FAQs (PHAC-CFIA merger)

Definitions

Health of Animal Regulations (HAR)

Human Pathogens Importation Regulations (HPIR)

Public Health Agency of Canada (PHAC)

Canadian Food Inspection Agency (CFIA)

Animal product: An animal product that originated from a bird or from any mammal except members of the *Rodentia, Cetacea, Pinnepedia*, and *Sirenia* orders. This includes cream, eggs, milk, non-fertilized ova, and semen.

Animal by-product: Blood or any of its components, bones, bristles, feathers, flesh, hair, hides, hoofs, horns, offal, skins, and wool, and any by product containing any of those components that originated from a bird or mammal (except members of the *Rodentia, Cetacea, Pinnepedia,* and *Sirenia* orders).

Aquatic animal: Any finfish, mollusc or crustacean, or any part of a finfish, mollusc or crustacean at any life stage, as well as any germplasm of those animals.

Emerging disease: A new infectious disease resulting from the evolution or change of an existing pathogenic agent, a known infectious disease spreading to a new geographic area or population, or a previously unrecognized pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or human health.

Foreign Animal Disease (FAD): Any disease that is listed in the World Organisation for Animal Health (OIE) Listed Diseases, as amended from time to time, and that is not indigenous to Canada. The OIE Listed Diseases is available on the World Organisation for Animal Health website at: http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2013

Zoonotic pathogen: A pathogen that can be transmitted from animals to humans and vice-versa.

Terrestrial Animal: Includes avian and amphibian animals, but does not include aquatic animals and bees.

Compliance letters/Importation permits

Which agency's compliance letter will be mandatory after April 1st 2013 in order to apply for an import permit or buy from a Canadian distributor?

PHAC will accept:

1. A valid post April 1st 2013 consolidated CL2 compliance letter
2. Both PHAC and CFIA pre April 1st 2013 valid CL2 compliance letters for zoonotic pathogens
3. A valid pre April 1st 2013 PHAC CL2 compliance letter for strict human pathogens
4. A valid pre April 1st 2013 CFIA CL2 compliance letter for strict animal pathogens

Note: When either your CFIA or PHAC CL2 compliance letter expires, you will be required to complete the new consolidated CL2 checklist.

Which CL2 checklist and *Application for Permit to Import* forms will PHAC accept as of April 1st, 2013? Will PHAC accept both applications? Will there be any grace period?

As of April 1st, 2013, only the PHAC new forms will be accepted.

If my CFIA Import permit expires in April, can I only use my valid PHAC import permit to import zoonotic pathogens or do I need to obtain a new Permit from PHAC?

You will need to apply for a new import permit from PHAC only. This new permit will allow you to import both terrestrial animal and human pathogens under both the HPIR and HAR.

To whom should I submit my import permit application in mid-March 2013 - CFIA or PHAC? And which importation permit application should I submit?

Up to March 15 2013, both Agencies have processed applications. Going forward, you should only use PHAC's new permit application form (covering HPIR and HAR), as only PHAC will process applications. New permits will be issued after April 1st, 2013.

Can we submit and receive importation permit and transfer letter applications by email? What about CL2 Compliance letter applications?

Yes, PHAC will accept importation permit, transfer letter and CL2 Compliance letter applications by email as long as they are signed. PHAC can issue Importation Permits, CL2 Compliance letters, and Transfer letters by email upon request.

Will PHAC be charging a fee for submitting a permit application?

No, PHAC does not charge for the issuance of regulatory documents.

After April 1st, 2013, am I still required to complete a CFIA *Application for Permit to Import* form from CFIA for animal samples? Will CFIA accept my new consolidated CL2 compliance letter?

CFIA will continue to regulate animal products and by-products, so you will need a CFIA permit to import animal samples. If the animal product or by-product contains a human pathogen, you will be required to obtain an Import permit from both PHAC and CFIA. If the animal product or by-product does not contain human pathogens, only a CFIA Import permit is required. CFIA will accept either a valid CFIA compliance letter or the new consolidated CL2 compliance letter issued by PHAC.

What happens if I want to import animal feces? Do I only need an Import permit from CFIA, if PHAC does not regulate animal by-products?

CFIA continues to regulate animal by-products, so you will require a CFIA import permit to import animal feces. If the feces is known to contain zoonotic pathogens, you need to apply for an import permit from PHAC as well.

Does PHAC issue Import permits for animal cell lines that contain human pathogens? Do I also need a permit from CFIA?

Only PHAC would regulate an established animal cell line that contains human and/or animal pathogens. For primary cell lines, if the pathogen is zoonotic, an Import permit from both CFIA and PHAC is required, since primary cell lines are considered animal by-products.

Do I only need an import permit from PHAC for toxins?

Yes. Only PHAC will regulate the import of toxins.

Note: Toxins regulated under the HPIR correspond to those listed under Schedule 1 of the HPTA.

What import permit(s) do I need to import influenza virus that is contained in chicken eggs?

Influenza virus is not naturally found in chicken eggs, which are considered animal by-products. Both CFIA and PHAC import permits would then be required.

Does PHAC still regulate the import of Non-Human Primate specimens? What about *Macaca* specimens with suspected herpesvirus B infection?

If the Non-Human Primate specimen is not suspected of harboring pathogens, PHAC does not regulate these imports. If the Non-Human Primate specimen is suspected of harboring pathogens, an importation permit from PHAC is required. In the case of *Macaca* specimens, it should be presumed that they harbor herpesvirus B and therefore an import permit from PHAC is required. CFIA regulates importation of live primates.

To whom should I submit an import permit application if I want to import animal blood samples that contain a zoonotic pathogen?

For all animal blood samples that contain a zoonotic pathogen you need an import permit from both PHAC and CFIA.

Compliance Level 3

Is my CL3/TSE certification letter issued by CFIA still valid after April 1st, 2013? If so, will it be recognized by PHAC?

CL3/TSE certification letters issued by CFIA prior to April 1st, 2013 will be recognized by PHAC until the date of expiration.

I am applying to CFIA to obtain an import permit for tissue containing TSE/animal pathogen/human pathogen. How does CFIA know that my laboratory has been certified by PHAC?

You must provide a copy of your PHAC certification letter along with your application for a permit to import tissue containing TSE/animal/human pathogens to CFIA in order to help facilitate the processing of the import permit. CFIA will be contacting PHAC directly to confirm your laboratory's certification, including date of expiry, room numbers, and program intent.

Who do I submit my CL3 certification submission to? Do I still need to submit to CFIA, and if so, when do I need to submit to CFIA?

You will submit your CL3 laboratory certification submission to PHAC. For laboratories working with and importing emerging pathogens and FADs, PHAC will coordinate with CFIA for its review of the biocontainment components required for these pathogens. The exception to this would be laboratories belonging to the CFIA FAD Laboratory Network; these laboratories will submit their FAD laboratory certification submission to CFIA.

Who do I submit my TSE certification submission to? Do I still need to submit to CFIA, and if so, when do I need to submit to CFIA?

You will submit your TSE certification submission to PHAC. The exception to this would be laboratories belonging to the CFIA Prion Laboratory Network; these facilities will submit their prion laboratory certification submission to CFIA.

I have a CL3/TSE laboratory that was not previously regulated by PHAC. Now that PHAC will assume the role of CFIA in issuing animal pathogen importation permits and certifying laboratories, do I need to register under the Human Pathogens and Toxins Act (HPTA)?

Section 70 of the HPTA requires anyone responsible for activities involving human pathogens belonging to Risk Group 2, 3, or 4, or toxins on Schedule 1 of the Act, to register under the HPTA. If you are responsible for activities involving human pathogens, then you must register under the HPTA. If you are not responsible for activities involving human pathogens, then you do not need to register under the HPTA.

I have a CL3/TSE laboratory that was not previously regulated by PHAC. Now that PHAC will assume the role of CFIA in issuing animal pathogen importation permits and certifying laboratories, will PHAC have my facility's background and history or will we have to provide this to PHAC?

PHAC and CFIA are working together to ensure that the background and history of laboratories are transferred.

I have a CL3/TSE laboratory that was not previously regulated by PHAC. Now that PHAC will assume the role of CFIA in issuing animal pathogen importation permits and certifying laboratories, will my laboratory be audited/inspected by PHAC?

Yes, your laboratory can now be inspected by PHAC. PHAC inspectors will be conducting the regulatory enforcement activities for authorities under the Health of Animals Act (HAA) and Health of Animals Regulations (HAR) that are transferred to PHAC. PHAC inspectors will be designated as CFIA inspectors. When enforcing the HAA and HAR, PHAC inspectors will then be acting on behalf of CFIA.

What is the recertification process for CL3 laboratories handling FADs?

This will depend on your laboratory's program intent. If you are working with and importing FADs in addition to other human and/or animal pathogens, you will submit your CL3 certification submission to PHAC. PHAC will then coordinate with CFIA for its review of the biocontainment components required for these pathogens. If you are working with and importing only FADs (e.g. and no other human and/or animal pathogens), then you will submit your CL3 certification to CFIA. Laboratories belonging to CFIA FAD Laboratory Network will also submit their FAD laboratory certification submission to CFIA.

Will there be new certification/recertification forms? If so, where can I find them?

Yes, there will be new certification and recertification forms. These forms will be updated to reflect the merger as well as the first edition of the Canadian Biosafety Standards and Guidelines (CBSG). They will be made available on the PHAC Pathogen Regulation Directorate website upon publication of the CBSG.

What will be the new service delivery standard for CL3 laboratory recertification by PHAC (e.g. how many business days from when PHAC receives my CL3 recertification submission to when I receive the review report from PHAC)?

The service delivery standard for CL3 recertification will be 15 business days for CL3 laboratories that do not work with or import FADs. The service delivery standard for CL3 recertification for laboratories working with or importing FADs will be 30 business days. *This does not include laboratories belonging to the CFIA FAD Laboratory Network.*

What will be the new service delivery standard for TSE laboratory recertification by PHAC?

The service delivery standard for TSE recertification will be 15 business days. *This does not include laboratories belonging to CFIA TSE Laboratory Network.*

Will PHAC accept documentation related to CL3/TSE certification and recertification electronically? This has been acceptable to CFIA.

Yes, PHAC will accept documentation in support of CL3/TSE certification and recertification electronically.