Subject line: Invitation HPTA Consultations

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Dear Stakeholder,

You have previously indicated your interest in participating in the *Human Pathogens and Toxins Act* (HPTA) engagement process to provide input into the development of regulations, programs, and policies under this *Act.*

The HPTA received Royal Assent on June 23, 2009. The purpose of the *Act* is to improve and enhance a safety and security regime to protect the health and safety of Canadians against risks posed by human pathogens and toxins. The Public Health Agency of Canada (the Agency) has been given the responsibility of developing a program and regulatory framework to support the implementation of the HPTA. Ongoing robust and meaningful engagement with stakeholders will inform the regulatory and program development process.

The Agency has been engaged in a four-year, multiple phase consultation with stakeholders concerning the development of the program and regulatory framework for the *Human Pathogens and Toxins Act* (HPTA). Phase II was completed in summer 2012, and sought stakeholder input regarding the issues of:

1. **Licensing**
2. Functions and qualifications of **Biosafety Officers (BSOs)**
3. **Inventory** requirements
4. The development of an **exposure reporting and prevention program**
5. **Security Requirements** for those working with Risk Group 3 or 4 human pathogens and certain toxins

This current phase of engagement (Phase III) will seek stakeholder input regarding the Agency's proposed policy approaches to these same issues and identify any potential operational challenges to implementation. The proposed approaches were informed by HPTA requirements, input received from stakeholders during Phase II consultations, policy decisions as well as other considerations. As security clearances apply only to those individuals possessing risk group 3 and 4 human pathogens and some toxins, separate information sessions are being organized for impacted stakeholders. However, information on security clearances will be shared electronically to all interested parties in the coming weeks.

Your recommendations, suggestions and comments regarding the proposed approaches will assist the Agency in further refining the program and regulatory framework for the HPTA.

Policy papers were developed to provide a description on the proposed approaches for each of the key areas. In addition, brief background papers were developed on the HPTA and the Government of Canada’s regulatory development process. These documents will be distributed to all participants prior to the engagement events. If you are unable to attend but would like a copy of the documents, please do not hesitate to contact us.

We would appreciate it if you would circulate this invitation to any other colleagues or stakeholders who may be interested in participating in an HPTA engagement opportunity (either in person or online). For planning purposes, we require confirmation five business days prior to any in-person event.

Please confirm your attendance and direct any questions or concerns to Lody Nesrallah, Outreach Officer, at hpta.lapht.consultations@phac-aspc.gc.ca or by telephone at 613-941-3709 indicating your preferred event (based on the sector session from the list below that best represents your organization), the sector to which you belong, your role and the official language of your choice. Logistical information and background material will be sent to you upon registration confirmation no later than two weeks prior to each event. An electronic engagement process will also be launched spring 2013 for stakeholders who are unable to attend an in-person event.

Sector-specific Consultation Sessions:

1 – Ottawa, ON (Bilingual session)
- 1.1) March 19, 2013 – Federal Government

2 – Vancouver, BC
- 2.1) March 26, 2013 – Academic Research (including Hospitals)
- 2.2) March 27, 2013 – Hospital/Private Diagnostic and Other Sectors
- 2.3) March 28, 2013 – Industry (Biotechnology and Pharmaceutical)

3 – Toronto, ON
- 3.1) April 9, 2013 – Academic Research (including Hospitals)
- 3.2) April 10, 2013 – Hospital/Private Diagnostic and Other Sectors
- 3.3) April 11, 2013 – Industry (Biotechnology and Pharmaceutical)

4 – Halifax, NS (Bilingual session)
- 4.1) April 16, 2013 – Academic Research (including Hospitals)
- 4.2) April 17, 2013 – Hospital/Private Diagnostic and Other Sectors
- 4.3) April 18, 2013 – Industry (Biotechnology and Pharmaceutical)

5 – Montreal, QC (Bilingual session with simultaneous translation)
- 5.1) April 23, 2013 – Academic Research (including Hospitals)
- 5.2) April 24, 2013 - Hospital and Private Diagnostics
- 5.3) April 25, 2013 – Industry (Biotechnology and Pharmaceutical)

Sector:

A. Academic Research (including Hospitals)
B. Biotechnology Industry
C. Pharmaceutical Industry
D. Hospital Diagnostic
E. Private Diagnostic
F. Environmental Testing Laboratory

G. Water Industry
H. Provincial/Territorial/Municipal Government
I. Federal Government
J. Distributor/Broker
K. Other (please specify)

Role:

A. Biosafety/Environmental Health and Safety Officer/Quality Assurance (Safety)
B. Manager/Director (Management)
C. Researcher/Educator (Training and Research)
D. Laboratory Technician/Laboratory Technologist
E. Other (please specify)

Please visit www.publichealth.gc.ca/pathogens for further information.

Thank you in advance for your time and valuable input and we look forward to meeting with you soon.

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