Public Health Agency of Canada | Agence de la santé publique du Canada

# AUDIT REPORT

## LABORATORY MANAGEMENT

Audit Services Division

June 2010

Approved by Chief Public Health Officer
on June 22, 2010

Canada

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# Executive Summary

1. The overall objective of the audit was to provide Public Health Agency of Canada (PHAC or the Agency) management with an independent assessment of the extent to which the Agency's two major scientific laboratories are being managed with due regard to economy, efficiency and effectiveness, in accordance with the Agency's mandate and with the needs of its clients and stakeholders.

2. The audit work was conducted between January and June 2010, and included site visits to the Laboratory for Foodborne Zoonoses (LFZ) in Guelph, the National Microbiology Laboratory (NML) in Winnipeg and the National HIV and Retrovirology Laboratories in Ottawa, which are also part of NML. Interviews were also held with officials responsible for the management of laboratories at the National Research Council of Canada, Health Canada and the Centres for Diseases Control and Prevention in Atlanta.

3. The audit examined the Agency's governance, management framework and accountability structures to assess whether the science and research performed in the laboratories ensured the efficient, effective and economical use of the Agency's resources. We sought to determine whether program objectives and priorities had been established for the work performed by the laboratories, whether the work was performed to the level of excellence required by its clients and stakeholders, and whether there was adequate senior management oversight of the laboratory activities. Our audit criteria were derived from the Core Management Controls Framework and Audit Criteria, prepared by the Office of the Comptroller General.

### Structure of the Agency's Program Delivery

4. The Agency's multitude of programs are being delivered in part by the laboratories and in part by program Centres. Program activities in the Centres are generally surveillance activities, but requiring some science and research support from the laboratories. The laboratories perform science and research activities for both internal and external clients and stakeholders. Clearly defined statements of accountability, authority, roles and responsibilities do not exist for the interactions of the Centres and the laboratories, which has led to a lack of communication and the potential for gaps and duplication of effort in program delivery.

### Governance and Strategic Directions

5. The Agency has published its first Strategic Plan 2007-2012, which is intended to guide and set priorities for the work of the Agency. Of the Agency's two program Branches, the Infectious Disease Prevention and Control (IDPC) Branch has not prepared a strategic planning document to guide and set priorities for its program Centres and the two scientific laboratories. This has led to the Centres and the laboratories setting their own strategic directions and priorities, with little assurance for senior management that they align well with the strategic directions

and priorities of the Agency. The IDPC Branch management held a retreat in April 2010 and has begun a strategic planning process that could result in the preparation of a strategic plan for the Branch.

6. The Strategic Plan is intended to provide the foundation for the Agency to critically review all of its programs and make decisions concerning rationalization, reallocation, adjustment and re-engineering, with a view to enhance the management and effective delivery of the Agency's programs. Our review of the proceedings of the Agency's Executive Committee, and the fact that some program Centres continue to lapse funds annually while the laboratories continue to be underfunded, lead us to conclude that the Agency's senior management has not engaged in the program rationalization and reallocation activities intended in the Strategic Plan.

7. The Strategic Plan emphasizes that science is at the core of what the Agency does, yet the Agency currently lacks a strategic plan for its science and research activities, to bring a measure of cohesion to the work of the program Centres and the laboratories. The Agency has recognized the need for a Science and Research Strategic Plan, and has appointed a team to solicit inputs from Agency staff and develop a plan by March 2011.

## Role of the Chief Science Advisor / Officer

8. The incumbent of the position of Scientific Director General of NML has been assigned a second role as the Agency's Chief Science Advisor. As Scientific Director General of NML, the position reports to the Assistant Deputy Minister (ADM) of IDPC Branch. As the Chief Science Advisor, the position reports directly to the Chief Public Health Officer (CPHO).

9. No job description exists for the position of Chief Science Advisor, and the absence of clearly defined roles and responsibilities has created confusion on the role the position is intended to play. We noted that there is currently no science coordination and science policy integration within the Agency. This has an impact on the nature and scope of the science and research activities undertaken by the laboratories. As well, there is a perception of a potential lack of objectivity in decisions regarding the NML due to the two responsibilities being held by one individual.

10. The Agency's new organization chart identifies the position as Chief Science Officer, still reporting to the CPHO, but it is unclear whether the name change is intended to reflect a new role for the position.

## Adequacy of Resources

11. The Agency has a Strategic Human Resources Plan. However it is not aligned with the strategic plans at the Agency, Branch or laboratory levels, as envisioned in the Agency's Strategic Plan. The lack of integrated human resources planning for the laboratories and annual business planning could lead to challenges in achieving proper delivery of human resource services for the laboratories.There is a need for

the Agency to strengthen its planning efforts for the laboratories.

12. While the laboratories have undertaken some initial succession planning, the need for more comprehensive planning remains, particularly at the more senior management levels and where the recruitment of highly qualified scientists must be done internationally.

13. Some areas of the Agency have historically lapsed funds, while the NML has faced annual funding shortfalls and relied on the Agency's lapsing funds for core, ongoing activities. There is a need for the Agency to address these ongoing funding shortfalls.

### Quality and Relevance of Laboratory Science and Research Activities

14. We found that the scientific staff at the NML, the LFZ and the National HIV and Retrovirology Laboratories has access to state-of-the-art scientific tools and equipment that enable them to perform the science and research to the level of excellence required to maintain their accreditation as reference laboratories, and to provide the testing services required of their clients and stakeholders.

15. Both NML and LFZ continue to meet their accreditation requirements under ISO 17025 and ISO 15189. They have appropriate quality management systems in place as required for ISO accreditation, and to fulfil their reference laboratory services.

16. Both NML and LFZ have recently completed client / stakeholder satisfaction surveys. The results of the client satisfaction survey we conducted as part of the audit were consistent with those carried out by the laboratories. While turn-around times and enhanced communications were noted as potential areas for improvement, the survey results clearly indicated a high level of client satisfaction with the services provided by both laboratories.

### Conclusion

17. We concluded that the laboratories appear to be **doing things right** – program objectives and priorities exist for the laboratory activities, and the level of excellence of the science and research continues to meet the ISO accreditation requirements and the needs of the clients and stakeholders.

18. What is not clear is whether the laboratories are **doing the right things** – there is a lack of senior corporate management oversight of the science and research activities of the laboratories, the lack of strategic direction at the Branch level to guide and set priorities for the laboratories and the Centres to ensure alignment with the Agency's strategic priorities, and the lack of clearly defined authorities, accountabilities, roles and responsibilities for the laboratories and the Centres to ensure the best use of Agency resources.

## Statement of Assurance

19. In my professional judgment as Chief Audit and Evaluation Executive, sufficient and appropriate audit procedures have been conducted and evidence gathered to support the accuracy of the audit conclusion provided and contained in this report. The audit conclusion is based on a comparison of the conditions, as they existed at the time, against pre-established audit criteria (see Appendix A) within the scope described herein.

Christian Asselin, CA, CMA, CFE
Chief Audit and Evaluation Executive

## Management Response

20. The Agency's management agrees with our findings and recommendations and a management action plan is presented in Appendix B.

# Background

21. Science is at the core of what the Agency does, and to fulfill its mandate it is essential that PHAC have a strong and responsive science and research capacity. The Agency's laboratory science and research activities are carried out in two laboratories, the National Microbiology Laboratory (NML) and the Laboratory for Foodborne Zoonoses (LFZ).

22. On February 15, 2010, the Chief Public Health Officer (CPHO) announced a new organizational structure for the Agency. The new structure includes two program Branches reporting to the CPHO through the Senior Assistant Deputy Minister Programs. The program Branches include the Infectious Disease Prevention and Control (IDPC) Branch and the Health Promotion and Chronic Disease Prevention (HPCDP) Branch.

23. The Agency's two scientific laboratories form part of the IDPC Branch and report to the Assistant Deputy Minister IDPC Branch. Figure 1 presents the Agency's new organizational structure.

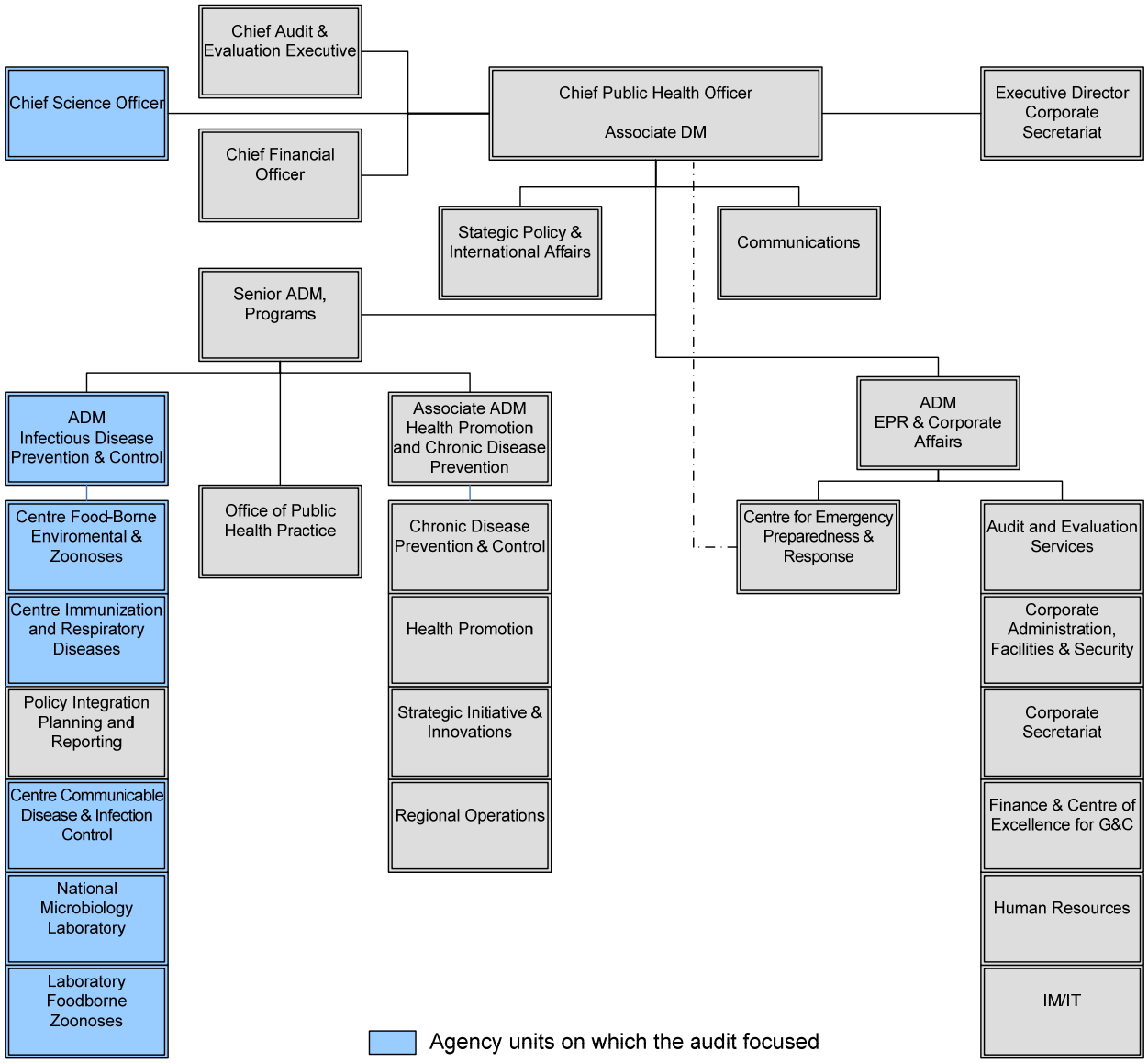
## Mandates of PHAC and Selected Organizational Units

24. In order to assess the management of the Agency's laboratories, we first needed to establish whether the science and research activities being performed in the laboratories were within the Agency's mandate.

25. The Agency was established under the *Public Health Agency of Canada Act* for "the purpose of assisting the Minister of Health in exercising or performing the Minister's powers, duties and functions in relation to public health." Among other things, the powers, duties and functions of the Minister in relation to public health are included under the *Department of Health Act* and include:

    - The promotion and preservation of the physical, mental and social well-being of the people of Canada;
    - The protection of the people of Canada against risks to health and the spreading of diseases;
    - The investigation and research into public health, including the monitoring of diseases;
    - The protection of public health on railways, ships, aircraft and all other methods of transportation, and their ancillary services;
    - The collection, analysis, interpretation, publication and distribution of information relating to public health; and,
    - The cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

**Figure 1: PHAC Organization Effective February 2010***




* Reflects current organizational structure at the time of the audit.

26. In developing our audit criteria (Appendix A), we also looked at the preamble to the *Public Health Agency of Canada Act*, which outlines the following principles and goals that Parliament sought to achieve through the creation of the Agency:

- To take public health measures, including measures relating to health protection and promotion, population health assessment, health surveillance, disease and injury prevention, and public health emergency preparedness and response;
- To foster collaboration within the field of public health and to coordinate federal policies and programs in the area of public health;
- To promote cooperation and consultation in the field of public health with provincial and territorial governments;

- To foster cooperation in that field with foreign governments and international organizations, as well as other interested persons or organizations; and
- To contribute to federal efforts to identify and reduce public health risk factors and to support national readiness for public health threats.

27. Based on this legislative context, the Agency has defined mandate statements for itself and for its organizational units. Figure 2 lists the formal mandate statements currently in use for those elements of the Agency examined in this audit.

| Figure 2: Mandates of PHAC and Selected Organizational Units |
|---|
| **Public Health Agency of Canada (PHAC)**<br>• Strengthen Canada's ability to protect the health and safety of Canadians<br>• Oversee federal efforts to strengthen national capacity to identify and reduce risks to public health<br>• Develop, implement and assess policies and programs that enable Canadians to live a healthier life |
| **Infectious Disease Prevention and Control Branch (IDPC)**<br>• Prevent, eliminate and control infectious diseases<br>• Maintain the safety and health security of people, both nationally and internationally<br>• Reduce the global disease burden of illness |
| **Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (CFEZID)**<br>To assess and reduce the risk of foodborne, waterborne and zoonotic disease in Canadians, and as a result of the environment, through national surveillance and targeted activities |
| **Centre for Immunization and Respiratory Infectious Diseases (CIRID)**<br>To prevent, reduce or eliminate vaccine-preventable infectious respiratory diseases; reduce the negative impact of emerging and re-emerging infections; and maintain public and professional confidence in immunization programs in Canada |
| **Centre for Communicable Diseases and Infection Control (CCDIC)**<br>To address communicable diseases at large, while undertaking targeted prevention, control, support and research activities for communicable diseases that can be acquired within the community or health care settings, with a particular focus on diseases that affect vulnerable populations |
| **Laboratory for Foodborne Zoonoses (LFZ)**<br>To generate, synthesize and communicate science-based information and advice, and to provide expertise on public health risks associated with infectious diseases arising from the interface between humans, animals and the environment |
| **National Microbiology Laboratory (NML)**<br>To advance human health through laboratory leadership, scientific excellence and public health innovation |

## National Microbiology Laboratory (NML)

28. The Agency's National Microbiology Laboratory (NML) is co-located with the Canadian Food Inspection Agency's National Centre for Foreign Animal Disease (NCFAD) at the Canadian Science Centre for Human and Animal Health (CSCHAH) in Winnipeg. The National HIV and Retrovirology Laboratories located in Ottawa, organizationally report to NML. The CSCHAH is unique in its capability to accommodate the study of infectious diseases in both humans and animals at the highest level of bio-containment. NML and NCFAD have been at the forefront of international infectious disease research and response. The CSCHAH was the

first facility in the world to accommodate both human and animal research. Along with its Level 2 and Level 3 laboratories, it houses Canada's only Level 4 bio-containment laboratory, joining a select group of countries capable of working with the world's most deadly pathogens.

29. As Canada's leading public health infectious disease laboratory, NML continues to play a very significant role within the Agency. Its activities contribute directly to the health of Canadians by helping to monitor and control the spread of infectious disease through the core functions of reference and diagnostic services, surveillance, applied and discovery research, development and training, and emergency preparedness and outbreak response.

30. The NML is home to more than 400 employees, among them some of the world's most accomplished research scientists. At the same time, the NML has cultivated a training environment for the study of microbiology and infectious diseases; well over 100 post-doctoral fellows and graduate and undergraduate students are supervised by NML scientists in a given year.

## NML Programs

31. The NML combines both a national public health laboratory service mandate and internationally-recognized research programming aimed at established, emerging and rare pathogens. The NML resources are allocated to the national laboratory programs shown in Figure 3.

| Figure 3: National Microbiology Laboratory Programs |
|---|
| **Bacteriology and Enterics** - focussing on bacterial diseases, such as tuberculosis and meningitis, along with food and water-borne pathogens, such as E. coli and Salmonella, and infections affecting the human nervous and/or motor system including septicaemia and atypical respiratory tract infections |
| **Prion Diseases** - dealing with transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease |
| **Viral Diseases** - addressing a range of viral diseases, including hepatitis and other blood-borne pathogens, respiratory viruses and viral exanthemata, such as measles |
| **Zoonotic Diseases and Special Pathogens** - dealing with viral, bacterial and rickettsial zoonoses (diseases transmitted to humans from other species), such as West Nile Virus, along with biosafety level 4 agents such as Ebola, Marburg and Lassa fever viruses |
| **HIV and Retrovirology** - providing a comprehensive range of laboratory services and scientific expertise relating to HIV and emerging retroviruses |

32. The NML works directly or indirectly with a wide range of health partners, including academia, provincial and territorial laboratories, regional health authorities, international health organizations, research organizations, and other federal departments and agencies.

33. The NML has provided information on its significant achievements and contributions, which we have included in Appendix C.

### Financial Information

34. The following table outlines notional budgets of the NML by fund description for fiscal years 2008-2009 and 2009-2010.

| Fund Description | FY 08-09 (000's) | FY 09-10 (000's) |
|---|---|---|
| Salaries & Wages | $17,139 | $19,295 |
| Other Operating | $14,382 | $13,886 |
| **Total** | **$31,521** | **$33,181** |

Source: IDPC Notional Budget

## Laboratory for Foodborne Zoonoses (LFZ)

35. The Laboratory for Foodborne Zoonoses (LFZ) is located in Guelph, Ontario with satellite units in Lethbridge, Alberta and St-Hyacinthe, Québec. The Office of Biotechnology, Genomics and Population Health (BGPH), also part of the LFZ, is located in Toronto, Ontario. LFZ has the mandate to generate, synthesize and communicate science-based information and advice and to provide expertise on public health risks associated with infectious diseases arising from the interface between humans, animals and the environment. It has the ability to integrate scientific information and expertise from the molecular to the population level at the human /animal /environment interface.

36. LFZ activities are conducted by multi-disciplinary teams from a staff of 106 in traditional and molecular microbiology, microbial genomics, surveillance, immunology, risk assessment, predictive modeling, advanced epidemiological techniques, medical geography, veterinary science and veterinary public health, health policy and bioethics, and medicine.

### LFZ Programs

37. The work of LFZ is carried out under seven programs and activities as shown in Figure 4.

38. LFZ has strong linkages to local universities, partnerships and collaborations with other federal and provincial agencies working in related fields of activity, and involvement of relevant industry stakeholders. LFZ has reference laboratories for serotyping and phage typing of Salmonella spp, serotyping of Escherichia coli (VTEC) and antimicrobial resistance testing of enteric pathogens. The Salmonella Typing Laboratory is designated as an Office Internationale des Epizooties (OIE) Reference Laboratory for Salmonellosis.

| Figure 4: Laboratory for Foodborne Zoonoses Programs |
|---|
| **Policy advice and effectiveness.** To anticipate food safety / zoonoses issues and provide the best scientific evidence in support of policy and decision-making that optimizes public health impact |
| **Antimicrobial resistance in agri-food and aqua-culture and impact on human health.** To provide policy-makers and other governmental and non-governmental stakeholders with scientific information and advice to reduce or eliminate the impact on human health from antimicrobial resistant micro-organisms resulting from the use of antimicrobials in agri-food, aqua-culture and veterinary medicine |
| **Health risk modelling**. To develop models, tools and interpretations that improve the understanding of the human/animal/environment/microbe interface, so as to facilitate risk management decision-making |
| **Biotechnology, genomics and population health.** To apply knowledge from advances in biotechnology and genome-based research to prevent disease and improve the health of populations within an ethical, legal and socially acceptable framework in collaboration with federal and provincial government partners academia, and other national and international groups |
| **Host and pathogen determinants.** To conduct research into microbial and host factors that influence the emergence, persistence, virulence, and transmission of foodborne and water-borne pathogens from animals to humans |
| **Population and environmental determinants of zoonotic infections.** To provide research, geographical analysis and surveillance methods on population- and regional-level factors linked to the emergence, maintenance and transmission of zoonotic pathogens |
| **Integrated enteric pathogen surveillance.** To facilitate/support decisions made by policy-makers, regulators, public health departments, industry and the scientific community relative to the health risks associated with zoonotic enteropathogenic microorgamisms |

39. The LFZ has provided information on its significant achievements and contributions, which we have included in Appendix D.

## Financial Information

40. The following table outlines notional budgets of the LFZ by fund description for fiscal years 2008-2009 and 2009-2010.

| Fund Description | FY 08-09 (000's) | FY 09-10 (000's) |
|---|---|---|
| Salaries & Wages | $5,966 | $7,049 |
| Other Operating | $3,178 | $4,323 |
| **Total** | **$9,144** | **$11,372** |

Source: IDPC Notional Budget

# About the Audit

## Objectives

41. The objectives of this audit were to:

- Assess the Agency's governance and accountability framework, systems and practices for managing its laboratories with due regard to economy, efficiency and effectiveness and in accordance with its mandate;
- Assess the extent to which the Agency's laboratory activities support the Agency's program needs and those of its internal and external clients and stakeholders; and,
- Identify relevant opportunities for improvement.

## Scope

42. The scope of the audit included an examination of the governance and accountability structures and the management framework related to the Agency's laboratory activities. Specifically, the audit addressed the following elements:

- The Agency's strategic planning with respect to laboratory activities;
- The mandates of the laboratories and their alignment with the Agency's mandate, and linkages with the external organizations they support;
- Operational planning for the laboratories;
- Management of human and financial resources;
- Adequacy of laboratory tools and equipment;
- Quality assurance systems and practices;
- Client and stakeholder communications; and
- Senior management oversight of laboratory activities.

43. The audit did not examine the laboratory security, safety and occupational health, asset management and the Agency's mobile laboratories.

44. In March 2009, the Audit Committee approved the Agency's Risk-Based Audit Plan (2009-2014). The plan identified the audit of Laboratory Management as an audit project for 2010/11.

## Approach and Methodology

45. This audit was conducted in accordance with the Treasury Board (TB) Policy on Internal Audit and the Institute of Internal Auditors' (IIA) International Standards for the Professional Practice of Internal Auditing, except that no complete external assessment was performed to demonstrate full compliance with the IIA Standards.

46. The audit criteria presented in Appendix A were derived from the Framework of Core Management Controls and Audit Criteria, prepared by the Office of the Comptroller General.

47. The audit team used a combination of audit methodologies, including:

- Interviews with PHAC corporate senior management and support services, and laboratory management at senior and middle management levels. Interviews were also held with officials at the National Research Council of Canada, Health Canada and Centres for Diseases Control and Prevention in Atlanta, USA;
- Review of the relevant documents related to strategic planning, science and research programs and laboratory Quality Management Systems;
- Site visits to the selected laboratories to review laboratory tools and equipment; and
- Survey questionnaires sent to selected clients and stakeholders of the laboratories.

# Audit Findings and Recommendations

## Structure of the Agency's Program Delivery

48. As we began our examination of the science and research work performed in the Agency's laboratories, it became apparent that the Agency's programs were not being delivered by the laboratories alone, but that the Infectious Disease Prevention and Control (IDPC) Branch Centres and the Health Promotion and Chronic Disease Prevention (HPCDP) Branch Centre also played a significant but different role in delivering programs. What was less apparent, not only to the audit team but to the Centres and the laboratories as well, was how these two program delivery models were intended to interact with each other.

49. The three Centres that form part of the IDPC Branch are the Centre for Food-borne, Environmental and Zoonotic Infectious Diseases (CFEZID), the Centre for Immunization and Respiratory Infectious Diseases (CIRID), and the Centre for Communicable Diseases and Infection Control (CCDIC). Mandate statements for each of the Centres have been written and are presented in the Background section of this report. What have not been formally defined and clearly communicated throughout the Agency are authority and accountability statements, and roles and responsibilities for the Centres and the laboratories, that would clearly delineate how the Centres and the laboratories are intended to interact and that would facilitate decisions and actions to be taken.

50. We were advised that a structural model introduced in the past by the Agency's senior management had the Centres providing a policy function and defining what science and research should be undertaken by the Agency. The laboratories were then to perform the science and research identified by the Centres. At the time of our audit, managers in both the Centres and the laboratories commented that this program delivery model was not functioning as originally designed. Instead, the Centres' programs mainly focused on surveillance activities, supported where necessary by science and research requested from the NML and LFZ, and in some cases from laboratories outside the Agency. Aside from supporting the

Centres, the laboratories are engaged in a wide range of science and research activities, reference and diagnostic testing services for a broad spectrum of clients and stakeholders, and national and international collaborative activities, as noted earlier in this report.

51. A concern expressed to us frequently during the audit was the need for improved communications between the Centres and the laboratories. We were advised that each was often not aware of the full range of activities of the other, particularly when they involved activities of primary interest to them. The stated lack of adequate communication thus provides the potential for gaps and duplications of work, or missed opportunities for synergy and collaborative work.

### Recommendations

52. The Assistant Deputy Minister Infectious Disease Prevention and Control (IDPC) Branch, in collaboration with the Directors General of the National Microbiology Laboratory, the Laboratory for Foodborne Zoonoses, and the program Centres of the IDPC Branch, should develop clearly defined mandate statements, including authorities, accountabilities, roles and responsibilities, for the Centres and the laboratories, and communicate these widely across the Agency.

53. In addressing the first recommendation, the Assistant Deputy Minister Infectious Disease Prevention and Control Branch should put in place mechanisms to improve the level of communications and interactions among the program Centres and the laboratories to ensure the efficient, effective and economical use of Agency resources.

## Governance and Strategic Directions

54. We expected to find that the Agency had set out its corporate strategic directions, objectives and priorities in a strategic plan, and that this plan would provide a framework for the PHAC Branches, program Centres and laboratories to develop their own strategic planning and governance documents, aligned with those of the Agency.

55. We also expected to find that program objectives and priorities had been established for all laboratory activities, consistent with the Agency's objectives and priorities, and with the needs of the clients and stakeholders of the laboratories. We considered it important that the objectives and priorities for all laboratory activities be effectively communicated to, and understood by, all Agency program and research staff.

### The Agency's Strategic Plan

56. The Agency has published its first Strategic Plan 2007-2012. The Plan is intended to guide and set priorities for the work of the Agency over its five-year planning horizon, to align resources behind those priorities, and to help coordinate the Agency's internal planning and management. It is also intended to help

communicate the Agency's vision to its partners, stakeholders, and to the public.

57. The Plan includes a statement from the Minister acknowledging that the Agency continues to support the Government of Canada's public health priorities, while operating in concert with and complementing the efforts of Health Canada, the Canadian Institutes of Health Research, and the other members of the Health Portfolio. The Chief Public Health Officer commits the Agency to deliver on the Government of Canada's commitment to help protect and promote the health and safety of all Canadians. He notes that science is at the core of what the Agency does, and it is therefore imperative that the information and knowledge the Agency acquires is translated for effective use not only in the public health community at large, but by the Agency itself.

58. The Plan sets out the Agency's strategic objectives / priorities as:

- To anticipate and respond to the health needs of Canadians;
- To ensure actions are supported by integrated information and knowledge functions; and
- To further develop PHAC's dedicated, professional workforce by providing it with the tools and leadership it needs and by ensuring a supportive culture.

59. The following extract sets out the Agency's expectations for the overall guidance that the Plan will provide to all aspects of the work of the Agency:

"Clear strategic directions and priorities will provide the policy overlay to ensure that annual business plans are well-integrated, resources are aligned accordingly, and the entire effort is supported by integrated human resources planning and clear accountabilities. The Plan also provides the foundation for the Agency to critically review all of its programs and make decisions concerning rationalization, reallocation, adjustment and re-engineering, with a view to enhance the management and effective delivery of the Agency's programs and to ensure that its interventions have achieved measureable progress."

60. We found that the guidance and intended outcomes envisioned by the Agency's Strategic Plan, as they relate to the work of the laboratories and that of the program Centres, have yet to be fully realized. As we discuss in the following sections of the report, clear strategic directions and priorities exist unevenly in the Agency. Furthermore, while the Plan highlights that science is at the core of what the Agency does, we found a lack of consensus on the meaning of the term "science" and the absence of a strategic plan for managing the science carried out in the laboratories and in the other Agency components.

### Strategic Plans of the Program Branches

61. The Health Promotion and Chronic Disease Prevention (HPCDP) Branch is one of the two program Branches reporting to the Senior Assistant Deputy Minister Programs (Figure 1). The Branch has published its Strategic Framework 2010-2015, the stated objective of which is "to identify and act on key areas of emphasis that will strengthen the results of the Branch in contributing to the Agency's

Strategic Outcomes and Priorities." The Branch considers the Framework as being fundamental to delivering on its mandate, providing a strong sense of direction and establishing a clear set of priorities to guide the Branch's work.

62. The Infectious Disease Prevention and Control (IDPC) Branch is the second program Branch reporting to the Senior Assistant Deputy Minister Programs (Figure 1). The Agency's two scientific laboratories and three of its program Centres are part of this Branch. The IDPC Branch has not prepared a strategic planning document to guide the work of the Agency's laboratories and that of the program Centres. Instead, the Branch relies on the Agency's Strategic Plan and works closely with the Strategic Planning Directorate (SPD) when input is required for strategic planning at the Agency level. The Branch also uses the annual Integrated Operational Plan (IOP) exercise to aid in its planning process. We noted that the IDPC Branch management held a retreat in April 2010 that considered refreshing the Branch's program strategy. This initial planning process could eventually result in the preparation of a strategic plan for the Branch that will provide the guidance and set priorities needed for the program Centres and the laboratories.

63. In our view, the lack of a strategic plan for the IDPC Branch is contributing to the current situation in which the laboratories and program Centres are establishing their strategic directions and priorities independently, but with little assurance that the individual priorities best serve the needs of the Branch or of the Agency. We believe it also contributes to the lack of a mutual understanding of priorities among the program Centres and the laboratories.

**Strategic Planning – National Microbiology Laboratory (NML)**

64. The NML has prepared a strategic planning document entitled Strategic Directions 2006. Since the document predates the Agency's Strategic Plan (2007-2012), it does not align itself with the Agency's existing corporate Plan. Instead, it sets out general directions for the NML to maximize its contribution to the prevention and control of infectious diseases in Canada and worldwide. The directions are designed to guide the creation of business and operating plans by the NML's component programs.

65. The Strategic Directions 2006 identified the following five strategic directions to guide the NML in the fulfillment of its vision as a world-class organization dedicated to the protection of Canadian and global public health and recognized for delivering excellence in public health laboratory programming and leadership, research and training:

- Become the Canadian and International laboratory of choice for research scientists, post-doctorates and graduate students as well as non-scientific employees pursuing a career in public health;
- Strengthen the NML's ties with its international partners and its presence in international communities, to foster mutual sharing, support and recognition;
- Improve emergency preparedness and outbreak response capabilities within the laboratory and at the national level;

- Continue to develop and transfer knowledge and tools to support the individual and collective efforts of the NML's public health partners in preventing and controlling the spread of infectious disease; and,
- Enhance laboratory and field capacity related to the surveillance, identification and characterization of emerging and rare infectious diseases in both human and animal populations.

### Strategic Planning – Laboratory for Foodborne Zoonoses (LFZ)

66. LFZ has not published a formal strategic plan, because there has not been an Agency policy or requirement for the laboratories to do so. It has, however, conducted internal visioning and strategic planning sessions, the most recent being in March 2010. The laboratory's strategic science goals confirmed at that time include the following:

    - To determine and monitor the incidence, trends, reservoirs and sources of enteric infections along the food chain and in the environment and their modes of transmissions to humans;
    - To identify and monitor the nature, determinants, trends and incidents of antimicrobial resistance in animal and foodborne microorganisms with respect to the impact of agri-food or aquaculture use of antimicrobials on the emergence and transmission of antimicrobial resistance in human pathogens;
    - To generate risk assessments of enteric pathogens with respect to their emergence and occurrence along the food chain, and their transmission to humans;
    - To determine the host, pathogen, and ecological risk factors influencing the emergence, maintenance and spread of enteric pathogens in animal reservoirs, the food chain, and the environment, and the occurrence of human infection and disease, with special reference to Salmonella, Campylobacter, and Vero-toxin producing E. coli;
    - To develop and/or evaluate strategies to reduce the occurrence of enteric pathogens in animal reservoirs, animal products and the environment, with special reference to Salmonella, Campylobacter, and Vero-toxin producing E. coli;
    - To evaluate the effectiveness of food safety and public health policies, programs and practices in reducing the impact of enteric disease in human populations; and,
    - The goal of the Office of Biotechnology, Genomics and Population Health (OBGPH) is to contribute to efforts to mitigate adverse outcomes of both infectious and chronic diseases that are influenced by individuals' genetic predisposition.

### Lack of an Agency Strategic Science Plan

67. Given the absence of an IDPC Branch Strategic Plan, we sought to determine how the priorities were established for the science and research that was being

conducted at the NML and LFZ laboratories, and at the program Centres as well. We wanted to identify what levels of management set the priorities and approved the proposed research projects, and whether the processes in place ensured that the science and research carried out in the laboratories supported the Agency's strategic priorities.

68. We expected that the Agency's senior management would be kept informed on a regular basis on the science and research activities and priorities of the laboratories, and that senior management would then use that knowledge to make organizational and program decisions where appropriate. We expected that an appropriate mechanism would be in place to regularly review proposed chronic and infectious disease science and research activities and to allocate budgets consistent with the Agency's strategic priorities.

69. We first noted that in our discussions with the senior managers in the laboratories and program Centres, there were differing definitions and interpretations applied to the terms "science" and "research". This is recognized by the Agency, and clarifying these definitions has been identified as a component of the work leading to a new strategic plan for science and research. We further noted that the science and research priorities carried out by the program Centres and the laboratories were established by the Centres and laboratories themselves. The practices varied for the two laboratories, in some cases the project approvals occurred at the scientist, section chief, and division director levels, and in other cases the Director General also played a role in establishing the priorities.

70. From our discussions with the senior managers of the laboratories, and our review of the records of decisions of the Agency's Executive Committee, we noted that the Agency's senior management are not kept informed, on a regular basis, of the science and research carried out in the laboratories and as a consequence do not make decisions concerning rationalization, reallocation, adjustment and re-engineering, with a view to enhance the management and effective delivery of the Agency's programs, as envisioned in the Agency's Strategic Plan.

71. The Agency is well aware of the importance of having a strategic plan for science and research, and has approved a project to put in place such a plan by March 2011. The project will provide for wide consultations for input from all staff levels and areas of expertise in the Agency, and will be led by the Chief Science Officer and the Director General, Strategic Policy and International Affairs.

## Recommendations

72. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should develop and communicate a strategic directions document for the Branch, establishing a clear set of priorities for the laboratories and program Centres, and aligned with the strategic directions and priorities of the Agency, and which would become guidance for the Agency's Science and Research Strategic Plan soon to be under development.

## Role of the Chief Science Advisor / Officer

73. The incumbent of the position of Scientific Director General of the National Microbiology Laboratory is also assigned a second responsibility as the Agency's Chief Science Advisor. As Scientific Director General of NML, the position reports to the ADM of IDPC Branch. As the Agency's Chief Science Advisor, the position reports directly to the Chief Public Health Officer (CPHO).

74. An Executive Position Description has been written for the position of Scientific Director General NML. However, the document was prepared effective April 1, 2002, and the information it contains relates to organizational structures, reporting relationships and the nature and scope of accountabilities that existed in Health Canada at the time. The document has not been updated to reflect the revised circumstances now existing since the creation of the Public Health Agency of Canada in 2004. No Executive Position Description exists for the position of the Chief Science Advisor. We were advised that this is because it is not a classified position.

75. The Agency's website contains a brief reference to the Office of Chief Science Advisor, as follows: "The Office has an Agency-wide mandate related to science co-ordination and science policy integration, and works toward strengthening the Agency's scientific networks both internally and nationally."

76. In our view, the absence of clearly defined responsibilities and accountabilities for the Chief Science Advisor position has led to confusion on the role the incumbent is intended to play. We noted that there is currently no formalized science coordination and science policy integration with in the Agency. This has an impact on the nature and scope of the science and research activities undertaken by the laboratories. This situation has also created a perception of potential lack of objectivity in decisions regarding the NML due to the two responsibilities being held by one individual.

77. The Agency's new organizational structure, which came into effect February 15, 2010, identifies the position of Chief Science Officer, reporting directly to the CPHO. It is not clear whether the change in title is intended to reflect a proposed change in the role of the Chief Science Advisor. In either case, it would appear to be an appropriate time to prepare and communicate a roles and responsibilities document for the position, under whichever title will prevail.

### Recommendations

78. The Director General Human Resources, in consultation with the Chief Science Officer, should draft, obtain approval for, and communicate widely throughout the Agency a clearly defined set of roles and responsibilities for the position of Chief Science Officer.

79. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should coordinate, approve and communicate widely throughout the Agency an updated job description, reporting relationships and accountabilities document for the position of Scientific Director General of the National Microbiology Laboratory.

## Adequacy of Resources

80. We expected that the Agency would have appropriate systems in place to ensure that the human and financial resources required for the science and research activities of the laboratories were properly planned and managed with due regard to economy and efficiency.

### Human Resources

81. The NML and LFZ receive human resources support services from advisors located in Winnipeg and Guelph respectively. Staffing is done locally with the exception of executive level positions, which are handled in Ottawa by the Agency's Executive Services Division.

82. The Agency has a Strategic Human Resources Plan. However, it is not aligned with strategic plans at the Agency, Branch or laboratory levels, as envisioned in the Agency's Strategic Plan. In our view, the lack of integrated human resources planning for the laboratories and annual business planning could lead to challenges in achieving proper delivery of human resources services for the laboratories.

83. While laboratories have undertaken some initial work on succession planning, the need to put in place a more rigorous plan remains, particularly at the more senior management levels in the laboratories. As with other science-based departments and agencies in government, the Agency faces common challenges in staffing and retention for certain scientific positions, including the need for security clearances and the ability to offer competitive rates of pay. These factors take on increased relevance when recruiting efforts to attract highly qualified scientists extend into many countries around the world.

### Financial Resources

84. We noted from the NML's Operational Business Plan that its program areas have historically incurred annual funding shortfalls for some of their core, ongoing activities, thus forcing the NML to rely on lapsing funds from other areas of the Agency. In addition, we noted that program Centres have historically been lapsing funds. Finally, the Agency as a whole has been lapsing funds on an annual basis. Therefore, the Agency needs to examine its funding allocations to the NML.

85. NML has identified that the lack of a stable, multi-year capital funding allocation is an impediment to proper project planning. LFZ has also informed us that the absence of long- term capital funding constitutes a challenge as it relates to budgetary and other planning functions.

### Recommendations

86. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should ensure that the Agency's human resources planning for the laboratories is fully integrated with its strategic and operational business planning, with particular attention to the staffing and succession planning requirements of the laboratories.

87. The Senior Assistant Deputy Minister Programs, Assistant Deputy Minister Infectious Disease Prevention and Control Branch and Scientific Director General National Microbiology Laboratory, in collaboration with the Chief Financial Officer, should review the annual funding allocations to address the recurring annual funding shortfall of the NML.

## Quality and Relevance of Laboratory Science and Research Activities

88. We expected to find that laboratory staff have access to adequate tools and equipment to perform the science and research to the level of excellence required of reference laboratories, that laboratory diagnostic and reference services meet the needs of the Agency's clients and stakeholders, and that appropriate quality assurance systems and practices are in place for the laboratories to ensure accurate and timely diagnostic and reference service information.

### Tools and Equipment

89. Our interviews with the laboratory management and scientific staff of both the NML and LFZ laboratories, and our site visits to individual laboratories within the facilities, all confirm that the laboratory staff have access to state-of-the-art equipment and the funding necessary to maintain and replace that equipment. This includes the National HIV and Retrovirology Laboratories, which organizationally report to NML but are physically located in Ottawa.

### Accreditations

90. To ensure excellence in its reference and diagnostic services, NML has attained ISO17025 accreditation, an international standard governing the "general requirements for the competence of testing and calibration laboratories." The Standards Council of Canada (SCC) is the accrediting body. NML notes that to date, 34 widely performed tests in 10 laboratory sections have been accredited or assessed for accreditation by the SCC, with work ongoing to increase the scope of accreditation.

91. The NML is an active member of many disease/issue specific international and World Health Organization (WHO) laboratory networks. For some of these WHO networks, there are accreditation/certification requirements to ensure there is high quality and standardization across the WHO laboratory networks. In this regard, the NML was certified in July 2008 as a Regional Reference Laboratory for the WHO Measles and Rubella LabNet. In October, 2009, the NML was granted full

entry into the Global Polio Laboratory Network and given formal accreditation as a Pan American Health Organization (PAHO) / WHO Polio Regional Reference Laboratory. The National HIV and Retrovirology Laboratories, which now report to NML, have attained accreditation under ISO15189.

92. LFZ has also attained SCC accreditation to ISO/IEC 17025. LFZ's accredited laboratory services are for serotyping of *E. coli,* antimicrobial resistance testing of enteric pathogens, and serotyping and phagetyping of *Salmonella spp* . LFZ is designated as an Office Internationale des Epizootes (OIE) reference laboratory for *Salmonellosis.*

93. Our audit included a review of the accreditation reports from SCC for both NML and LFZ, and the laboratory responses to the SCC audit findings. Both laboratories continue to maintain their accreditations and are thus meeting the level of excellence required of their reference and diagnostic activities.

### Quality Assurance Systems

94. A requirement for the ISO 17025 accreditation is to have a quality management system that incorporates provisions for performance standards and continuous improvement. Both NML and LFZ have Quality Manuals in place. The Quality Manuals set out in detail the quality assurance systems, including management oversight provisions and audit provisions that govern the testing services performed by the laboratories to ensure compliance with the requirements of the ISO Standards.

95. The Quality Manuals specify the roles and responsibilities of the key laboratory personnel who have an involvement or influence in testing services. These include various levels of the laboratory management, as well as staff appointed as Quality Manager and Quality Officer. The Manuals provide for an annual management review of quality issues, and for the recording of corrective or preventative actions or continuous improvement activities arising from the annual reviews to ensure appropriate follow-up is performed.

96. From our review of the Quality Manuals and the laboratories' achievement of ISO Standards accreditation for which they are a requirement, we conclude that the laboratories have appropriate quality assurance systems and practices in place to ensure accurate and timely diagnostic and reference service information.

### Client / Stakeholder Satisfaction Surveys

97. In March 2007, the LFZ distributed a customer survey to 75 clients in order to assess the level of client satisfaction with its reference services and to identify opportunities for improvement. There was a 40 percent response rate from customers that included government, academic, and private laboratories. The responses indicated an overall high level of satisfaction with the LFZ reference service, and a high level of confidence in the validity of the results. While more than half of respondents indicated the service turn-around time was either good or

better, areas for improvement would include investigating shortening laboratory testing turn-around times where possible, reviewing the LFZ Guelph's scope of accredited laboratory tests, and reviewing data sharing agreements. Another client satisfaction was sent out in February 2010, with the results expected to be tabulated in June.

98. The NML launched a web-based Client Satisfaction and Needs Assessment Survey in July 2008. By November 2008, 46 survey responses had been received. The respondents represented virtually all provinces of Canada, provincial laboratories, hospitals and public health units, and a range of professions. The results summary shows that the respondents indicated overall satisfaction with the reference services offered by the NML, ranking satisfaction with personnel and consultations services highly. Turn-around times and report forms were identified as areas to focus improvement efforts.

99. We conducted a limited client satisfaction survey of our own. We sent an email questionnaire to 11 major LFZ clients and 8 provincial laboratories as NML clients. Our response rate for LFZ was only 18 percent, but for NML was 50 percent. Despite the limited response rates, the respondents rated both laboratories as high or very high in level of satisfaction with the services provided. Once again, however, turn-around times were identified as an area for improvement, and the need for enhanced communication and expanded reference services were also identified.

100. While there remain areas for improvement for both laboratories in fully satisfying client needs, we conclude that overall client needs are being well met by both laboratories.

## Conclusion

101. We concluded that the laboratories appear to be **doing things right** – program objectives and priorities exist for the laboratory activities, and the level of excellence of the science and research continues to meet the ISO accreditation requirements and the needs of the clients and stakeholders.

102. What is not clear is whether the laboratories are **doing the right things** – there is a lack of senior corporate management oversight of the science and research activities of the laboratories, the lack of strategic direction at the Branch level to guide and set priorities for the laboratories and the Centres to ensure alignment with the Agency's strategic priorities, and the lack of clearly defined authorities, accountabilities, roles and responsibilities for the laboratories and the Centres to ensure the best use of Agency resources.

## Acknowledgments

103. We wish to express our appreciation for the cooperation and assistance afforded to the audit team by management and staff during the course of this audit.

# Appendix A: Audit Criteria

104. The following criteria were derived from the Framework of Core Management Controls and Audit Criteria, prepared by the Office of the Comptroller General:

### 1.0 Governance and strategic directions are in place and adequately communicated

| # | Audit Sub-Criteria | Link to audit objective # | Link to MAF |
|---|---|---|---|
| **1.1** | Strategic direction and objectives have been established and documented for the Agency and its Branches. Consideration is given to government priorities, identified risks and client needs. | Objective # 1 | Governance and Strategic Direction |
| **1.2** | Program objectives and priorities exist for all laboratory activities, and are aligned with the Agency's strategic objectives and priorities and to client needs. | Objective # 1 | Governance and Strategic Direction |
| **1.3** | Agency strategic direction and priorities and program objectives and priorities are effectively communicated to all Agency program and research staff. | Objective # 1 | Governance and Strategic Direction |

### 2.0 The management framework and accountability structures in place ensure the efficient, effective and economical use of PHAC resources

| # | Audit Sub-Criteria | Link to audit objective # | Link to MAF |
|---|---|---|---|
| **2.1** | Authority and accountability are clearly defined, documented and understood by staff so that decisions and actions are taken. | Objective # 1 | Accountability |
| **2.2** | The roles and responsibilities of the PHAC labsoratories, programs and Centres are formally defined and clearly communicated throughout the Agency and with its clients and stakeholders. | Objective # 1 | Accountability |
| **2.3** | An appropriate mechanism is operating on a regular basis to review proposed chronic and infectious disease science and research activities and to allocate budgets consistent with the Agency's strategic priorities. | Objective # 1 | Governance and Strategic Direction / Stewardship |

| | | | |
|---|---|---|---|
| **2.4** | Laboratory and program management report regularly to PHAC senior management on their science and research activities and performance, and their responsiveness to client needs. | Objectives # 1 & 2 | Accountability / Client-focused service |
| **2.5** | Documentary evidence exists to show that management uses the knowledge obtained from laboratory science and research activities to make organizational and program decisions. | Objectives # 1 & 2 | Policy and Programs / Client-focused Service |
| **2.6** | Resources (human, financial and information) are properly planned and managed with due regard to economy and efficiency. | Objectives # 1 & 2 | People / Stewardship |
| **2.7** | Laboratory staff have access to adequate tools and equipment to perform the research and science to the level of excellence required of reference laboratories as defined in ISO standards. | Objective # 2 | Stewardship / Results and Performance |
| **2.8** | Laboratory diagnostic/reference service activities meet the needs of the Agency's clients/stakeholders and include timely reporting of results to them according to agreed metrics. | Objective # 2 | Client-focused Service / Results and Performance |
| **2.9** | Laboratories have appropriate quality assurance systems and practices in place to ensure accurate and timely diagnostic/reference service information. | Objective # 2 | Results and Performance / Client-focused Service |

# Appendix B: Management Action Plan

| Recommendation | Management Action Plan | Officer of Prime Interest | Target Date |
|---|---|---|---|
| **Structure of the Agency's Program Delivery** | | | |
| 52. The Assistant Deputy Minister Infectious Disease Prevention and Control (IDPC) Branch, in collaboration with the Directors General of the National Microbiology Laboratory, the Laboratory for Foodborne Zoonoses, and the program Centres of the IDPC Branch, should develop clearly defined mandate statements, including authorities, accountabilities, roles and responsibilities, for the Centres and the laboratories, and communicate these widely across the Agency. | Agree. The Assistant Deputy Minister Infectious Disease Prevention and Control (ADM IDPC) will work collaboratively through the following mechanisms to determine the most effective means in articulating the Branch's authorities, accountabilities and roles and responsibilities by creating an ad hoc working group that reports to IDPC-BEC:<br>a) This working group will review key documents such as the Agency's Strategic Plan, RPP and DPR and ensure that roles and responsibilities align with current IOP exercise and outcomes;<br>b) The topic will be discussed at an IDPC Branch management retreat, which has been scheduled in July 2010;<br>c) Finalize recommendations for ADM and for presentation to various PHAC governance bodies, including PHAC-EC. | ADM IDPC | Sept 2010 |

| Recommendation | Management Action Plan | Officer of Prime Interest | Target Date |
|---|---|---|---|
| 53. In addressing the first recommendation, the Assistant Deputy Minister Infectious Disease Prevention and Control Branch should put in place mechanisms to improve the level of communications and interactions among the program Centres and the laboratories to ensure the efficient, effective and economical use of Agency resources. | Agree. The ADM IDPC will:<br>a) Build on existing models for collaboration and communication among Centres and Laboratories, such as is in place for HPV and HIV working groups<br>b) Apply and integrate the models to relevant Branch activities<br>c) Formalize processes of the existing models of communication and interactions among program Centres and the Laboratories | ADM IDPC | Sept 2010<br><br>Sept 2010<br><br>March 2011 |
| **Governance and Strategic Directions**<br><br>72. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should develop and communicate a strategic directions document for the Branch, establishing a clear set of priorities for the laboratories and program Centres, and aligned with the strategic directions and priorities of the Agency, and which would become guidance for the Agency's Science and Research Strategic Plan soon to be under development. | Agree. The ADM IDPC will:<br>a) Develop a Five-Year Branch Strategic Plan, ensuring to align its priorities to the Agency's strategic directions and priorities as evidenced in the annual RPP, and to the Science and Research Plan being developed.<br>b) Present its Strategic Plan to PHAC EC. | ADM IDPC | December 2010 (full draft)<br><br>March 2011 (final, approved) |
| **Role of the Chief Science Advisor / Officer**<br><br>78. In order to address the perception of a potential lack of objectivity noted above, the Director General Human Resources, in consultation with the Chief Science Officer, should draft, | Agree. The Director General Human Resources will work collaboratively with the CPHO to develop a description of roles and responsibilities for the position of Chief Science Officer. | DG HR & CPHO | September 2010 with a review by end of March |

| Recommendation | Management Action Plan | Officer of Prime Interest | Target Date |
|---|---|---|---|
| obtain approval for, and communicate widely throughout the Agency a clearly defined set of roles and responsibilities for the position of Chief Science Officer. | | | 2011 to align with the Science and Research Strategy Plan |
| 79. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should coordinate, approve and communicate widely throughout the Agency an updated job description, reporting relationships and accountabilities document for the position of Scientific Director General of the National Microbiology Laboratory. | Agree. The ADM IDPC will work collaboratively with PHAC Human Resources Directorate to develop and approve a work description and subsequent accountabilities for the position of Scientific Director General of the National Microbiology Laboratory and will present it to PHAC EC. | ADM IDPC, ADM EPR & Corporate Affairs, DG HR | Sept 2010 |
| **Adequacy of Resources**<br><br>86. The Assistant Deputy Minister Infectious Disease Prevention and Control Branch should ensure that the Agency's human resources planning for the laboratories is fully integrated with its strategic and operational business planning, with particular attention to the staffing and succession planning requirements of the laboratories.. | Agree. The ADM IDPC will ensure that the Agency's human resources planning for the laboratories is fully integrated with its strategic and operational business planning, as is evidenced in the 2010-11 Integrated Operational Planning (IOP) exercise, expanding it into its Five-Year Branch Strategic Plan. Development of the plan will include consultations with PHAC Human Resources Directorate. | ADM IDPC, ADM EPR & Corporate Affairs, DG HR | Dec 2010 |

| Recommendation | Management Action Plan | Officer of Prime Interest | Target Date |
|---|---|---|---|
| 87. The Senior Assistant Deputy Minister Programs, Assistant Deputy Minister Infectious Disease Prevention and Control Branch and Scientific Director General National Microbiology Laboratory, in collaboration with the Chief Financial Officer, should review the annual funding allocations to address the recurring annual funding shortfall of the NML. | Agree.<br><br>a. As part of the 2010-2011 IOP process, ADM IDPC will emphasize accurate forecasting, commitment management and timely declarations of variances.<br>b. As part of PHAC 2010-2011 IOP review and in consultation SADM, CFO, ADM IDPC and DG NML, NML 2010/11 budget base will be rationalized and stabilized.<br>c. Subsequently, on a quarterly basis, and at mid-year review of IDPC Branch budgets, ADM IDPC in consultation with DG NML will review NML's performance as consistent with budgets. | SADM Programs, ADM IDPC, DG NML & CFO | October 2010<br><br>October 2010<br><br>Quarterly, beginning October 2010 |

# Appendix C: Achievements and Contributions of the NML

*The information has been prepared by NML and has not been reviewed or validated as part of our audit. We include the information in this report simply to illustrate the nature and scope of the work being done at NML.*

| **Reference and Diagnostic Services** |
|---|
| Whether providing required expertise or supplementing local capacity, NML performs tens of thousands of tests per year involving a full spectrum of infectious disease pathogens. A multitude of different test types are offered by NML, the majority of which fall into one of the following categories: culture (growth of a microorganism) and identification; nucleic acid tests (e.g., polymerase chain reaction); susceptibility testing (determination of the ability of an antibiotic to kill or inhibit bacterial growth); and pathology (examination of organs, tissues, cells and body fluids). |
| Where it does not offer them in-house, NML funds external laboratories to provide specific microbiological reference services. Laboratories currently partnering with NML include the National Reference Centre for Parasitology (McGill, Montreal) and the National Centre for Streptococcus (ProvLab Alberta, Edmonton). In addition, NML supports the National Mycology Network, whose function is to identify and collaborate on priority activities such as surveillance and diagnostics for fungi. |
| In addition to ensuring the quality of its own testing services and equipment, NML divisions provide advice, standards and training to client laboratories. This increases their capacity to conduct testing for surveillance and produce and verify the quality of laboratory reagents. |
| **Surveillance Activities** |
| As of 2007, PHAC was participating in upwards of 50 surveillance systems, the majority of which involve NML. In addition to its domestic activities, NML is associated with numerous international surveillance systems and networks. The following are some of the ways in which NML supports national and global infectious disease surveillance, in cooperation with PHAC and other federal colleagues as well as provincial, territorial and international partners:<br>• Development and implementation of a national surveillance system to address the incursion and spread of West Nile virus in Canada, including the provision of diagnostic tests and national guidelines as well as regular reports documenting West Nile activity;<br>• Support for national and global influenza surveillance and assessment of pandemic potential, as a designated World Health Organization (WHO) National Influenza Centre and member of the WHO Global Influenza Surveillance Network;<br>• Coordination of Canada's National Enteric Surveillance Program and entering into a Memorandum of Understanding with the US Centers for Disease Control and Prevention (CDC)-based PulseNet (early warning systems for outbreaks of food-borne disease). |

This includes supporting surveillance through DNA "fingerprinting" on bacterial isolates from laboratory-confirmed cases of food-borne illnesses such as *Salmonella, Shigella, Listeria* and *E. coli*;

- Leadership in the development of a preliminary blueprint for national human papillomavirus (HPV) surveillance, and initiation of intensive monitoring of possible changes in viral genotype due to the introduction of immunization - critical steps in ensuring that future vaccine versions cover the greatest proportion of the carcinogenic variants of HPV; and,
- Coordination of national surveillance of Creutzfeldt-Jakob disease (CJD) and previously unobserved prion diseases (e.g., Chronic Wasting Disease in humans), as well as sharing of aggregate statistics through membership in the European and Allied Countries Collaborative Study Group of CJD.

**Applied and Discovery Research**

NML has established itself as a world-class research institute. Undertaken in concert with national and international partners, research into established and emerging infectious diseases, their characteristics, and the means by which they can be transmitted, prevented and treated, generates science-based evidence for the development of public health policies, programs and services as well as the discovery of new therapies and treatments.

NML's research capabilities and achievements include formulating new and improved diagnostic methods, discovering underlying factors in disease virulence, and developing seed stock for vaccine production. NML scientists have contributed to more than 300 national and international research publications in the past three years, commendations have been awarded, and patents have been filed or are pending for an impressive array of scientific breakthroughs.

The following are some examples of NML's contributions to the advancement of infectious disease research:

- NML was a lead member of a research team that, in NML's level 4 laboratories, recreated the "Spanish flu" virus from the severe 1918 influenza pandemic. Team members have since determined that the unique biology of this virus was responsible for the severity of illness it caused, by illustrating how it stimulated and persistently activated the immune response, ultimately contributing to lethality. This discovery is opening new doors for researchers, including the potential to develop therapies for similar viruses that might emerge in humans;
- NML scientists developed vaccines that protect monkeys from the deadly Ebola, Marburg and Lassa fever viruses – and may one day be found to protect humans. Created in NML's level 4 laboratories, an experimental vaccine for Ebola was injected into mice and found to be effective. Subsequent studies using non-human primates demonstrated the vaccine to be protective and effective post-exposure. The technique used to produce the Ebola vaccine was also used to develop vaccines for Marburg and Lassa fever, which were equally effective;
- NML researchers worked with scientists from the University of Wisconsin to develop a "safe" form of the Ebola virus. The altered Ebola has a similar structure and growth cycle

as wild Ebola, but, without the gene necessary for it to replicate and cause disease, is not infectious. Now scientists can safely study the pathogen in a level 2 as opposed to a level 4 laboratory. With more people studying Ebola's life cycles and potential treatments, the development of the new Ebola virus could lead to the creation of a potential vaccine for humans;

- With funding from the Bill and Melinda Gates Foundation, National Institutes of Health and Canadian Institutes of Health Research, NML is partnering with the University of Manitoba, the University of Nairobi and numerous other collaborators, to study why some individuals are resistant to HIV infection and others who become infected do not develop AIDS. Understanding what constitutes and results in protective immunity to HIV-1 will greatly advance HIV vaccine research and contribute to the development of novel therapies or treatments to fight HIV/AIDS;
- NML scientists led the discovery and characterization of the SARS-coronavirus during the 2003 outbreak. Research continues, with the goal of improving diagnostics as well as basic understanding of the SARS-coronavirus and its pathogenesis;
- NML has made significant contributions to the development and improvement of diagnostic reagents. NML developed neutralizing monoclonal antibodies to the SARS-coronavirus, capacity that is now being used to target other public health threats, such as Neisseria meningitidis, HIV-1, anthrax, pandemic influenza (H5N1, H7 and others) and botulinum toxins; and,
- NML researchers have identified a comprehensive list of genes that are consistently affected in rodent models of prion disease. Researchers are now building networks of interactions between these genes, increasing their understanding of the complex inflammatory and neurotoxic cascade of prion disease. Resolving the key factors that underlie prion pathogenesis is providing targets for the design of novel therapies and use of diagnostic biomarkers.

**Development and Training**

Each year NML programs offer a diverse slate of training courses covering all aspects of the laboratory's operation. Demand and enrolment have continued to increase, with several hundred people participating annually in courses offered on request or at regularly scheduled intervals. Training topics range from research and diagnostic testing methodologies to emergency response training to bio-containment operations and maintenance.

Now in its seventh year, the annual International High Containment Biosafety Workshop is delivered by PHAC, through NML's Office of Biorisk Management, and the International Centre for Infectious Diseases (Winnipeg), along with Smith Carter Architects and Engineers Inc. and the Center for Public Health Preparedness and Research of the Rollins School of Public Health at Emory University. The most advanced of its kind anywhere, the workshop provides training in critical aspects of bio-containment to biosafety professionals, facility operators and managers from around the globe. A rigorous five-day course allows participants to work hands-on in the level 3 and level 4 laboratories of CSCHAH.

In addition to offering training courses, NML delivers orientation sessions and hosts facility

tours for Canadian and international visiting scientists, many of whom are seeking knowledge and inspiration for laboratory construction or operation. As well, residency programs are provided under the supervision of NML scientists to post-doctoral fellows from around the world, local post-graduate medical fellows and graduate students (in collaboration with the University of Manitoba) and undergraduate students from across Canada. In 2006-2007, close to 150 individuals worked at NML in internship placements ranging from several months to several years in duration.

**Emergency Preparedness and Outbreak Response**

Emergency preparedness and outbreak response is the point at which all NML functions intersect. Reference and diagnostic services, surveillance, applied and discovery research, development and training - each activity contributes to the national laboratory's role in preparing for, monitoring, identifying and responding to outbreaks of disease as well as other threats involving infectious agents. Under the coordination of PHAC's Centre for Emergency Preparedness and Response (CEPR), NML works alongside other PHAC and federal government colleagues, as well as provincial, territorial and international organizations in outbreak response.

The following are some of the ways in which NML is contributing to Canadian and global capacity to prepare for and respond to infectious disease outbreaks or threats:

- In the wake of the 9-11 terrorist attacks, NML hosted directors from the world's high containment laboratories to discuss shared operational and emergency response issues. At the same time, laboratory representatives from the G7 countries and Mexico met to share their concerns and capabilities and to discuss ways of working more collaboratively together. These meetings resulted in the establishment of a laboratory working group of the Global Health Security Action Group (GHSAG), a network of international partners dedicated to strengthening the public health response to bioterrorist threats and naturally occurring infectious disease outbreaks. NML plays a central role in coordinating the activities of the laboratory working group of GHSAG;
- In 2005, NML established a state-of-the-art Operations Centre. Featuring a video-wall and the latest networking technologies, the facility enables NML staff to support national and international emergency responses by monitoring public health developments as they occur, incorporating laboratory results and coordinating laboratory information from various networks and surveillance systems. It also allows for rapid communication and effective coordination with PHAC's Ottawa-based CEPR, provincial public health laboratories and other national and international partners;
- NML operates and maintains two state-of-the-art mobile laboratory units that can be deployed on very short notice to assist with public health crises anywhere in Canada or the world. At the request of the WHO's Global Outbreak and Response Network (GOARN), teams of PHAC scientists are deployed with the laboratory units. Since 2003, the mobile laboratory units have responded to outbreaks of Nipah virus in Bangladesh, Crimean Congo hemorrhagic fever in Iran, SARS in Hong Kong and China (2003 and 2004), Ebola virus in the Democratic Republic of the Congo (2003 and 2007), avian influenza in Vietnam, Marburg virus in Angola and Rift Valley fever in Kenya;
- NML's mobile laboratory units are also used to enhance national and international

capacity to respond to events involving bioterrorism or biowarfare. NML's Microbiological Emergency Response Team (MERT) provides training to national and international partners and coordinates response exercises involving mobile laboratory operations, in-field identification of biological agents and sampling procedures. MERT also supports national security operations, through mobile laboratory deployment and the development of site security and laboratory response plans; and,

- Each year, NML divisions participate in the identification and investigation of numerous local, national and international outbreaks of infectious diseases that have the potential to pose a serious public health threat. Despite the existence of prevention and treatment programs, NML has frequently been called upon to support outbreaks of food-borne illnesses, *Legionella*, tuberculosis, measles, mumps and hepatitis viruses.

# Appendix D: Achievements and Contributions of the LFZ

*The information has been prepared by LFZ and has not been reviewed or validated as part of our audit. We include the information in this report simply to illustrate the nature and scope of the work being done at LFZ.*

## Science and Technology

### *Technology for rapid molecular serotyping of Salmonella*

The LFZ led Canada in the use of an innovative technology that will aid in the rapid detection and identification of Salmonella. The technology is based on an economical, rapid, and user-friendly platform that is attractive for Salmonella serotyping within reference, medical, academic and industrial laboratories. The assay's simple processing protocol makes it easily transferable to a wide range of disciplines. The technology will provide improved source identification of emerging Salmonella serotypes that will have major health and trade implications.

### *Award for the Verotoxigenic E. coli Network Team*

The LFZ was part of a science team that was recognized with the Health Canada ADM Excellence Award for collaborative leadership under the category of Science. Fresh produce has been identified as a significant vector for foodborne illness, and the project develops measures that will reduce produce-associated risks to public health, and is focused on filling critical gaps in knowledge about Verotoxigenic E. coli in agricultural production systems. The network will serve as a model for future multi-organizational scientific collaborations required to address other critical issues in public health.

### *Novel Genomic Tools for Fingerprinting of E. coli O157:H7*

The LFZ developed a novel method for genotyping the food- and water-borne pathogen Escherichia coli O157:H7, called comparative genomic fingerprinting. This method can be used to identify and differentiate among virulent E. coli O157:H7 strains and also to provide a high-resolution genetic “fingerprint” of outbreak-associated strains of the organism. Bioinformatics tools have also been developed to genotype bacteria in silico and to identify “novel sequences” in bacterial genomes. These genotyping methods will help public health laboratories rapidly interpret new genome sequence data and reduce the cost of shipping reference strains among laboratories, a task made more difficult by restrictions on international shipment of pathogenic strains.

### *OECD QA Guidelines for Molecular Genetic Testing*

PHAC led work with Health Portfolio partners and CNPHI to create an electronic mechanism to gather national data on genetic testing for the development of evidence-based policies, programs and practices. Broad stakeholder support for this initiative exists as it will develop coherence among current health/public health programs in Canada on quality assurance.

### *Diabetes and Public Health Genomics*

Research in collaboration with the University of Toronto has been initiated to synthesize information about the role of genetic, behavioural and environmental factors in the onset of type II diabetes mellitus. Genes, involved in this process, have been identified and used for initiating the development of a panel of multiple biomarkers. These biomarkers could provide evidence for earlier detection, monitoring and surveillance in the general population, and for improvements to chronic disease prevention and control programs.

***Vitamin D and Public Health Genomics***

Low serum vitamin D levels are associated with poor health for common chronic and infectious diseases. Research in collaboration with McGill University has been initiated to identify genetic variation associated with vitamin D. Such associations will allow the Agency to identify vulnerable sub-populations and develop disease prevention strategies such as vitamin D supplementation.

**National Dialogue on the Use of Genome-Based Information in Public Health**

LFZ facilitated national talks and obtained F/P/T support on key issues related to genome-based information and its use in public health. The Agency established strong and meaningful working collaborations across the Health Portfolio, with provincial ministries of health and key stakeholders. The Agency provided federal leadership and was looked to as the champion for issues related to genome-based information and its use in public health.

## Population and Environmental Determinants

Extensive consultations resulted in the establishment of a single-window model for coordinating and promoting the efficient delivery of services and expertise in relation to Geomatic, geospatial analyses and GIS capacity. The model is named the "Public Health Agency of Canada Geomatics Network " and is governed within the Surveillance Integration Team (SIT) structure. An agency-wide review was conducted to address the management of spatial data, GIS infrastructure and geospatial modelling for public health.

## The Agency in Space

The LFZ joined the United Nation Action Team 6 which was established for examining peaceful uses of outer space. Innovative agro-environmental research within the Agency will now contribute to public health improvements through the use of space technologies in developing early infectious disease warning systems.

## Surveillance

To understand the risk factors for antimicrobial resistance, the Agency is collecting drug use information from farms across Canada through the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS). Currently, the program is operating across Canada in the swine industry and a research project is being conducted in the beef industry in Alberta. Through CIPARS, the Agency is actively participating in negotiations with the chicken industry to collect both antimicrobial use and antimicrobial resistance information, particularly since CIPARS has previously reported fluctuating and now again rising levels of

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| ceftiofur resistance in Salmonella Heidelberg and E. coli, likely related to changes in drug use practices, though the lack of drug use information has been cited by industry as a major gap in the story. CIPARS has also acquired manufacturer data from the Canadian Animal Health Industry, as a means to fill the gaps in knowledge regarding antimicrobials used in animals and this information has been published in the CIPARS 2006 Annual Report. During this time period, the AMR program has also produced three peer-reviewed publications exploring drug use in beef cattle, sheep, and swine. |
| C-EnterNet data was used to link data from pathogens in the environment, meteorological data and endemic human cases producing two manuscripts, one each for Campylobacter and Salmonella. These manuscripts, using recent years of Canadian data, will be published to distribute this information about the interrelationship of human, animal and environmental health. |
| For the public health concern of antimicrobial resistance developing and spreading through the food-chain, the Agency follows an integrated 'One World One Health' approach by collecting information through the food-chain via CIPARS. CIPARS was presented as an example of this approach at the One World One Health Conference in 2009. During the 2008-2009 time period, CIPARS actively communicated surveillance findings, to a broad group of stakeholders both within government as well as amongst industry, such as through the production of CIPARS 2006 Annual Report, CIPARS 2007 Preliminary Results web-report, CIPARS Salmonella Heidelberg web-update, as well as four briefing notes on Salmonella Heidelberg. CIPARS has additionally produced one peer-reviewed publication and two publications are in the submission process for peer-review, including one which has an in-depth discussion of the Salmonella Heidelberg issue. Different aspects of the CIPARS findings have been presented either orally or by poster (22 times) to different interested parties varying from farm-level organizations to international audiences, where in particular the Salmonella Heidelberg issue has gained renown as an example of the link between antimicrobial use in farm-animals and disease in humans. CIPARS continues to expand to meet stakeholder and public health needs, including expanding retail surveillance to include the Maritime provinces, to including imported shellfish and finfish, and in collaboration with C-EnterNet, CFIA, a discussion of including produce. |
| C-EnterNet provided a One World One Health perspective on foodborne and waterborne diseases in Canada through publication of the C-EnterNet 2007 Short Report, C-EnterNet 2007 Annual Report and three peer reviewed articles. |
| The LFZ actively participated in the Codex Alimentarius ad hoc Intergovernmental Task Force on Antimicrobial Resistance (AMR), and formed part of the official Canadian delegation. In collaboration with Health Canada, the Agency was involved with drafting guidelines for this task force regarding antimicrobial resistance risks arising from the food-chain, including evaluation of non-human antimicrobial use in relation to the Codex mandates of consumer safety and fair trading practices, making sure that Canadian position was well reflected in the document. The AMR program also participates as secretariat to Health Canada's Expert Advisory Committee on Antimicrobial Resistance Risk Assessment, which provides input to the Veterinary Drug's Directorate regarding their process for policy decisions on antimicrobials used in food-animal production in relation to human safety. This committee provides an important link between surveillance activities and policy outcomes. |

The AMR program has also provided input to a briefing note on the Canadian Medical Association Journal's article on Own-Use Importation of Veterinary Drugs in which written support was given to any action to restrict this particular antibiotic distribution channel to better protect public health and that the AMR program would support a revision to the Own-Use provision applied to animals which would include an antimicrobial (drug) use monitoring component. Finally, the CIPARS surveillance findings on Salmonella Heidelberg were presented at the Real World Policy Case Series in 2009, as a means of moving forward from surveillance activity to action.

The LFZ has been extremely active regarding synthesizing and exchanging knowledge on antimicrobial use and antimicrobial resistance in agriculture. To bring together Canadian experts in the field, the AMR program (together with the Antimicrobial Resistance Research Team of Guelph) organized a symposium on Research in Antimicrobial Resistance in Animal Health and Zoonotic Agents (September 19th, 2008) at the Central Public Health Laboratory in Etobicoke, Ontario. The Agency and university partners also received formal acceptance from the American Society of Microbiology to organize and host the second conference on Antimicrobial Resistance in Zoonotic Bacteria and Foodborne Pathogens in June 2010. The AMR program also presented research on antimicrobial use and resistance at a variety of scientific fora (31 oral/poster presentations), submitted a briefing note on Clostridium difficile, and had 29 peer-reviewed publications. These publications and presentations also include non-food animal and environmental research which contextualizes the food animal data.

## Science to Policy

The LFZ synthesized evidence examining the link between Johne's disease of cattle and Crohn's disease in humans. The synthesis provided an excellent foundation for discussion between policy makers and research experts regarding possible control options and research priorities within Canada. The Agency was commended for providing key information in this decision-making process, resulting in additional requests for research synthesis.

## Horizontal Initiative: Food and Consumer Safety

A new horizontal initiative started in collaboration with Health Canada and the Canadian Food Inspection Agency that will ultimately provide safer food for Canadians. LFZ expertise in surveillance, risk modelling and molecular typing along the "farm to fork" continuum will ensure that illness in Canada is linked with actions to improve food safety. The initiative offers an integrated, proactive approach that will address food risks in the Canadian marketplace in addition to providing enhanced efforts in addressing risks along the food chain from production to consumption. A key driver in the initiative is the recognition that food safety is a shared responsibility between industry, government and the consumer.

# Appendix E: List of Acronyms

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| ADM | Assistant Deputy Minister |
| Agency | Public Health Agency of Canada |
| CCDIC | Centre for Communicable Diseases and Infection Control |
| CFEZID | Centre for Food-Borne, Environmental and Zoonotic Infectious Diseases |
| CFIA | Canadian Food Inspection Agency |
| CFO | Chief Financial Officer |
| CIRID | Centre for Immunization and Respiratory Infectious Diseases |
| CPHO | Chief Public health Officer |
| CSCHAH | Canadian Science Centre for Human and Animal Health |
| DG | Director General |
| FY | Financial Year |
| FTE | Full-Time Equivalent |
| HC | Health Canada |
| HIV | Human Immunodeficiency Virus |
| HPCDP | Health Promotion and Chronic Disease Prevention (Branch) |
| IDPC | Infectious Disease Prevention and Control (Branch) |
| IIA | Institute of Internal Auditors |
| IOP | Integrated Operational Plan |
| ISO | International Organization for Standardization |
| LFZ | Laboratory for Foodborne Zoonoses |
| MOU | Memorandum of Understanding |
| NCAFD | National Centre for Foreign Animal Disease |
| NML | National Microbiology Laboratory |
| OIE | Office Internationale des Epizootes |
| PAHO | Pan American Health Organization |
| PHAC | Public Health Agency of Canada |
| SCC | Standards Council of Canada |
| SPD | Strategic Planning Directorate |
| TB | Treasury Board |
| WHO | World Health Organization |