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Geneva, 10 – 14 November 2003

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CANADIAN MEASURES TO ENHANCE DOMESTIC LABORATORY SECURITY FOR BIOLOGICAL AGENTS

Prepared by Canada

1. The Canadian Food Inspection Agency (CFIA) and Health Canada (HC) recognize that biological agents pose unique security challenges because they can replicate, theft of minute quantities is significant, there are no devices to detect agents being removed from a facility, and the facilities handling these materials (e.g. universities, hospitals) are usually accessible to the public.

2. Both Departments have responsibility for the regulation of pathogens in Canada through the Biohazard Containment and Safety Division (CFIA - Animal) and the Office of Laboratory Security (Human - HC). With the largest number of high containment labs in Canada, CFIA also runs an internal Biosafety and Biosecurity program.

3. To address the adequacy of security at laboratories who work with, store or transport infectious agents (particularly those agents associated with bioterrorism), biosecurity programs, proposals and recommendations have been developed by these offices in order to mitigate the risk associated with:

   - unauthorized entry to laboratory areas
   - unauthorized removal of biological agents and toxins from laboratories
   - illegal import of pathogens

4. Both offices also work to promote the safe use of high consequence pathogens using appropriate import controls, procedures and containment

Programs specific to CFIA Laboratories

5. The focus of the CFIA’s initial efforts in the area of Biosecurity will be restricted to CFIA Laboratories. When these measures are in place, extending developed polices and requirements to private laboratories, universities and other government laboratories working with animal pathogens will be pursued through the regulatory process.
6. The program is divided into three key areas:

- Implementation of a security readiness and response system;
- The assessment and upgrading of physical and operational security at CFIA laboratories;
- Development and implementation of a microbial/toxin security program at CFIA laboratories.

7. The **security readiness and response system** is based upon the Canadian Treasury Board’s Operational Security Standard: *Readiness Levels for Federal Government Facilities*.

8. With Corporate Security, the requirements prescribed were modified to consider the unique aspects of the laboratories. This policy outlines enhanced security levels for government facilities during times of increased threat. The levels described in the standard are announced and administered by the Office of the Privy Council (PCO) and the Treasury Board Secretariat (TBS). A temporary level of readiness that is higher than the national level can be imposed in individual departments in response to a threat or imminent threat. Each security level prescribes additional safeguards increasing from 1 to 4. The Labs directorate has surveyed all national laboratories to ensure that they meet level 2 requirements, and are capable of moving to level 3 if required.

9. Elements of this program include:

- Security Screening
- Physical Security including mandatory control of all access points & visitor control.
- Screening for suspicious packages of incoming mail/deliveries.
- Information Technology Security
- Business Continuity Planning
- Security in Contracting
- Security Awareness
- Protection of personnel

**Assessment and upgrading of physical and operational security at CFIA laboratories**

10. A national laboratory physical security plan was created to review the physical security of all laboratories and update as needed. Outside consultants are being brought in to conduct Threat Risk Assessments (TRAs) on all laboratories and make recommendations. TRAs will be conducted in order of a developed selection matrix, i.e., higher ranked facilities first. Terms of reference have been written and competition is currently under way to secure a private security firm to conduct the TRA’s.

**Development and implementation of a microbial/toxin security program at CFIA laboratories**

11. The development of CFIA’s Microbial Security Standard is being based on: the Canadian Government Security Policy (previously described), Agency Policy, review of American Legislation and Regulations such as the Public Health Security and Bioterrorism Preparedness Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002, guidance documents such as Health Canada’s *Laboratory Biosafety Guidelines*, MMWR, Laboratory
Security and Emergency Response Guidance for Laboratories Working with Select Agents (BMBL appendix F), the ABSA Biosecurity Task force White Paper and finally policies other agencies have developed, such as the USDA Security Policies and Procedures for Biosafety Level 3 Facilities.

12. Corporate and IT security are heavily involved in the development in areas such as Physical security, personnel screening, and cyber security. Stakeholders at all levels will be involved to ensure the needs of the individual laboratories are met.

13. The key elements of this program will be: Physical protection, personnel reliability, pathogen accountability, cybersecurity, and incident response.

14. **Personnel Screening** requirements for all federal institutions are described in the GSP. The Corporate Security Branch of the CFIA, has been developing a new standard for the screening of foreign nationals who will be working in CFIA laboratories. The “Security Screening Standard for Foreign Nationals” will include supporting procedures to ensure that communication and assistance is sought from lead federal government departments who are integral to the security screening process, prior to individual beginning work with the CFIA.

15. **Information Technology (IT) security** requirements for all Federal institutions are also outlined in the GSP. IT security is currently developing a corporate IT security policy to cover all aspects of cyber security for our laboratories, including access controls, business resumption planning, intrusion detection and other measures. The CFIA is working closely with the RCMP and the Communications Security Establishment in developing its cyber security posture.

16. A *pathogen and toxin inventory and tracking system* is being developed for the CFIA laboratories. Initially a review of the systems currently in place at each laboratory will be conducted, with a goal of national standardization. This will involve the collaboration of the lab managers and other stakeholders, in addition to requirements stemming from the passage of Bill C-17, the Public Safety Act.

**Regulatory and external programs**

**Border controls for pathogens:**

17. The CFIA and Health Canada are currently working with the Canada Customs and Revenue Agency (CCRA) on its Compliance Improvement Plan, in which targets are developed and put in place for high risk commodities, such as pathogens. A training program is being implemented jointly by both departments for CFIA, CCRA and other border staff and on how to recognize illegal imports of pathogens, either by concealment or permit violations.

**Inspections and certifications:**

18. All laboratories importing and transferring agents infectious to **humans** in Canada are already required to adhere to the *Laboratory Biosafety Guidelines* in accordance with the Human Pathogens Importation Regulations (HPIR).

19. All laboratories importing and transferring agents infectious to animals (including zoonotics) in Canada are already required to adhere to the *Containment Standards for Veterinary*
Facilities \(^3\) in accordance with the Health of Animals Act and regulations

20. Facilities wishing to import level 3 or 4 agents are required to go through a detailed inspection and certification program prior to the issuance of a permit. The CFIA also has a verification program in place for level 2 agents. Both departments are currently reviewing and improving this inspection and certification process.

*Regulation enhancement and development:*

21. Health Canada has incorporated biosecurity recommendations (encompassing physical security for the facility, personnel in the facility, agent inventories, and response to biosecurity incidents) into the 3rd edition draft Laboratory Biosafety Guidelines \(^4\). It is expected that the final version of the 3rd edition will be published this fall. All laboratories importing and transferring infectious agents in Canada are required to adhere to the Guidelines in accordance with the Human Pathogens Importation Regulations (HPIR). Health Canada is currently reviewing the requirements in the HPIR from a biosecurity perspective to ensure the secure and safe handling of biological agents in Canada. This involves a close evaluation of the US Public Health Security and Bioterrorism Response Act and Notification of Possession of Select Agents requirements to determine whether or not the HPIR is the correct vehicle to regulate all laboratories possessing biological agents or toxins (i.e. not only those laboratories importing agents into the country). This may also involve restricting regulatory control to possession of not only "select agents" but all risk group 3 and 4 agents.

22. Both Health Canada and the CFIA are also being consulted on the development of Bill C-17, which includes the *Biological and Toxic Weapons Convention Implementation Act* \(^5\). Discussions at this stage of regulatory development are essential for the harmonization of all mandated pathogens control activities in Canada.

\(^1\) http://www.tbs-sct.gc.ca/pubs_pol/gospubs/tbm_12a/siglist_e.asp

\(^2\) http://www.hc-sc.gc.ca/pphb-dgpsp/publicat/lbg-lmdbl-96/index.html

\(^3\) http://www.inspection.gc.ca/english/sci/lab/convet/convete.shtml


\(^5\) http://www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/C-17/C-17_1/C-17_cover-e.html