



Audit of the Management of Non- Enteric Zoonotic Infectious Disease Activities at the Public Health Agency of Canada

Final Report

October 2016



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Executive summary

The focus of the audit was on the day-to-day management of non-enteric zoonotic infectious diseases activities at the Public Health Agency of Canada (PHAC). Non-enteric zoonotic diseases and infections are transmitted between animals and humans and may be a bacterium, a virus, a fungus or other communicable disease agent. Examples include avian influenza, the hantavirus pulmonary syndrome and rabies, as well as diseases transmitted by vectors such as ticks and mosquitoes, including Lyme disease and the West Nile virus.

The Infectious Disease Prevention and Control Branch (IDPCB) has the overall responsibility for assessing the risk and reducing the impact of zoonotic infectious diseases. The Branch does this through the Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (Centre) and the National Microbiology Laboratory (NML).

The IDPCB also manages Canada's national and international response to zoonotic infectious disease outbreaks. During the two years spanning the audit, PHAC was active in managing the international response to the Ebola outbreak in Africa, in continuing to surveil and assess the incidence of the West Nile virus and Lyme disease and in communicating information to Canadians on how to protect themselves from these diseases. More recently, staff at PHAC has been active in detecting, preventing and controlling new public health threats such as the chikungunya and Zika viruses.

The objective of the audit was to assess the effectiveness of the management control framework as it relates to governance, risk management and internal controls for PHAC's non-enteric zoonotic infectious disease activities. The audit did not examine the Centre for Emergency Preparedness and Response risk-based approach to emergency management. Sufficient and appropriate procedures were performed and evidence was gathered in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing.

Why is the management of non-enteric zoonotic infectious disease activities important?

PHAC's 2013-2015 Corporate Risk Profile identified emerging and re-emerging vector-borne zoonotic infectious diseases as one of the organization's top five risks that need to be monitored and managed. Up to 75 percent of newly emerging human infectious diseases originate as zoonoses, often transmitted by mosquitoes and ticks. Environmental change is leading to the expanded geographical range of vector-borne diseases, which is increasing the risk of Canadians being exposed.

What was found?

The activities delivered by the Centre and by the NML include providing reference and diagnostic services, undertaking research (laboratory, field and epidemiological), conducting surveillance, developing risk assessments and models, providing information to public health partners and raising awareness among Canadians. While there is collaboration between the NML and the Centre in these activities, several activities operate independently of each other. As such, the audit recommends that PHAC develop a zoonotic infectious diseases framework to optimize the integration and coordination of the activities. The framework should include

expectations for governance, roles and responsibilities, risk assessments, risk management and performance measurement. It would serve as the focal point for providing a programmatic direction for the portfolio of zoonotic activities.

The audit found that while the NML has a current event preparedness and response plan, the Centre does not. Given the collaboration and coordination required by the Centre and the NML during an event, the audit recommends developing a formal non-enteric zoonotic illness outbreak response standard operating procedure (SOP) for PHAC. The SOP should document what needs to be done, when, where and by whom.

In summary, the audit makes two recommendations to strengthen the internal controls related to the management of non-enteric zoonotic infectious disease activities:

- Develop a zoonotic infectious diseases framework that includes governance, roles and responsibilities, risk management and performance measurement;
- Develop an outbreak response standard operating procedure for non-enteric zoonotic infectious diseases.

Management agrees with the recommendation in this report and has provided an action plan that will further strengthen the management control framework supporting non-enteric zoonotic infectious disease activities.

A - Introduction

1. Background

Zoonotic diseases are infections that occur in animals that can also infect humans (i.e., that are spread through contact with animals). They are caused by bacteria, viruses, parasites and fungi that are carried by animals and insects. Examples of non-enteric zoonotic diseases include avian influenza, the hantavirus pulmonary syndrome and rabies, as well as vector-borne diseases such as Lyme disease, the West Nile virus and chikungunya (see [Appendix E](#)).

In Canada, the management of non-enteric zoonotic infectious diseases is a shared responsibility among the federal, provincial and territorial and municipal governments and non-governmental partners. The federal government, through the Public Health Agency of Canada (PHAC), is responsible for assessing the risk and reducing the impact of non-enteric zoonotic infectious diseases. PHAC also manages Canada's national responses to international threats of infectious disease outbreaks. On a global level, PHAC works with its international partners to help reduce the threat of emerging zoonotic infectious diseases. Within Canada, the provinces and territories have primary responsibility for detecting, monitoring and reporting infectious disease cases. In addition to working in collaboration with the provinces and territories, PHAC also partners with a broad range of non-government organizations, including a number of associations and academic institutions.

Within PHAC, the Infectious Disease Prevention and Control Branch (IDPCB) has the overall responsibility for assessing the risk and reducing the impact of zoonotic infectious diseases. The Branch does this through the Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (Centre) and the National Microbiology Laboratory (NML).

The Centre undertakes national surveillance of zoonotic diseases, conducts targeted epidemiological research projects aimed at reducing infectious disease emergence and manages Canada's national and international response to food and water-borne disease outbreaks. It works with federal, provincial, territorial and regional stakeholders, as well as with international health and public health organizations, to address emerging global food-borne, water-borne, environmental and zoonotic infectious diseases, in keeping with Canada's obligations under the *International Health Regulations*.

The Centre comprises eight divisions. Three of these divisions, namely the Environmental Issues Division, the Program Development and Integration Division and the Zoonotics Division, undertake work included in the scope of this audit.

- The Environmental Issues Division (EID) examines the impact that climate change could have on food-borne, water-borne and vector-borne infectious diseases and how they could affect humans, animals and the ecosystem.
- The Program Development and Integration Division (PDID) looks at complex health issues from a policy perspective. It analyzes technical advice provided by the program areas, coordinates their input and provides non-technical subject-matter expertise. The policy information and PDID's analyses are then used to develop strategies, plans, policies and frameworks for the Centre.

- The Zoonotics Division (ZD) provides technical expertise on zoonotic and vector-borne diseases. It coordinates national monitoring, surveillance, planning and response activities related to existing, emerging and re-emerging zoonotic diseases. ZD carries out its work with the assistance of the EID and PDID, as well as research and guidance provided by the NML.

The NML's Zoonotic Diseases and Special Pathogens Division, located in Winnipeg, is a World Health Organization (WHO) Collaborating Centre for Zoonotic Diseases. Comprising the following sections, it serves as the national reference library for zoonotic diseases:

- Special Pathogens;
- Viral Zoonoses;
- Field Studies;
- Emerging Bacterial Diseases/Microbiological Emergency Response Teams;
- Rabies, Rickettsia and Related Zoonotic Diseases.

The Division is both a leader and responder in the identification and control of zoonotic diseases and special pathogens in Canada and worldwide. Housing Canada's only Level 4 laboratory for human testing and Level 3 insectary, the Division works with a range of viral, bacterial and rickettsia zoonotic diseases. Its core activities include reference and diagnostic services, infectious diseases surveillance and field study, emergency outbreak preparedness and response, applied infectious disease research, biosafety training and prevention strategy development. The Division supports provincial, national and international public health partners in tracking, diagnosing, controlling and treating zoonotic and other rare or emerging pathogens.

The NML's Public Health Risk Sciences Division, located in Guelph, provides scientific knowledge, expertise and technical solutions to prevent and control zoonoses. The Division uses four complimentary approaches:

- Performing epidemiological studies to identify public health risk factors;
- Evaluating the state of scientific knowledge on diseases, risk factors and interventions, to enable evidence-based public health decisions;
- Developing risk models and decision analysis tools to understand and reduce public health risks; and
- Developing public health geomatics and modelling tools and services to strengthen PHAC's decision-making, surveillance and emergency response to zoonoses.

These activities support programs in public health surveillance, research and outbreak management.

In 2014-15, approximately \$2.1 million was spent in the Centre on work related to zoonotic activities, with 14 full-time equivalent (FTE) staff. This amount included a small contribution agreement of \$125,000 for research on the environmental impacts of zoonotic diseases. Laboratory Services funds spent related to zoonotic activities in 2014-15 totalled approximately \$5.4 million, with 40 FTEs. Therefore, the total approximate amount of resources spent on zoonotic activities is \$7.5 million, with 54 FTEs.

2. Authority

This audit engagement was identified in the Office of Audit and Evaluation's 2014-17 Risk-Based Audit Plan (RBAP). The RBAP was recommended for approval by the PHAC Departmental Audit Committee in December 2013 and approved by the Acting Deputy Head in January 2014. The RBAP is updated annually.

3. Audit objective

The objective of this audit was to assess effectiveness of the management control framework for the delivery of non-enteric zoonotic infectious disease activities, as it relates to governance, risk and internal controls.

4. Audit scope

The scope of the audit included an examination of the administrative practices, processes and systems in place to ensure effective and efficient fulfillment of PHAC's mandate with respect to non-enteric zoonotic infectious diseases, up to the event of an outbreak. Specifically, the audit focussed on the IDPCB centres and laboratories, as follows:

- The Centre for Foodborne, Environmental and Zoonotic Infectious Diseases – three divisions in the Centre that conduct work or fund activities related to non-enteric zoonotic infectious disease, namely, the Zoonoses Division, the Environmental Issues Division and the Program Development and Integration Division; and
- The National Microbiology Laboratories (NML) – two divisions in NML, namely, the Zoonotic Diseases and Special Pathogens Division in Winnipeg, the Public Health Risk Sciences Division in Guelph (formerly the Laboratory for Foodborne Zoonoses) and the St. Hyacinthe Laboratory.

The period of examination included the 2013-14 and 2014-15 fiscal year and the 2015-16 fiscal year to the end of January 2016. The audit did not examine the Centre for Emergency Preparedness and Response risk-based approach to emergency management.

5. Audit approach

The audit procedures included a review of documentation, policies, standards, guidelines and frameworks; interviews and observation; inquiry, testing and analysis. Fieldwork was undertaken at PHAC's headquarters in Ottawa and site visits were conducted at the NML in Winnipeg, Guelph and St. Hyacinthe. The audit criteria, outlined in [Appendix A](#), were derived from the Zoonotic and Vector-Borne Diseases Draft Logic Model; Office of the Comptroller General Internal Audit Sector's Audit Criteria Related to the Management Accountability Framework: A Tool for Internal Auditors (March 2011); Canada's Action Plan on Open Government; the *Communications Policy for the Government of Canada*; and the *Policy on Transfer Payments*.

The audit was conducted in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing, examined sufficient, relevant, reliable and useful evidence and obtained sufficient

information and explanations to provide a reasonable level of assurance in support of the audit conclusion.

6. Statement of conformance

In the professional judgment of the Chief Audit Executive, sufficient and appropriate procedures were performed and evidence gathered to support the accuracy of the audit conclusion. The audit findings and conclusion are based on a comparison of the conditions that existed as of the date of the audit, against established criteria that were agreed upon with management. Further, the evidence was gathered in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing. The audit conforms to the Internal Auditing Standards for the Government of Canada, as supported by the results of the quality assurance and improvement program.

B - Findings, recommendations and management responses

The audit's approach to the subject of zoonotics focused on the two key areas of overall responsibility for the Public Health Agency of Canada (PHAC):

- Assessing the risk and reducing the impact of zoonotic infectious diseases; and
- Managing Canada's national and international response to zoonotic infectious disease outbreaks.

The audit looked at the activities within the Infectious Diseases Prevention and Control Branch (IDPCB), specifically within the National Microbiology Laboratory and the Centre for Foodborne, Environmental and Zoonotic Infectious Diseases.

1. Assessing the risk and reducing the impact of non-enteric zoonotic infectious diseases

The activities carried out by PHAC to assess the risk and reduce the impact of zoonotic infectious diseases include: providing reference testing and diagnostic services; undertaking research; conducting surveillance; risk assessments and risk modeling; coordination of the federal, provincial and territorial (F/P/T) outbreak response; public health liaison with other Government Departments; and providing information/recommendations to public health partners, stakeholders and Canadians. These activities are carried out by the Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (the Centre) and the National Microbiology Laboratory (NML).

1.1 Reference testing and diagnostic services

Audit criterion: Reference and diagnostic services are conducted to support partners in tracking, diagnosing, controlling and treating non-enteric zoonotic diseases.

A reference laboratory has validated laboratory methods and the ability to deliver accurate confirmation of diagnostics results. Reference laboratories develop and maintain a collection of relevant reference material. This material is provided to support other laboratories and provide scientific advice and policy recommendations to public health officials such as, for example, expert advice related to vaccine issues or outbreak response management. Reference laboratory officials offer training, participate in public health microbiology laboratory networks, collaborate on research initiatives and provide surge capacity.

Services Provided

1. Providing quality assurance and proficiency testing;
2. Developing and applying new diagnostic methods and technologies;
3. Providing highly specialized diagnostic services, including the identification and characterization of emerging and rare infectious diseases;
4. Performing confirmatory tests;
5. Disseminating standard processes to provincial and territorial public health laboratories.

These types of services are a routine priority for the non-enteric zoonotic infectious disease staff at the NML. It provides timely and highly specialized reference laboratory services to enable public health professionals to address emerging public health risks. The NML also works closely with the provinces and territories by completing reference and diagnostic testing on various emerging non-enteric zoonotic infectious diseases. The NML reports that it provides timely and highly specialized reference laboratory services to enable public health professionals to address emerging public health risks. The results of these tests are reported to the provinces and territorial labs and health care providers. Diagnostic tests and training are developed at the NML and shared with the provinces and territories (when and where appropriate capacity exists). This provides the provinces and territories with the tools and expertise to perform their own diagnostic testing.

Canadian and international clients rely on the NML for its wide range of reference and diagnostic testing capabilities. Increased reference and diagnostic services on Lyme disease, the West Nile virus and Ebola dominated staff efforts during the period under review. Increased and present incidents in Canada of chikungunya (in travellers) and hantavirus were also addressed. For example, the NML reports that it identified over 500 imported cases of chikungunya among Canadian travellers using state-of-the-art serological and molecular testing. More recently, the Zika virus has dominated the reference testing services with several thousand samples being tested. NML scientists are working to better understand and prevent the Zika virus and its transmission.

Six of the zoonotic or zoonotic-related tests are ISO 17025 accredited tests. Turn-around times are maintained for diagnostics to ensure that quality assurance standards are met. Each year, the NML is subject to a cycle of audits by the Canadian Standards Council for the Standard Operating Procedures (SOP), to ensure continued improvement. The NML tracks development activities and the length of time needed to implement requests, and conducts client surveys every second year. A draft terms of reference for the Reference Centre Advisory Committee of the Canadian Public Health Laboratory Network provides recommendations to assess, evaluate and monitor the provision of microbiology reference centre services in Canada, providing advice and guidance specifically to the NML.

The NML scientists maintain and report on statistics, including year-over-year comparisons (increases/decreases in case numbers and tests performed) within the laboratory and externally. The NML has been able to maintain and in some cases increase the number of tests it performs on an annual basis, while responding to other competing priorities such as the Ebola outbreak in Africa in 2014-15. While the NML maintains performance statistics on diagnostic tests, there was no evidence of performance measures for operational processes such as the effects on operations caused by outbreak management activities.

In conclusion, reference and diagnostic services are conducted to support partners in tracking, diagnosing, controlling and treating non-enteric zoonotic diseases. However, performance indicators for the operational management of non-enteric zoonotic activities are currently under development (See [Recommendation 1](#)).

1.2 Research

Audit criterion: Research is conducted to advance and inform the knowledge of non-enteric zoonotic infectious diseases. Transfer payments are managed in accordance with central agency requirements, including the Treasury Board *Policy on Transfer Payments* and related directives.

PHAC's Framework for Science and Research Excellence focuses on the federal role in public health science and research, clarifies leadership responsibilities and continues to put evidence and science information at the heart of policies and programs. For 2015-16, PHAC planned to strengthen the formal mechanisms of the public health system by connecting research and evidence to disseminate information and tools that promote good health and prevent disease and injury.

The majority of non-enteric zoonotic research projects involve partnerships and collaborative efforts with academic institutions, with funding from outside sources. For example, in 2013-14 and 2014-15, PHAC received authority to increase reference levels of transfer payment funding for additional research to better understand the impacts of climate change under Canada's Clean Air Agenda. In 2013-14, the funding was not transferred due to delays in receiving approvals; however in 2014-15, it was successfully transferred to a Canadian university to perform knowledge transfer and capacity building, supporting the development of tools for the management of Lyme disease and other vector-borne diseases in the context of adaptation to climate change. A range of studies are performed as requested, generally in collaboration with universities. The decision to conduct research is often determined by requests from collaborators and the availability of resources. Management reports that since August 2014, NML scientists have published 11 peer-reviewed papers on ground-breaking work on an Ebola treatment and vaccine.

Management at the NML reported that, based on many years of Ebola virus research, the NML discovered two of the three antibodies used to create the ZMapp™ drug treatment for Ebola; it also supported clinical trials of the Ebola vaccine (VSV-EBOV) by donating 800 vials to the World Health Organization (WHO) for trials in West Africa and elsewhere. During this time, management also reports that the NML employed its Containment Level 4 laboratory capacity to provide safe, efficient and accurate testing for 39 domestic Ebola investigations, all of which tested negative. These requests for Ebola testing demonstrated a heightened domestic vigilance, as well as Canada's capacity to provide highly specialized laboratory testing.

The NML Management Council provides a forum for senior management to discuss issues and topics affecting the laboratory. The Council meets bi-weekly, has terms of reference and keeps minutes of its meetings. A review of the minutes found that the Council focusses primarily on administrative and operational matters and less on scientific matters. As a result, in an effort to increase general awareness of current projects, senior management introduced a forum called "Lab Rounds", which focusses on detailed scientific discussions of current laboratory issues and research.

The staff interviewed noted that research is performed as time permits. Given the recent increased demand for reference and diagnostic services, research has therefore decreased. As well, laboratory staff and the 2013-14 NML Operational Plan noted that research capacity has

decreased over time and indicate that there is a resulting risk of being unable to recruit and retain essential personnel. The audit was unable to determine the full impact on research as performance information is not always tracked.

Generally, the Centre is not always aware of the research projects underway. Likewise, NML staff would like to know the needs of the Centre in relation to research information. More knowledge sharing would assist both partners in better assessing the risks and reducing the impact of non-enteric zoonotic infectious diseases.

In conclusion, while research is being conducted, because no performance data was available for review, the audit was unable to determine how the research is used to advance and inform the knowledge of non-enteric zoonotic infectious diseases and whether research was materially impacted due to competing priorities (see [Recommendation 1](#)).

1.3 Monitoring and surveillance

Audit criterion: Surveillance is conducted to detect and assess non-enteric zoonotic infectious disease risks and trends.

Health surveillance is a core public health function for PHAC, contributing to the reduction of the impact of non-enteric zoonotic infectious diseases. Emerging vector-borne and non-enteric zoonotic diseases are initially identified at the NML when the provinces and territories provide specimen samples. Initial surveillance work is carried out by the NML during the evolving stages of the emerging disease, at which point the results are shared with the Centre if the risk to public health is deemed to be sufficiently high. In addition, the Centre regularly monitors surveillance information from international sources and Canadian Notifiable Disease Surveillance System (CNDSS). The Centre also works with information from the Canadian Wildlife Health Cooperative to identify disease trends in wildlife that may impact Canadians.

Currently, PHAC actively conducts surveillance on two vector-borne infectious diseases: Lyme disease and the West Nile virus. For Lyme disease, the Centre works with the NML, provincial and territorial public health authorities and other experts and stakeholders to report on the number of people with Lyme disease and the locations of tick populations. In 2014, the Lyme Disease Enhanced Surveillance Working Group was established, chaired by the Centre, to facilitate, manage and support the exchange and analysis of data and share findings. Similarly, West Nile virus surveillance is a joint effort between the federal government, provinces and territories, First Nations authorities and blood agencies. A National West Nile Virus and Other Mosquito Diseases Working Group has been established, chaired by the Centre. It includes representatives from the provinces and territories, as well as from other government departments.

The West Nile virus and Lyme disease were designated nationally notifiable diseases in 2003 and 2009 respectively. Surveillance case data is provided by the provinces and territories through the CNDSS, which provides long-term trend data for all 59 notifiable diseases. The NML also conducts passive surveillance (i.e., voluntary data submission) for other infectious diseases such as rabies, rickettsia, Q fever and other emerging and re-emerging non-enteric

zoonotic infectious diseases. Surveillance of infectious diseases is included in PHAC's Strategic Surveillance Plan (Phase 3) and in the NML Operational Plan.

Surveillance infrastructure issues are dealt with by the Public Health Infrastructure Steering Committee and the Communicable Infectious Disease Steering Committee (CIDSC), which both work to support the strategic direction of the Conference of federal, provincial and territorial (F/P/T) Deputy Ministers of Health and the Pan-Canadian Public Health Network. The CIDSC is the key F/P/T governance mechanism for the Centre's work; it serves as the table for policy and direction setting and consensus building on F/P/T initiatives. The Steering Committee looks at the foundations for the national surveillance infrastructure within the context of communicable disease and urgent public health events.

In conclusion, monitoring and surveillance is conducted to detect and assess non-enteric zoonotic infectious disease risks and trends.

1.4 Risk modelling and assessments

Audit criterion: Risk modelling and/or assessments are conducted to develop decision analysis tools, to understand and reduce public health risks.

Risk modelling and risk assessments are conducted at the NML (Guelph and St. Hyacinthe) as part of the population health assessments and economic analyses of particular diseases, to better understand and reduce public health risks. The Centre also provides rapid risk assessments and epidemiological studies. These risk tools help to determine the impact and risk of diseases such as the risk of disease transmission through blood transfusions or the risk of emerging diseases migrating to northerly areas of Canada due to climate change or from animals to humans. For example, NML scientists are developing a risk model on the potential expansion of chikungunya into Canada, to support a public health action plan now, before the virus becomes a domestic threat. As well, PHAC scientists contributed decision-making tools related to the Ebola epidemic in West Africa, such as outbreak distribution maps on countries with public health measures in place, reports on health care worker infections and modelling approaches to look at health care worker risks related to deployments to West Africa.

At present, models and assessments are often completed in an ad hoc manner, based on a response to current priorities or initiatives. As well, the location and movement of staff and shifting priorities have made coordination of risk modelling and assessments a challenge. Evidence of an operational or long-term strategy or coordination of risk initiatives was not apparent at the time of the audit fieldwork.

Recently, the Winnipeg, St. Hyacinthe, Guelph and Lethbridge facilities were amalgamated to form the NML. This amalgamation could serve to provide some focused attention on the activities within the NML.

In conclusion, risk modelling and assessments are conducted to develop decision-making analysis tools that help to understand and reduce public health risks; however, additional coordination and integration between the Centre and the NML will be required (see [Recommendation 1](#)).

1.5 Governance and stakeholder collaboration

Audit criterion: PHAC has an effective governance structure in place to support and achieve the objectives of activities related to non-enteric infectious disease. Governance structures, policy and partner protocols and engagement approaches/mechanisms are developed and shared with stakeholders.

The multi-jurisdictional nature of public health means that PHAC must work closely with domestic and international partners and stakeholders to respond to non-enteric zoonotic events and to build on lessons learned. In regard to domestic collaboration, PHAC is an active member and co-chair of the Pan-Canadian Public Health Network (PHN), which is governed by a 17-member council composed of federal, provincial and territorial government officials, including the Chief Public Health Officer of Canada and senior government officials from all the jurisdictions responsible for public health. The PHN Council is accountable to the Conference of Federal, Provincial and Territorial Deputy Ministers of Health, which provides direction and approves public health priorities for Canada.

The NML provides international and domestic leadership in research, technical innovation, reference laboratory services, surveillance, outbreak response capacity and national laboratory coordination to inform public health policy and practice. The NML also participates in the Canadian Public Health Laboratory Network, whose role is to provide a forum for public health laboratory leaders to share knowledge.

The Centre works closely with the provinces and territories by coordinating surveillance activities for the West Nile virus and Lyme disease. PHAC is working through PHN to finalize a Multi-lateral Information Sharing Agreement. The purpose of this agreement is to articulate the parameters for surveillance information to be shared. The technical annexes to the agreement define why, how, what and when information and biological substances can be shared among various health authorities in Canada. These annexes, which will include parameters for non-enteric zoonotic diseases, are to be negotiated.

A private Member's bill (C-442) led to the *Federal Framework on Lyme Disease Act*. The Centre is developing the Federal Framework on Lyme Disease, which will include a national medical surveillance program, guidelines for prevention, identification, treatment and management of Lyme disease, standard educational materials and a mechanism for sharing best practices. To address its responsibilities in developing the framework, PHAC is required to collaborate with a number of stakeholders. The first step in the development of this framework was to host a conference with participation from patient groups, the medical community and provincial and territorial health departments. The conference was held in May 2016.

Interviews and reviews of documents indicate that stakeholder collaboration has evolved with the restructuring of the PHN's governance. The original model had more than 100 working groups and communities of practice that convened regularly to discuss public health matters, share expertise and build capacity. The restructured PHN now comprises three steering committees. Working and middle-level management do not currently have a formal structure for intergovernmental collaboration. As such, communication for middle-level staff has been limited to the preparation of briefing notes for senior management represented at the PHN.

PHAC also participates on other committees to support stakeholder collaboration, including the Council of Chief Medical Officers of Health and the Council of Chief Veterinary Officers, both of which provide advice, guidance and recommendations nationally. As well, PHAC acts as the liaison between the two Councils. In addition, there is a joint PHAC/Canadian Food Inspection Agency Non-Enteric Zoonotic Diseases Steering Committee, whose role is to integrate advice on non-enteric zoonotic diseases, planning and priority setting, to inform effective policy, program interventions and actions and to facilitate risk analysis and risk management recommendations.

In conclusion, stakeholder collaboration occurs through governing bodies, leading to the sharing of surveillance information, policy and partner protocols; the development of engagement approaches and mechanisms; attendance at conferences and participation and hosting of workshops and other governing mechanisms.

1.6 Public awareness

Audit criterion: Public awareness materials are accessible to stakeholders.

Education and awareness regarding the risks and prevention of non-enteric zoonotic infectious diseases are integral to PHAC attaining its objectives. The Centre and the NML work closely with the Public Health Strategic Communications Directorate within the Communications and Public Affairs Branch (CPAB) to develop and implement communication materials that increase public awareness on non-enteric zoonotic infectious diseases.

Communications planning and implementation is a shared responsibility between CPAB and the Centre. CPAB provides advice to the Centre on a variety of communication approaches and is responsible for leading the planning and implementation of communication strategies for the NML and the Centre. For their part, the NML and the Centre have a designated communications advisor. As well, zoonotic disease experts employed at the NML and the Centre are often called upon to provide their expertise on a given topic, using different communication tools such as social media, publications and television.

The Infectious Diseases Prevention and Control Branch (IDPCB) has a 2013-16 Communications Strategy that identified vector-borne diseases as a priority initiative for the Branch. In 2014, in order to reduce the risks of Lyme disease, the Branch implemented a social marketing strategy on Lyme disease prevention, testing and treatment. CPAB also conducted a survey on Canadians' knowledge and behaviours related to Lyme disease to assess the effectiveness of the communication prevention campaign. Management reports that survey results showed that the campaign was successful in increasing public awareness.

The Centre also provides regular surveillance updates on PHAC's website. Data on the annual number of human cases for a given infectious disease by province and territory is made available through the CNDSS. PHAC uses maps that identify the number of active cases and location. Relevant data on non-enteric zoonotic diseases is also shared with international partners, in keeping with PHAC's obligations under the *International Health Regulations (2005)*. In addition to the published data and maps, PHAC prepares annual national surveillance reports on the West Nile virus and Lyme disease in Canada.

The Centre regularly posts Public Health Notices and Travel Health Notices, as well as general information on non-enteric zoonotic diseases. Other published information on zoonotic diseases is found in the monthly Canada Communicable Disease Report. Geared to clinicians and public health professionals, this free online scientific peer-reviewed journal is published on PHAC's website and distributed to subscribers. The reports include the latest statistics on infectious disease trends in Canada, original research, summaries of PHAC and advisory committee statements and rapid communications, as well as useful links to online resources and continuing education events.

In conclusion, public awareness materials are prepared, communicated and made accessible to inform stakeholders.

1.7 Risk management

Audit criterion: Internal and external risks related to the management of zoonotic diseases are identified, assessed and managed. Management has identified comprehensive performance management indicators linked to planned results and performance monitoring.

The 2013-15 PHAC Corporate Risk Profile identified zoonotic infectious diseases as a key risk that could impact the organization. PHAC notes that there is a risk that the total burden of vector-borne diseases will increase without a national approach to monitor and assess these diseases and to enable the implementation of prevention and control measures, adversely affecting the public trust.

PHAC has identified 11 risk drivers to support the zoonotic infectious disease risk. As well, PHAC has identified four control measures to mitigate the risks and has established a risk treatment strategy, with timelines for delivery. Specifically, PHAC has committed to implementing the Action Plan on Lyme Disease, which will pilot novel approaches to promoting awareness, prevention and protection of Canadians regarding Lyme disease. To evaluate the impacts of the Action Plan on Lyme Disease, an evaluation is to take place during the roll out, in collaboration with key partners. An internal assessment of the impacts is to be completed by the end of 2015-16. Based on the results of the internal assessment and lessons learned from the implementation of the Action Plan, PHAC will work with partners to finalize an emerging infectious disease response framework that can be applied to other emerging zoonotic infectious diseases.

Action on these mitigating strategies has been slower than planned. The audit found that while there is collaboration between the NML and the Centre, several activities (surveillance, research, diagnostics, risk modelling, and public awareness strategies) designed to assess the risk and reduce the impact of non-enteric zoonotic infectious diseases operate independently of each other. It would therefore be important to complete the development of a zoonotic framework.

In 2013, there was an initiative to discuss developing a zoonotic diseases framework and determining priorities among the diseases requiring enhanced attention. However, a zoonotic disease framework has not been developed as planned and the two entities (the NML and the Centre) have continued their informal and ad hoc work on initiatives pertaining to Lyme disease

and the West Nile virus. As well, both the Centre and the NML have separate governance structures to guide the zoonotic work, but the roles and responsibilities between the two organizations are not clearly defined. Interviews with staff indicated that since 2008, efforts have been made to delineate roles and responsibilities. While staff consistently rise to the challenges posed by non-enteric zoonotic infectious disease events, the lack of clear and documented responsibilities and communication can result in gaps and overlap, posing risks for both organizations. Common and recurring references for the need to clarify roles and responsibilities emerged from document reviews, as well as from the 33 interviews conducted with staff at the NML (Winnipeg, St. Hyacinthe and Guelph) and the Centre (Ottawa, St. Hyacinthe and Guelph).

A zoonotic infectious diseases framework would optimize the integration and coordination among the activities. It should include expectations for governance, roles and responsibilities, risk assessment, risk management and performance measurement. The framework would serve as the focal point, providing a programmatic direction for the portfolio of zoonotic activities.

The audit also noted that specific performance indicators to monitor activity commitments have not yet been developed. The Branch has committed to developing specific indicators for risk treatments and to assess periodically and annually the Corporate Risk Profile processes that monitor risk treatment and risk control progress as stated in the Corporate Risk Profile 2013-15.

Recommendation 1

It is recommended that the Assistant Deputy Minister, Infectious Diseases Prevention and Control Branch, develop a zoonotic infectious diseases framework that includes governance, roles and responsibilities, risk management and performance measurement.

Management response

Management agrees with the recommendation.

PHAC recognizes the need to engage in a more programmatic response to non-enteric zoonotic diseases and other emerging infectious diseases. Management of the Centre and the NML will develop a strategic approach, to respond systematically to non-enteric zoonotic diseases.

The Branch will continue to maintain the Health Portfolio governance structure on non-enteric zoonotic diseases in support of the Public Health Agency of Canada-Canadian Food Inspection Agency Memorandum of Understanding (i.e., PHAC-CFIA Steering Committee on Non-enteric Zoonotic Infectious Diseases).

2. Managing a response to an infectious disease outbreak

2.1 Event response

Audit criterion: Operational plans demonstrate the use of resources to support the management of non-enteric zoonotic infectious diseases. Roles and responsibilities are documented and operating effectively. Event preparedness and response plans are established and current, to respond to non-enteric zoonotic and vector-borne disease illness events.

The Centre and NML staff regularly monitors zoonotic disease threats to Canadians. PHAC also leads Canada's national (in collaboration with the provinces and territories) and international response to infectious disease outbreaks. Internationally, PHAC works with its partners to help reduce the worldwide threat of emerging zoonotic infectious diseases.

The capacity to act dynamically in rapidly evolving situations relies on close collaboration, transparency and engagement of all levels of an organization in a collaborative process consisting of risk assessment, decision-making and response. Outbreak responses are determined and directed by PHAC through the weekday morning meetings at which events that might have a public health impact are reviewed and assessed. An initial daily meeting provides an opportunity for PHAC managers to review key threats (events, issues and risks), prioritize appropriate risk management options and approaches and initiate briefings. The meeting is co-chaired by the Assistant Deputy Minister, Infectious Disease Prevention and Control Branch, and the Branch Head of the Health Security and Infrastructure Branch. Members are accountable for performing reliable and valid risk assessments for each potential and actual threat and opportunity identified. The co-chairs brief executives at the second morning meeting called the Daily Update. Daily Update membership includes the Chief Public Health Officer, Branch Heads and senior management and staff. Risks requiring PHAC mitigation and escalation are identified in the Daily Intelligence Report, which includes a risk tolerance chart corresponding to the risk decision chart used by the World Health Organization and the *International Health Regulations*.

An example of a non-enteric zoonotic event during the audit period was the response to a field investigation of hantavirus cases acquired at a military training centre in Alberta. Activities included the collection and testing of deer mice, a rodent risk assessment, epizootiological support and determination of recommendations to the Department of National Defence on how to prevent further transmission of the disease. While the event was being handled by the NML, the Centre only learned of the event at the Daily Update rather than through any interaction with the NML. There have been other instances where the NML and the Centre have been working on the same issue without any knowledge of what the other is doing, thus potentially leading to missed opportunities for collaboration and coordination.

The auditors conducted 33 interviews with staff at the Centre and the NML. The interview results noted that over the last two years, more than 90 percent had been affected by one or more of the following examples related to roles and responsibilities: no job description or a generic job description that did not reflect the work being undertaken (especially during an outbreak); a perception that messaging to internal and external stakeholders may be inconsistent; duplication or gaps may exist between the NML and the Centre; expectations and

standard operating procedures (SOP) within both organizations have not been defined or communicated.

However, the audit also noted that the recent appointments of senior management at both the NML and the Centre should help to stabilize the two organizations. Initiatives such as Lab Rounds at the NML and the reinstatement of the Director position in the Zoonotics Division at the Centre should also contribute to further stabilizing the organizations.

NML staff reported that dealing with an outbreak situation is typically reactive, with decisions on what to do being based on professional judgment and not on a formal SOP. Management at both the NML and the Centre recognizes the benefits of a formal SOP that documents what should be done, when, where and by whom. Given the multidisciplinary team effort required in an outbreak, a documented and approved SOP would ensure a more complete and consistent approach by the Centre and the NML to responding to non-enteric zoonotic events. The SOP should take into consideration the NML's other event preparedness and response SOPs such as the emergency preparedness and response activities.

Recommendation 2

It is recommended that the Assistant Deputy Minister, Infectious Diseases Prevention and Control Branch, develop standard operating procedures for activities related to outbreaks of non-enteric zoonotic infectious diseases.

Management response

Management agrees with recommendation.

The Branch will apply learnings from foodborne outbreak management to develop and implement standard operating procedures for activities related to outbreaks of non-enteric zoonotic infectious diseases.

C - Conclusion

The audit concluded that PHAC's Infectious Diseases Prevention and Control Branch has activities in place to address many non-enteric zoonotic infectious diseases through the work completed at the National Microbiology Laboratory (NML) and the Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (Centre). There are, however, some areas that need to be strengthened in order to have an effective national program to combat non-enteric zoonotic infectious diseases.

The NML conducts reference and diagnostic services to support partners in tracking, diagnosing, controlling and treating non-enteric zoonotic diseases. However, performance indicators for the operational management of non-enteric zoonotic activities were under development at the time of the audit. As well, the audit was unable to determine how the research is used to advance and inform the knowledge of non-enteric zoonotic infectious diseases and whether research was materially impacted due to competing priorities, since no performance data was available for review.

Monitoring and surveillance is conducted to detect and assess non-enteric zoonotic infectious disease risks and trends, and public awareness materials are prepared, communicated and made accessible to inform stakeholders.

Risk modelling and assessments are conducted to develop decision-making analysis tools that help to understand and reduce public health risks; however, the audit noted that additional coordination and integration between the NML and the Centre will be required.

Specific performance indicators to monitor activity commitments and support the Corporate Risk Profile processes have yet to be developed.

Event preparedness and response standard operating procedures, such as the emergency preparedness and response activities, should be formalized to ensure a consistent approach by the NML and the Centre in responding to non-enteric zoonotic events.

The areas for improvement that have been noted in this audit report will strengthen the effectiveness of the management of non-enteric zoonotic infectious disease activities.

Appendix A – Lines of enquiry and criteria

Audit of the Management of Non-Enteric Zoonotic Infectious Disease Activities	
Criteria Title	Audit Criteria
Line of Enquiry 1: Governance	
Governance ¹	PHAC has an effective governance structure in place to support and achieve the objectives of non-enteric zoonotic infectious disease related activities.
Roles and responsibilities ¹	Roles and responsibilities are documented and operating effectively.
Line of Enquiry 2: Risk management	
Risk management ¹	Internal and external risks related to the management of non-enteric zoonotic diseases are identified, assessed and managed.
Line of Enquiry 3: Internal controls	
Planning ^{1,2}	Operational plans demonstrate the use of resources to support the management of non-enteric zoonotic infectious diseases.
Reference testing and diagnostic services	Reference and diagnostic services are conducted to support partners in tracking, diagnosing, controlling and treating non-enteric zoonotic diseases.
Scientific research ³	Research is conducted to advance and inform the knowledge of non-enteric zoonotic infectious diseases. Transfer payments are managed in accordance with central agency requirements, including the Treasury Board <i>Policy on Transfer Payments</i> and related directives.
Monitoring and surveillance ³	Surveillance is conducted to detect and assess non-enteric zoonotic infectious disease risks and trends.
Risk modelling and assessments	Risk modelling and/or assessment are conducted to develop decision analysis tools, to understand and reduce public health risks.
Stakeholder collaboration ^{3,4}	Governance structures, policy and partner protocols and engagement approaches/mechanisms are developed and shared with stakeholders.
Public awareness ⁵	Public awareness materials are accessible to stakeholders.
Event response ³	Event preparedness and response plans are established and current, to respond to non-enteric zoonotic and vector-borne disease illness events ⁶ .
Performance measurement ¹	Management has identified comprehensive performance measurement indicators linked to planned results and performance monitoring.

¹ Office of the Comptroller General – Core Controls

² Treasury Board of Canada *Policy on Transfer Payments*

³ Zoonotic and Vector-Borne Diseases Draft Logic Model

⁴ International Health Regulations – World Health Organization, Federal, Provincial and Territorial protocols

⁵ *Canada's Action Plan on Open Government* and the *Communications Policy for the Government of Canada*

⁶ An “event” means a manifestation of disease or an occurrence that creates a potential for disease (World Health Organization International Health Regulations, 2005, p. 7)

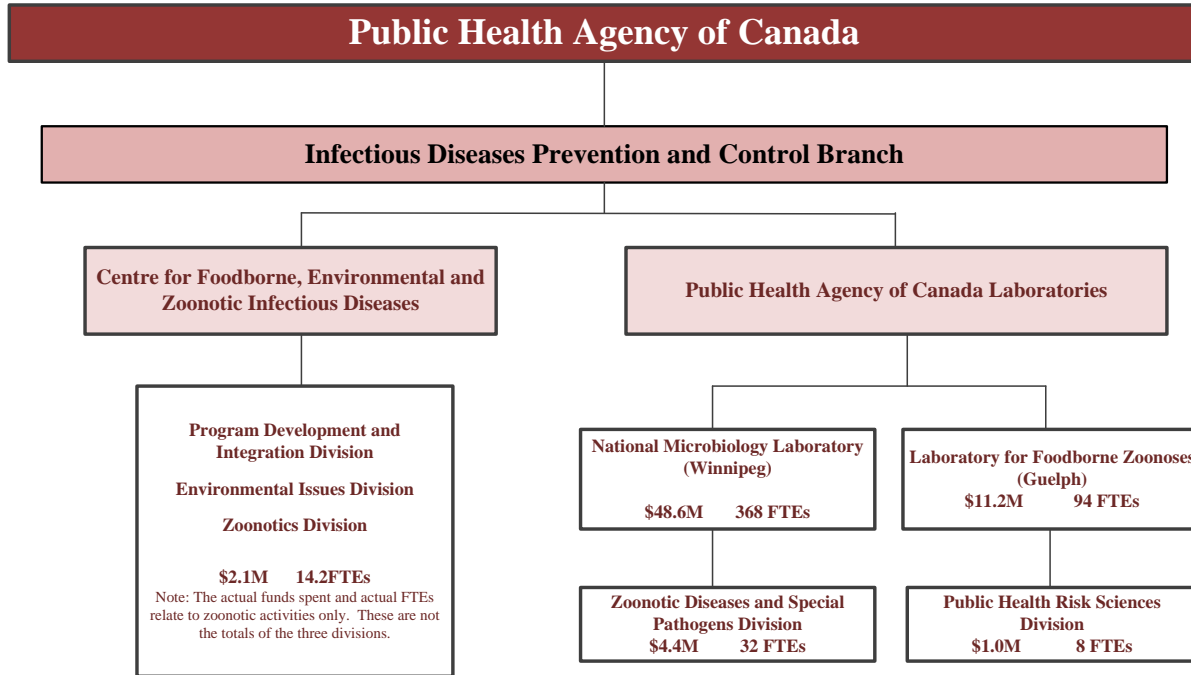
Appendix B – Scorecard

Audit of the Management on Non-Enteric Zoonotic Disease Activities			
Criterion	Rating	Conclusion	Rec #
Governance			
Governance		PHAC should develop a zoonotic infectious disease framework to strengthen integration and coordination of activities.	1
Roles and responsibilities		Develop event response standard operating procedures, to clarify roles and responsibilities.	1, 2
Risk Management			
Risk management		Develop performance measures to track the effectiveness of the mitigating actions.	1
Internal Controls			
Planning		The Branch operational plan included objectives, timelines and resource allocations for the Centre and the NML. The NML also has its own operational plan at a more detailed level.	
Reference testing and diagnostic services		Reference and diagnostic services support partners in tracking, diagnosing, controlling and treating zoonotic infectious diseases, and these services are measured.	1
Scientific research		Scientific research is conducted at the NML; however, scientists report that less research is being undertaken, given recent budget reductions and recent outbreak events. The Centre conducts epidemiological research.	1
Monitoring and surveillance		PHAC currently has an active surveillance system for the West Nile virus and Lyme disease.	
Risk modelling and assessments		A coordinated approach among the laboratories and the Centre regarding risk modelling and risk assessment would facilitate operational and strategic planning.	1
Stakeholder collaboration		Policy and partner protocols and engagement approaches/mechanisms are developed and shared with stakeholders.	
Public awareness		Public awareness materials are prepared, communicated and made accessible to stakeholders.	
Event response		Develop event outbreak standard operating procedures. The NML has event preparedness and response plans.	2
Performance measurement		A performance measurement strategy should be included in a zoonotic infectious diseases framework.	1

Satisfactory	Needs Minor Improvement	Needs Moderate Improvement	Needs Improvement	Unsatisfactory	Unknown; Cannot Be Measured

Appendix C – Organizational Chart

The chart includes only the Divisions within the scope of the audit. Figures are actual funds spent and actual FTEs for the 2014-15 fiscal year.



Appendix D – Auditee Profile

Zoonotics FTE, Planned and Actual Spending (2013-2015), in \$ millions

FY	The Centre*			One Laboratory						Total		
				NML**			LFZ***					
	FTE	Planned	Actual	FTE	Planned	Actual	FTE	Planned	Actual	FTE	Planned	Actual
2013-14	10.9	1.4	1.7	28.0	3.9	3.9	8.0	1.1	1.00	46.9	6.3	6.6
2014-15	14.2	1.1	2.1	32.0	3.6	4.4	8.0	0.9	1.00	54.2	5.6	7.5

- * These numbers include the following components: Program Development and Integration Division/Executive Director, Environmental Issues Division (Zoonoses Related), Zoonotics Division.
- ** These numbers only include the Zoonotic Diseases and Special Pathogens Division; planned amounts are inclusive of in-year approved adjustments; capital funding and Ebola deployments not included.
- *** These numbers only include the zoonotic portion of the work of the Laboratory for Food-borne Zoonoses (LFZ) (percent estimate applied to cost centres where a portion of work included zoonotics); capital funding not included.

Appendix E – Listing of Non-Enteric Zoonotic Diseases

This is a partial list of zoonotic and vector-borne diseases, included for example purposes only.

Zoonotic diseases

Avian influenza¹: Avian influenza refers to the disease caused by infection with avian (bird) influenza (flu) Type A viruses. These viruses occur naturally among wild aquatic birds worldwide and can infect domestic poultry and other bird and animal species. Avian flu viruses do not normally infect humans. However, sporadic human infections with avian flu viruses have occurred.

Hantavirus pulmonary syndrome²: Hantaviruses are a group of viruses that can cause severe illness in humans. The two most prevalent illnesses are: hantavirus pulmonary syndrome (found in North and South America) and hemorrhagic fever with renal syndrome (found mainly in Europe and Asia). People can get hantavirus when they breathe in tiny particles of rodent waste (urine, droppings or saliva) that are infected with the virus. This can occur when the rodent waste is stirred into the air such as through vacuuming or sweeping. Hantavirus infections do occur in Canada but are rare. The risk to Canadians is low.

Rabies²: Rabies is a deadly illness caused by a Lyssavirus that spreads to humans through close contact with the saliva of an infected animal, most often from licks, bites or scratches. Rabies can be carried in any warm-blooded animal (domestic or wild). Rabies is spread from an infected animal when the virus from its saliva enters the victim's nervous system through a bite, scratch, or lick on open skin or mucous membranes (eyes, nose and mouth).

Vector-borne diseases

Lyme disease²: Lyme disease is a serious illness caused by the bite of an infected blacklegged tick. Ticks are small, ranging from the size of a poppy seed to a pea. The size of the tick varies, depending on its age and whether it has fed recently. The bite is usually painless so a person may not know that he or she has been bitten. Blacklegged ticks are most often found in forests and the overgrown areas between woods and open spaces.

West Nile virus²: The West Nile virus is an infection that is carried by mosquitoes in many countries of the world, including Canada and the United States. Mosquitoes are infected with the virus when they bite an infected bird. People then get the virus when the infected mosquito bites them. Most people who get the West Nile virus (70% to 80%) experience no symptoms at all. The first human case of West Nile virus infection in Canada was reported in Ontario in 2002. Since then, cases have been reported so far in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario and Quebec. Outside of these provinces, any reported cases have been linked to travel.

Chikungunya¹: The chikungunya (pronunciation: \chik-en-gun-ye) virus is transmitted to people by mosquitoes. The most common symptoms of chikungunya virus infection are fever and joint pain. Other symptoms may include headache, muscle pain, joint swelling or rash. Outbreaks have occurred in countries in Africa, Asia, Europe and the Indian and Pacific Oceans. In late

2013, the chikungunya virus was found for the first time in the Americas, on islands in the Caribbean. There is a risk that the virus will be imported to new areas by infected travelers. There is no vaccine to prevent or medicine to treat chikungunya virus infection.

Zika virus²: Zika virus infection is caused by a virus that is spread by the bite of an infected mosquito. The mosquitoes that transmit the Zika virus are the same type of mosquito that spread chikungunya and dengue viruses. There are no reports of local transmission of the Zika virus in Canada. Currently, the mosquitoes that transmit the Zika virus are not found in Canada because of the climate.

¹ Centers for Disease Control and Prevention: www.cdc.gov

² Public Health Agency of Canada: www.phac-aspc.gc.ca

Appendix F – Definitions

Infectious disease

Illness caused by the spread of bacteria, virus and other infecting agents from person to person or from animal to human.

Zoonotic Infectious Diseases

Infectious diseases whose transmission involves animal hosts or vectors. Vector-borne diseases, such as malaria, are those in which an organism, typically insects, ticks or mites, carry a pathogen from one host to another.

Non-enteric Zoonotic Infectious Diseases

Bacterial and viral infections that affect organs other than the stomach and digestive tract, such as: anisakiasis, anthrax, avian influenza, brucellosis, chikungunya, Ebola, echinococcus, hantavirus, histoplasmosis, leishmaniasis, leptospirosis, Lyme disease, lymphocytic choriomeningitis, monkeypox, plague, psittacosis, Q fever, rabies, Rift Valley fever, ringworm, Rocky Mountain spotted fever, roundworm, scabies, tularemia, West Nile virus, yellow fever, Zika.

Enteric (Foodborne and Waterborne) Zoonotic Infectious Diseases

Bacterial and viral infections that affect the stomach or digestive tract, such as: bacillus cereus, campylobacteriosis, cholera, clostridium botulinum, clostridium perfringens, cryptosporidiosis, cyclosporiasis, escherichia coli, giardiasis, listeria monocytogenes, rotavirus, salmonella, staphylococcus aureus, toxoplasmosis, toxocariasis, trichinellosis, vibrio parahaemolyticus, yersinia enterocolitica.