry of Environment (MOE). The FLNRO (Resource Stewardship Division) and MOE (Environmental Stewardship Division) share overall responsibility for delivery of the WPP. The Wildlife Act and Wildlife Amendment Act apply when treating bats directly, but environmental intervention activities could also be subject to prohibitions under these acts to avoid causing harm to other wildlife.



A permit is required for the capture, harassment, transportation, captive management, and release of bats. A permit application for treating bats against WNS, in accordance with the WPP, can be made at <http://www.frontcounterbc.gov.bc.ca/>. The provincial veterinarian is responsible for review of animal care during the review process for permits under the WPP.

BC Park Act

Any activities conducted on lands classified as a Provincial Park are subject to the Park Act, in addition to other provincial acts listed. A resource use permit must be issued by the Minister of Environment to gain authorization to use or disturb any natural resource in a Park. Information on Parks use permit application can be found at: <http://www.frontcounterbc.gov.bc.ca/guides/parks/research/overview/>

The Park, Conservancy and Recreation Area Regulation under the BC Park Act addresses management and protection of park resources and applies to ecological reserves as if they were parks under the BC Park Act. To conduct any research in an ecological reserve, a Parks use permit must be issued by the Minister.

Other Acts that may apply

BC's Environmental Management Act can provide authority to introduce wastes into the environment (e.g., to control/eradicate Pd in the environment) but generally regulates industrial and municipal waste discharge, pollution, and hazardous wastes. The Minister of Environment should be informed if a treatment has, or potentially has, a detrimental environmental impact. If a new, innovative treatment with a pesticide is used, there are options to have pest management specialists provide comments under the Integrated Pest Management Act.

3.2.2 Manitoba

The Wildlife Branch and Fisheries Branch have responsibility under the Ministry of Sustainable Development for the application of the provincial Wildlife Act and Endangered Species and Ecosystems Act. The Parks and Protected Spaces Branch has responsibility for the application of the provincial Ecological Reserves Act and the Provincial Parks Act.

MB Wildlife Act

Schedule A of The Wildlife Act categorizes regulated wildlife into one of six divisions. Although bats are not listed in Schedule A, they are designated as protected species and are declared to be wild animals by the Designation of Wild Animals Regulation.

If wildlife is found to have a disease, the Minister may allow treatment that is reasonable under the circumstances (article 71(4)). Permits are required to trap and (experimentally) treat wildlife (i.e. wild animal capture permit, field trial permit). Permit application forms can be found on the website of the Wildlife Branch: <http://www.gov.mb.ca/sd/wildlife/legislation/applying.html>.

MB Endangered Species and Ecosystems Act

Both Little brown myotis and Northern myotis are provincially listed as endangered species under this Act. Permits to kill, take, collect or capture and hold alive a listed species may only be issued for scientific purposes or for purposes related to the protection, management, or reintroduction of the species (section 11(1)).



MB Ecological Reserves Act

Any activities conducted on lands classified as an Ecological Reserve are subject to the Ecological Reserves Act and permission must be obtained from the Minister of Sustainable Development to enter the reserve and carry out any activity.

MB Provincial Parks Act

The Minister of Sustainable Development makes regulations respecting the protection of flora and fauna and the taking of specimens for scientific propagation purposes (section 33(e)) in provincial parks. As such, permission must be obtained before treating bats for WNS or the environment to control or eradicate Pd on any land designated as a provincial park.

3.2.3 Ontario

The Ministry of Natural Resources and Forestry (MNRF) is responsible for the Fish and Wildlife Conservation Act and Endangered Species Act. The Ministry for Environment and Climate Change (MECC) is responsible for the Environmental Assessment Act. These ministries issue would be responsible for permits for WNS treatment in bats or control/eradication of Pd in the environment.

ON Fish and Wildlife Conservation Act

If the activity is not conducted by MNRF or a partner, then a Wildlife Scientific Collectors Authorization (WSCA) needs to be issued under the Fish and Wildlife Conservation Act to allow the activity to proceed. An animal care protocol approved by the MNRF Wildlife Animal Care Committee (WACC) is required prior to the issuing of a WSCA under the Fish and Wildlife Conservation Act. This is a requirement for any project involving the trapping, handling, etc. of the bats and/or the treatment of bats for WNS which includes documentation of product safety prior to the application of said treatment. The capture and testing of some of the treated bats post treatment for potential adverse effects caused by treatment protocols should be included as follow-up procedures. The WSCA is issued by **MNRF district office** staff in the district where the treatment is to be applied. Any proposals involving species at risk in Ontario need to be reviewed by WACC even if the proposal has already been reviewed by another institutional animal care committee.

ON Environmental Assessment Act

If an activity may cause potentially significant net negative environmental effects and/or significant public or agency concern, the activity can be screened under the Class Environmental Assessments and be subjected to further evaluation. Government project proposals are screened for possible significant environmental impacts using a standard review process. If a project is deemed to have the potential for significant impacts, it must be posted to the Environmental Registry for a period of public consultation. Subsequent review of comments determines whether the further environmental assessment screening is required.

If the proposed activity is considered as research defined under Section 11 of Ontario Regulation 334 of the Environmental Assessment Act and is undertaken by MNRF or a partner on behalf of MNRF, the activity is not subject to the Environmental Assessment Act. This activity is considered exempt from environmental assessment approval process under Part II of the Act. Until a treatment of bats for WNS or the environment to control/eradicate Pd has been field tested, it would likely be considered experimental.



Therefore, this activity would be categorized as research.

If the activity is proposed within a Provincial Park or a Conservation Reserve, then the Class Environmental Assessment for Provincial Parks and Conservation Reserves (Class EA-PPCR) applies. A Written Research Authorization is required from the appropriate Zone Manager of Ontario Parks (or conservation reserves manager) even if the work is being conducted by MNRF staff. Conducting authorized research is pre-categorized under the Class EA-PPCR as a Category A activity and may proceed without further environmental assessment evaluation.

ON Endangered Species Act

Bat species listed as endangered under the Endangered Species Act in Ontario include: Eastern small-footed myotis, little brown myotis, northern myotis and tri-colored bat. Activities undertaken to help a species protected under Ontario's Endangered Species Act require a protection or recovery authorization (per O. Reg. 242/08 s. 23 (17)). Streamlined approvals are available on the Ontario government website if certain rules in the regulation are followed. The rules include registering, minimizing effects, creating a mitigation plan, reporting sightings, monitoring the work and submitting a final report to the Natural Heritage and Information Centre. Obtaining the authorization can be done on-line at the following website: <https://www.ontario.ca/page/help-protect-or-recover-species-risk>

The streamlined approvals could not be used for the activity if the species at risk are going to be killed. If that is a requirement of the treatment research protocol, the MNRF district office would need to be contacted to obtain a protection or recovery permit.

4. Summary

The following steps may have to be taken to comply with federal and provincial/territorial acts and regulations to implement interventions to prevent, control or eliminate WNS:

- 1) Prepare detailed information on safe and efficacious application of the proposed compound for experimental field trials.
- 2) Submit a licensing application for a new substance with the CEPA committee, a new veterinary biologic with the CCVB, or a new veterinary drug with the VDD.
- 3) If the treatment involves a listed species at risk, apply for permits authorizing an activity affecting listed wildlife species under SARA and Provincial Endangered Species Acts and apply for additional appropriate permits as required by the provincial or territorial agencies.
- 4) Depending on who conducts the treatment, the organization or agency involved, the bat species to be treated, and the land ownership of the site where the treatment is applied, several permits or permissions may be required including, but not limited to, wildlife acts, environmental assessment acts, fish and wildlife conservation acts, endangered species acts, ecological reserves acts, and provincial park acts.
- 5) Animal care protocols may have to be approved by the animal care committee of the government agency(ies) with jurisdiction.

²Assuming the interventions have sufficient experimental evidence to demonstrate safety and efficacy prior to field implementation.



A single treatment can be regulated under multiple laws and by multiple agencies. Contact your federal and provincial/territorial agencies early on in the planning phase of your treatment project.

While research is being conducted on the efficacy of many different compounds for treating WNS in bats or controlling/eradicating Pd in their hibernation environment, at this time it is not clear if or when an efficacious treatment protocol will be identified. This review has not considered other feasibility or cost:benefits of implementing WNS interventions.

5. Acknowledgements

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Appendix I: Additional web links

All links confirmed on June 21, 2017

Canadian Environmental Protection Act and related links

CEPA: <https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=26A03BFA-1>

Framework for Science-Based Risk Assessment of Micro-Organisms Regulated under CEPA: <http://www.ec.gc.ca/subsnouvelles-news subs/default.asp?lang=En&n=120842D5-1>

Chemical Management Plan: <http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>

Health of Animals Act and related links

Health of Animals Act: <http://laws-lois.justice.gc.ca/eng/acts/H-3.3/>

Health of Animals Regulations: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._296/index.html

Veterinary biologics: <http://www.inspection.gc.ca/animals/veterinary-biologics/eng/1299159403979/1320545281259>

Veterinary Biologics forms: <http://www.inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/eng/1299160285341/1320704254070>

Food and Drugs Act and related links

Food and drugs Act and Regulations: <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/canada-food-drugs.html>

Veterinary drugs directorate: <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/veterinary-drugs-directorate.html>

The approval process for new veterinary drugs: <http://www.hc-sc.gc.ca/dhp-mps/vet/applic-demande/proces/approval-approbation-eng.php>

Guidance For Industry Management of Regulatory Submission: <https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/legislation-guidelines/guidance-documents/management-regulatory-submissions-guidance-industry-health-canada-2009-2.html>

Experimental Study Certificate: <https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/applications-submissions/forms/cover-page-application-experimental-studies-certificate-veterinary-drug.html>

Species at Risk Act and related links

Species at Risk Act: <https://www.ec.gc.ca/alef-ewe/default.asp?lang=en&n=ED2FFC37-1>

SARA permits and agreements: http://www.registrelep-sararegistry.gc.ca/sar/permit/permits_e.cfm

Recovery Strategy for Little Brown Myotis (*Myotis lucifugus*), Northern Myotis (*Myotis septentrionalis*), and Tri-colored Bat (*Perimyotis subflavus*) in Canada: http://www.registrelep-sararegistry.gc.ca/document/default_e.cfm?documentID=2475

Aboriginal Affairs and Northern Development Canada: <https://www.aadnc-aandc.gc.ca/>

North American bats table of WNS and protection status [October 2016]: <https://www.whitenosesyndrome.org/resource/north-american-bats-table-wns-and-protection-status-october-2016-excel>

[whitenosesyndrome.org/resource/north-american-bats-table-wns-and-protection-status-october-2016-excel](https://www.whitenosesyndrome.org/resource/north-american-bats-table-wns-and-protection-status-october-2016-excel)



Canada National Parks Act and related links

Canada National Parks Act: <http://laws-lois.justice.gc.ca/eng/acts/n-14.01/>

Parks Canada Guiding Principles and Operational Policies: <http://www.pc.gc.ca/en/docs/pc/poli/princip/sec2/part2a>

Research and Collection Permit System: http://www.pc.gc.ca/apps/RPS/page1_e.asp

Bats and Parks Canada: <http://www.pc.gc.ca/en/nature/eep-sar/chauve-souris-bats>

British Columbia Acts and related links

Wildlife Act: http://www.bclaws.ca/Recon/document/ID/freeside/00_96488_01

Park Act: http://www.bclaws.ca/civix/document/id/complete/statreg/96344_01

Parks, Conservancy and Recreation Area Regulation: [http://www.bclaws.ca/civix/document/LOC/complete/statreg/--%20P%20--/03_Park%20Act%20\[RSBC%201996\]%20c.%20344/05_Regulations/13_Park,%20Conservancy%20and%20Recreation%20Area%20Regulation%20-%20180_90/180_90_01.xml](http://www.bclaws.ca/civix/document/LOC/complete/statreg/--%20P%20--/03_Park%20Act%20[RSBC%201996]%20c.%20344/05_Regulations/13_Park,%20Conservancy%20and%20Recreation%20Area%20Regulation%20-%20180_90/180_90_01.xml)

Ecological Reserves Act: http://www.bclaws.ca/civix/document/id/complete/statreg/96103_01

Wildlife Program Plan: <http://www.env.gov.bc.ca/fw/docs/WildlifeProgramPlan.pdf>

Manitoba Acts and related links

The Wildlife Act: http://web2.gov.mb.ca/laws/statutes/ccsm/_pdf.php?cap=w130

The Endangered Species and Ecosystems Act: <http://web2.gov.mb.ca/laws/statutes/ccsm/e111e.php>

Ecological Reserves Act: <http://web2.gov.mb.ca/laws/statutes/ccsm/e005e.php>

Provincial Parks Act: <http://web2.gov.mb.ca/laws/statutes/ccsm/p020e.php>

Ontario Acts and related links

Environmental Assessment Act: <https://www.ontario.ca/laws/statute/90e18>

Class EA for MNRF Resource Stewardship and Facility Development Projects: <https://www.ontario.ca/page/class-ea-resource-stewardship-and-facility-development-projects>

Class EA for Provincial Parks and Conservation Reserves: <https://www.ontario.ca/page/class-ea-provincial-parks-and-conservation-reserves>

Endangered Species Act: <https://www.ontario.ca/laws/statute/07e06>

Wildlife Scientific Collector's Authorization: <http://www.monarchteacher.ca/dotAsset/136845.pdf>



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