Importation

• ... is bringing an item from outside of Canada, into Canada
• Regulated items relevant to the biosafety program include:
  – Microorganisms, toxins and prions
  – Certain human samples
  – Soil
  – Certain plants and seeds
  – Certain invertebrates
  – Certain aquatic species
  – Certain animal samples

• Regulators are Public Health Agency of Canada and the Canadian Food Inspection Agency

McMaster University is the IMPORTER OF RECORD therefore YOUR actions result in sanctions against the University.
Human Pathogens & Toxins Regulations

- **(Reg) 4. (1)(b)** a person who intends to conduct any of the following controlled activities must communicate that intention to the biological safety officer **BEFORE** they make any arrangements to do so:
  - (i) importing or exporting a human pathogen or toxin,
  - (ii) possessing a human pathogen or toxin as a result of receiving from another licence holder or from a person who is conducting controlled activities authorized by another licence, or
  - (iii) transferring a human pathogen or toxin to another licence holder or to a person who is conducting controlled activities authorized by another licence;

- **(Act) 53.** Subject to sections 54 to 58, every person who contravenes this Act or the regulations is guilty of an offence and liable, on summary conviction,
  1. **(a)** in the case of a contravention with respect to a human pathogen that falls into Risk Group 2,
     - (i) for a first offence, to a fine of not more than $50,000, and
     - (ii) for a subsequent offence, to a fine of not more than $250,000 or to imprisonment for a term of not more than three months, or to both; and
  2. **(b)** in all other cases,
     - (i) for a first offence, to a fine of not more than $250,000 or to imprisonment for a term of not more than three months, or to both, and
     - (ii) for a subsequent offence, to a fine of not more than $500,000 or to imprisonment for a term of not more than six months, or to both.

The government determines what constitutes a human pathogen and its risk group level.
Health of Animals Act/Regulations

- Importation of animal pathogens without an import permit is prohibited.
- *(Reg) 51.* Subject to section 51.2, no person shall, except under and in accordance with a permit issued by the Minister under section 160, import into Canada any:
  - *(a)* animal pathogen;
  - *(b)* animal, animal product, animal by-product or other organism carrying an animal pathogen or part of one; or
  - *(c)* animal blood or animal serum, other than a veterinary biologic,
    - *(i)* from a bird or a mammal, except a member of the orders *Rodentia, Cetacea, Pinnipedia* and *Sirenia*, and
    - *(ii)* that are to be used in animals.
- *(Act)65. (1)* Every person who contravenes any provision of this Act, other than section 15, or the regulations or who refuses or neglects to perform any duty imposed by or under the Act or the regulations is guilty of:
  - *(a)* an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars or to imprisonment for a term not exceeding six months, or to both; or
  - *(b)* an indictable offence and liable to a fine not exceeding two hundred and fifty thousand dollars or to imprisonment for a term not exceeding two years, or to both.

$50,000 / 6 months in jail or $250,000 / 2 years in jail

The government determines what constitutes an animal pathogen and its risk group level.
Plant Protection Act/Regulations

- **Importation of plant pests without an import permit is prohibited**
- **(Reg) 29. (1)** Subject to subsections (1.1) to (5) and the conditions set out in sections 38 to 44, no person shall import into Canada any thing that is a pest, is or could be infested or constitutes or could constitute a biological obstacle to the control of a pest, unless the person has obtained and furnished to an inspector a valid permit number and, as applicable, a foreign Phytosanitary Certificate or a foreign Phytosanitary Certificate for Re-export.
- **(Act) 9. (1)** No person shall possess or dispose of a thing that the person knows was imported in contravention of this Act or the regulations.
- **(Act) 48. (1)** Every person who contravenes any provision of this Act, other than section 9, or the regulations or who refuses or neglects to perform any duty imposed by or under the Act or the regulations is guilty of
  - (a) an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars or to imprisonment for a term not exceeding six months, or to both; or
  - (b) an indictable offence and liable to a fine not exceeding two hundred and fifty thousand dollars or to imprisonment for a term not exceeding two years, or to both.
- **(Act) 48. (2)** Every person who contravenes section 9 is guilty of an offence punishable on summary conviction and liable to a fine not exceeding fifty thousand dollars.

$50,000 / 6 months in jail or $250,000 / 2 years in jail

The government determines what constitutes a plant pest and its risk group level.

NO CHANGE in this legislation. Permits under this are STILL REQUIRED.
Importation Infraction

• ... is bringing an item into Canada without the correct documentation, usually import permits
• If an item requires a permit, and you did not get one or more, and you have imported that item or caused that item to arrive at the Canadian border, you have broken the law
  – Plant Protection Act, Seeds Act, Invasive Plants Act
  – Health of Animals Act
  – Human Pathogens and Toxins Act
• Just because you may have got it in without a permit, does not erase the infraction
• We were inspected by PHAC because of this, one of our requirements was to implement an import incident tracking system, follow up and determination of root causes – we now log these cases as incidents
• We were also required to implement a system of progressive discipline – we did (RMM106-submitted for approval Sept 2015)
Importation Permits

• Even though you may not consider an item hazardous to humans, it may be hazardous to animals or plants
• PHAC permits for human pathogens are not required after Dec 1, 2015 BUT HPTA regulations mandate that the biosafety office is NOTIFIED prior to ARRANGING to receive an item
• CFIA permits plant/aquatic are still required if applicable
• How do I know if it is applicable?
  – Email customs@mcmaster.ca They MUST be able to tell you definitely NOT. If they cannot rule out a permit requirement i.e. they cannot find the entry in the database, you must apply for a permit.
  – Apply for a permit, anyways
  – (CFIA will not answer this question without an import permit application)
Does the distributor **import** the item / Is the collaborator **outside** of Canada??

Yes

Is the item a regulated plant pest??

Yes, its on the list

Send email notification to the biosafety manager (robertjv@mcmaster.ca) Please add the item to your BUP. No other action is necessary until PBAC review.

No

Has internal Customs & Traffic (customs@mcmaster.ca) determined if an import permit is **NOT** needed from CFIA?

Yes

DO NOT ORDER OR ARRANGE DELIVERY UNTIL THIS IS COMPLETED. Please contact the biosafety manager (robertjv@mcmaster.ca) to initiate permit and checklist applications. Please contact the biosafety auditor (carte@mcmaster.ca) to complete an AQC and/or PPC checklist. Please complete and application for Written Authorization for Use from CFIA for domestically regulated plant pests ***. All applications are submitted to the relevant government agency through the Biosafety Office.

No

No

Does the item infect* terrestrial animals, aquatic animals or plants? Is it a foreign animal disease agent or an emerging disease agent? Is the item a plant, invertebrate, seeds or soil? Is the item an animal product, tissue, embryo or germplasm? Is the item a Risk Group 3 or 4 agent?

Yes or I am not sure

Yes

No

Send email notification to the biosafety manager (robertjv@mcmaster.ca) Please add the item to your BUP. No other action is necessary until PBAC review.

* the ability to infect does not necessarily imply that disease can result


*** http://www.inspection.gc.ca/plants/plant-pests-invasive-species/directives/date/d-12-03/eng/1432656209220/1432751554580#a14
Is it a lot of work to get a permit from CFIA?

• Depends
• You require a lab inspection according to one or two checklists
  – CFIA Containment Standards for Facilities Handling Plant Pests
  – CFIA Containment Standards for Facilities Handling Aquatic Animal Pathogens
• The biosafety auditor, Carol Carte, does the audit (carte@mcmaster.ca)
• The checklist and import permit application are sent in together
• Once approved by the gov’t, the checklist will last for two years, therefore you don’t have to do the inspection for each import permit application within those two years
• CFIA(plant) division will likely want to come and inspect your lab if you are ordering a plant pest or receiving soil – we hear that they are doing this more regularly
Can’t I just borrow a cup of microorganism from a collaborator?

• Depends if there is an MTA and it allows this
• Yes, but there may be paperwork required before the transfer
• Most imported items come with transfer restrictions that require the receiver to do the checklists prior to transfer
• If no stipulations on your permit or the item you wish to give was not originally imported, no checklists required to be filled in but compliance with the standards must be maintained (receiver has valid BUP of appropriate biosafety level)
• Use the flowchart to determine if you can GIVE a sample or microorganism to a collaborator.
Is the item you want to give associated with an import permit – even if expired?

Yes

Does the import permit list transfer restrictions?

Yes

Do the restrictions include requiring permission from the agency?

Yes

Contact the Biosafety Office to initiate a pathogen transfer application.

No

No

No

You may transfer the item if the MTA allows it. Assure yourself that the receiver has the facilities and trained personnel to handle the item safely by receiving a statement. Retain that statement for due diligence.

No

No

Yes