



## WHAT YOU SHOULD KNOW ABOUT IMPORTING HUMAN PATHOGENS INTO CANADA

### INTRODUCTION

*Health Canada introduced regulations to control the importation of human pathogens into Canada and to ensure that adequate facilities exist for proper laboratory handling and containment of these pathogens. These regulations allow the Public Health Agency of Canada to assess, control and manage the risk of inadvertent transmission of communicable disease caused by imported pathogens. The regulations came into effect in 1994.*

### QUESTIONS AND ANSWERS

#### 1. What is a human pathogen?

A human pathogen is any microorganism or parasite that causes disease in humans. This includes zoonotics. Human pathogens may be contained in cultures, diagnostic specimens, or tissue.

#### 2. What is an infectious substance?

An infectious substance as defined in the *Human Pathogens Importation Regulations* means a microorganism or parasite that is capable of causing human disease or an artificially produced hybrid or mutant microorganism that contains genetically altered components of any microorganism capable of causing human disease.

#### 3. What do I need to import a human pathogen into Canada?

An application to import human pathogens into Canada must be submitted to the Public Health Agency of Canada. After evaluation and approval by the Public Health Agency of Canada, an importation permit will be issued which must accompany the shipment of the pathogen into Canada. A single- or multiple-entry permit will be issued according to the particular situation.

#### 4. How and where do I get a Human Pathogens Importation Permit application or a copy of the 3<sup>rd</sup> Edition of the Laboratory Biosafety Guidelines (2004)?

You may obtain application forms\* or copies of the 3<sup>rd</sup> Edition of the *Laboratory Biosafety Guidelines (2004)* by contacting:

Office of Laboratory Security  
Centre for Emergency Preparedness  
and Response  
100 Colonnade Road, (Loc.: 6201A)  
Ottawa, Ontario K1A 0K9  
Tel. (613) 957-1779  
Fax (613) 941-0596

\*Applications and the 3<sup>rd</sup> Edition of the *Laboratory Biosafety Guidelines (2004)* are also available via our internet address:

<http://www.phac-aspc.gc.ca/ols-bsl>

#### 5. How long will it take to get a permit?

Under ordinary circumstances, and if all conditions for importation are met, a permit can be issued usually within five working days after receipt of an application. If there is an urgent situation that requires that an application/permit be processed urgently,

direct attention will be given to the matter.

#### 6. How do these regulations interact with *Transport of Dangerous Goods Regulations* and other international regulations?

*Human Pathogens Importation Regulations* do not in any way diminish the responsibility of the importer/shipper to comply with international and domestic regulations regarding the transportation and packaging of dangerous goods.

#### 7. Before the introduction of these regulations, what controls were in place for importing these pathogens?

The Canadian Food Inspection Agency has the authority to regulate the importation of animal pathogens under the *Health of Animals Act*. In the past where a human pathogen was involved, the Canadian Food Inspection Agency, in consultation with Health Canada, would issue a permit. The new *Human Pathogens Importation Regulations* have corrected this situation.

#### 8. Will two permits be required (ie. one from the Canadian Food Inspection Agency and one from the Public Health Agency of Canada) to import a pathogen which is both a human and animal (zoonotic) pathogen?

Yes. Two permits will be required. Please contact Ms. Nicole Latreille, of the Canadian Food Inspection Agency, at: 613-221-7068.

**9. If a human pathogen is a pharmaceutical/drug or vaccine as described in the *Food and Drug Act*, do I need a Human Pathogens Import Permit to import it into Canada?**

No. If a human pathogen is a pharmaceutical/drug or a vaccine regulated by the *Food and Drug Act*, then a permit to import human pathogens is not required. However, there may be specific requirements/restrictions under the *Food and Drug Act and Regulations* that apply.

**10. Will I need a permit to import proficiency panels used in the verification of clinical diagnostic testing?**

Yes. If the importer has reasonable grounds to believe that there are human infectious substances or toxins of infectious substances contained in any material, then an import permit is required.

**11. What can I do if I am refused a permit to import a human pathogen?**

There is an appeal process outlined in these regulations which may be launched if a permit has been refused.

**12. How do I determine what laboratory containment facilities I need?**

Depending on your laboratory facilities and equipment and in conjunction with the identified infectious substance you

wish to import, you should refer to the 3<sup>rd</sup> Edition of the *Laboratory Biosafety Guidelines (2004)* (Public Health Agency of Canada) to verify if your laboratory's containment arrangements are adequate.

**13. Before I obtain a permit to import a particular pathogen that belongs to Risk Group 3 or 4, will it be necessary to have my laboratory facilities inspected?**

No, not necessarily. If your laboratory is an established containment facility that has been reviewed by the Office of Laboratory Security, Public Health Agency of Canada, or another established body such as a provincial inspection agency and meets the criteria of the 3<sup>rd</sup> Edition of the *Laboratory Biosafety Guidelines (2004)*, a further review may not be required.

**14. Once a permit to import a human pathogen has been issued, will I be able to import this pathogen anytime I want?**

If a permit to import a human pathogen has been issued, it will clearly indicate whether it is a single-entry or multiple-entry permit. Only Risk Group 2 human pathogens can be imported using multiple-entry permits.

**Any other questions that we have not answered? Please contact:**

The Public Health Agency of Canada's Office of Laboratory Security and we will do our best to answer your questions.

Tel.: (613) 957-1779

Fax: (613) 941-0596