

Notification and Assessment under the *Canadian Environmental Protection Act, 1999* of *Influenza virus* cold-adapted B/Massachusetts/2/2012 (Q&A summary)

What is it?

- The notified micro-organism is a live, genetically modified, cold-adapted and temperature-sensitive attenuated flu virus which was derived from the seasonal influenza B virus. The strain is a component of the 2013-2014 FluMist[®] flu vaccine (live, attenuated, nasal spray) and will be imported to Canada by AstraZeneca Canada Inc.
- Influenza viruses, members of the *Orthomyxoviridae* family, are enveloped viruses that contain a segmented genome composed of negative-sense, single-stranded RNA. There are three types of influenza virus, A, B and C, and these are distinguished by differences between their nucleocapsid (NP) and matrix (M) proteins.

How is it used?

- *Influenza virus* cold-adapted B/Massachusetts/2/2012 will be used in the preparation of FluMist[®] vaccine for 2013-2014 seasonal flu immunization.

Why did the Government of Canada assess it?

- A micro-organism that is not on the *Domestic Substances List* (DSL) and is not subject to federal legislation listed in Schedule 4 of *the Canadian Environmental Protection Act, 1999* (CEPA 1999), is considered “new” and before it is manufactured in or imported into Canada, the Government must assess its potential to harm human health and the environment under the *New Substances Notifications Regulations (Organisms)*, as required by Section 106 of CEPA 1999. *Influenza virus* cold-adapted B/Massachusetts/2/2012 is not on the DSL.
- The Government of Canada conducted an assessment on *Influenza virus* cold-adapted B/Massachusetts/2/2012 because AstraZeneca Canada Inc. submitted a notification of its intention to import this product containing a new micro-organism into Canada for use in the FluMist[®] vaccine for 2013-2014 seasonal immunization.

How is it released to the environment?

- Immunization with FluMist[®] vaccine is expected to occur in flu vaccination clinics and pharmacies only. Potential routes of introduction of *ca* B/Massachusetts into the environment are through coughing and sneezing by immunized patients or through the touching of surfaces and through the disposal of unused portions of the vaccine.

How are Canadians exposed to it?

- Flu viruses are passed from person to person by coughing and sneezing or by touching surfaces contaminated by a cough or sneeze. Like other respiratory viruses, *ca* B/Massachusetts may be transmitted either by large droplets (> 100 µm diameter) or by respirable airborne droplets (<5 µm diameter). Larger droplets settle quickly and are more likely to contaminate surfaces. Small droplets remain suspended, travel further and are more likely to cause infection in the lower respiratory tract. Transmission via hand contact is also a possibility; however, this is limited due to the rapid inactivation of influenza virus on non-living objects.
- Water is unlikely to be a source of transmission of the vaccine strain since drinking water treatment plants are expected to inactivate the flu viruses.
- Unused portions of the vaccine are disposed of as biological waste or steam sterilized. Further procedures are in place to prevent inadvertent release of the notified vaccine strain during transport and at the clinical sites
- Taking all these factors into consideration, the indirect human health exposure to the notified organism was considered to be low.

What are the results of the assessment?

- The Government of Canada has conducted a science-based risk assessment of *Influenza virus* cold-adapted B/Massachusetts/2/2012.
- Risk assessments address potential for harm to the general population in Canada (not including workplace exposures) and the environment.
- *Influenza virus* cold-adapted B/Massachusetts/2/2012 has not been found to cause serious adverse effects in humans, animals or plants.
- *Influenza virus* cold-adapted B/Massachusetts/2/2012 was therefore not considered to be harmful to human health or the environment based on the intended use, and the Government of Canada has concluded that *Influenza virus* cold-adapted B/Massachusetts/2/2012 is not entering the environment in a quantity or under conditions that constitute a danger to the environment or humans.

What is the Government of Canada doing?

- Based on the conclusion of the risk assessment, the Government of Canada will take no further action on *Influenza virus* cold-adapted B/Massachusetts/2/2012.