



☎ (905) 333-8188
Fax: (905) 333-0500
Toll Free: 1-800-363-7907
E-mail: pulsescientific@msn.com

Canadian Food Inspection Agency (CFIA) Requirements

Dear Customer,

In an effort to control the import of infectious substances, the Canadian Food Inspection Agency of Canada (CFIA) requires Pulse Scientific Inc. and the End-User of these infectious substances (Customers of Pulse Scientific) to have proper facilities to handles these substances.

Pulse Scientific Inc. is required to request our customers to sign the following documents. Only the Import Conditions Letter is to be returned to Pulse Scientific. CFIA Checklist and Waiver Form need to be returned via fax to CFIA directly. The explanation below should clarify these documents.

Documents	Source	Return To
CFIA Checklist	CFIA	CFIA via Fax at 613-228-6129
Waiver Form	Pulse Scientific	CFIA via Fax at 613-228-6129
Import Condition Letter	Pulse Scientific	PULSE via Fax at 905-333-0500

Contact at CFIA

Permit Clerk

Canadian Food Inspection Agency – Office of Biohazard Containment & Safety

59 Camelot Drive

Ottawa, Ontario K1A 0Y9

Phone 613-221-7068

Fax 613-228-6129

Email: ImportZoopath@inspection.gc.ca

PS: The Office of CFIA will send you a "Compliance Letter" upon approval of your company's Checklist. It is then your responsibility to fax a copy of this letter to Pulse Scientific Inc. at 905-333-0500.



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CFIA Import Permit Conditions for Pulse Scientific

Dear Customer,

Pulse Scientific Inc. is an importer and distributor of Lyophilized Bacterial/Fungal Cultures produced by Microbiologics. In order to comply with the regulations imposed upon us by the Canadian Food Inspection Agency (CFIA), we need to inform you of these following conditions as required by CFIA.

Conditions:

1. All infectious materials must be handled in an appropriate animal pathogen containment level 2 facilities as described in Containment Standards for Veterinary Facilities, 1996, AAFC publications no. 1921.
2. The material authorized for importation by this permit is to be used in vitro studies ONLY and must not to be introduced into laboratory, domestic or wild animals (including birds and fish) unless written authorization is obtained from the Canadian Food Inspection Agency.
3. Upon completion of the tests or experiments, the imported material as described on this permit and any derivatives thereof must be autoclaved, incinerated or alternatively disposed of in a manner approved by an inspector of the Canadian Food Inspection Agency.
4. Records pertaining to the imported product's use, storage and disposal must be maintained for two (2) years following importation. These records must be made available for inspection by the Canadian Food Inspection Agency upon request.

Your signature below will attest to the fact that you were informed by writing of the conditions of the Import Permit for Pulse Scientific.

Company Name

Name of Person, Position and Date

Phone

Fax

email



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Waiver Form for CFIA

I hereby agree and so authorize and direct that Canadian Food Inspection Agency of Canada (CFIA) shall hereby authorize to release to Pulse Scientific Inc., any and all checklists or details regarding the compliance of checklists in accordance with the *Laboratory Biosafety Guidelines*, 3rd Edition, 2004 that I have provided to CFIA.

Please answer the following questions listed in the table below:

Room # in which the Imported Material will be used:
Type of work being performed with the Imported Material: <input type="checkbox"/> In Vitro <input type="checkbox"/> In Vivo

Company Name

Company Address

Approved By: Name & Signature of the Person, Position and Date

Phone #:

Fax #:

Email:



CFIA-ACIA

Canadian Food Inspection Agency
 Biohazard Containment & Safety Division
 Laboratories Directorate
 159 Cleopatra Dr.
 Ottawa, ON K1A 0Y9
 Tel: (613) 221-7068
 Fax: (613) 228-6129
 Email: latreillen@inspection.gc.ca

Division des biorisques, du confinement et de la sécurité
 Direction des laboratoires
 159 Promenade Cleopatra
 Ottawa, ON K1A 0Y9
 Tel: (613) 221-7068
 Fax: (613) 228-6129
 Email: latreillen@inspection.gc.ca

Inspection Checklist - Animal Pathogen Containment Level 2 Laboratories

Importer's Name:	Safety Officer:
Address:	Address:
Phone: Fax:	Phone: Fax:
Imported Material:	
Building / Room # where material will be handled:	

Item	Reference to Standard	Questions	Satisfactory (S) Unsatisfactory (US) N/A	Comments
1- Organizational Structure				
Biological Safety Officer		Is there a Biological Safety Officer or individual responsible for biological safety? <i>(this individual should be present during the inspection)</i>		
Safety Manual	p. 45	Is there a laboratory procedural or safety manual? <i>(quickly review the manual)</i>		
		Is there a copy of "Containment Standards for Veterinary Facilities" available to lab staff? <i>(have staff read this document)</i>		

Inspection Checklist - Animal Pathogen Containment Level 2 Laboratories

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Item	Reference to Standard	Questions	Satisfactory (S) Unsatisfactory (US) N/A	Comments
2- Training				
Training	p. 45	Have lab staff read and understood the safety manual? <i>(ask a lab staff member if they read the manual)</i>		
	p. 45	Do all persons in the laboratory know and follow the operational protocols for the projects in process?		
	p. 45	Is there written documentation of the training provided? <i>(review this documentation)</i>		
	p. 45	Are housekeeping staff trained in the hazards associated with the imported material? <i>(what kind of training to cleaners receive)</i>		
	p. 45	Are other staff entering the lab (e.g. maintenance workers) trained in hazards specific to the imported material? <i>(what kind of training do maintenance workers receive)</i>		
3- Physical Requirements				
Access	p. 6	Is access to the laboratory area restricted to persons on official business? <i>(determine how - locks and/or signs)</i>		
Signs	p. 6	Are biohazard signs posted on the laboratory doors warning of the agents in use?		
	p. 6	Do the signs list the name and phone number of the person to contact in case of emergency?		
Offices	p. 7	Are office areas located outside of lab working areas? <i>(paperwork stations are permitted within the lab areas)</i>		
	p. 7	Are the paperwork stations in the labs located away from hazardous materials? <i>(check that manipulation of biologicals is done away from the paperwork)</i>		
General Condition	p. 47	Is the lab kept neat, orderly and clean?		
Perimeter	p. 8	Are doors and windows to the laboratory area kept closed? <i>(check to make sure there are no door stops by the doors)</i>		

Inspection Checklist - Animal Pathogen Containment Level 2 Laboratories

Item	Reference to Standard	Questions	Satisfactory (S) Unsatisfactory (US) N/A	Comments
Furnishings	p. 37	Are bench tops in good condition and general repair? <i>(they should be cleanable and resistant to disinfection, ie. no open wood on the bench tops)</i>		
	p. 38	Are hand washing sinks provided in the laboratory?		
Air Handling System	p. 10	Does the laboratory have inward directional airflow? <i>(check this at doorway using a smoke pencil or tissue)</i>		
	p. 43	Does the HVAC system interfere with the airflows of biological safety cabinets? <i>(check to make sure cabinets are not located directly under a supply diffuser)</i>		
Biological Safety Cabinets (BSC)	p. 48	Are BSC's used for heavy aerosol generating procedures? <i>(work with agents on the bench is permitted at level 2 - lab supervisor should assess which procedures to be done in BSC)</i>		
	p. 44	Are BSC's certified in accordance with CSA Z316.3-95 at least annually? <i>(check for certification sticker - certification to NSF 49 is also permitted)</i>		
	p. 44	Does the certification sticker indicate the date of next certification, to what standards the tests were performed and the name of the certifier?		
	p. 44	Is a copy of the certification report readily available? <i>(ask to see a copy of the report)</i>		
Autoclaves	p. 9	Is there an autoclave in the laboratory area? <i>(can be located in a central decontamination area for the facility)</i>		
	p. 9	Is the autoclave equipped with a cycle log recorder? <i>(examine one of the print outs of a run and check for sterilization, ie. 121°C)</i>		
Pest Program	p. 9	Is the laboratory proofed against vermin and insects? <i>(check for dead flies and mouse droppings)</i>		
4- Operational Practices				
Uniforms	p. 47	Are lab coats, gowns or coveralls worn when working in the laboratory?		

Inspection Checklist - Animal Pathogen Containment Level 2 Laboratories

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Item	Reference to Standard	Questions	Satisfactory (S) Unsatisfactory (US) N/A	Comments
	p. 47	Are the lab coats worn only in the laboratory areas? <i>(check to see if anyone is wearing lab coats in offices, cafeteria, library)</i>		
	p. 47	Are gloves worn when directly contacting the imported infectious materials?		
	p. 48	Are gloves decontaminated before disposal? <i>(check to ensure no latex gloves are disposed of in regular garbage)</i>		
	p. 47	Are hands washed after handling infectious materials and before leaving the laboratory? <i>(If you've touched anything in the lab, do they make you wash your hands when you leave the area)</i>		
	p. 47	Is eating, chewing gum, smoking, storing food and applying cosmetics prohibited? <i>(check the fridge for food)</i>		
	p. 47	Are only closed toe and heel footwear worn in the laboratory area?		
	p. 47	Is long hair tied back so that it cannot come into contact with hands, specimens and equipment?		
Decontamination	p. 60	Are written procedures available for the decontamination methods used? <i>(ask to review a copy of these documents)</i>		
	p. 48	Are all contaminated materials decontaminated before disposal? <i>(Please specify - autoclaving / disinfection / incineration)</i>		
	p. 48	Are contaminated work surfaces decontaminated at the end of the day? <i>(do they swab the bench tops with disinfectant)</i>		
	p. 61	Are the disinfectants used for decontamination effective against the imported agent? <i>(Please specify which disinfectants are being used)</i>		
	p. 48	Is the efficacy of the autoclave monitored using biological indicators? <i>(ask to see their indicators and how they conduct this testing)</i>		
	p. 48	Are records of the efficacy testing kept on file? <i>(review these files)</i>		

Item	Reference to Standard	Questions	Satisfactory (S) Unsatisfactory (US) N/A	Comments
	<i>p. 48</i>	Are the autoclave cycle log recordings kept on file? <i>(review these files)</i>		
Emergency Procedures	<i>p. 46</i>	Are there written emergency procedures for spill clean-up, BSC failure, power failure, animal escape and other emergencies? <i>(review a copy of these procedures)</i>		
Records		Are there records kept of the imported pathogen? <i>(review these records)</i>		
		Do the records indicate where the pathogen was used/stored and the date of disposal? <i>(trace an imported pathogen through the record system from receipt to disposal)</i>		

 Laboratory Representative

 Institutional Safety Officer

 Date