VIVENTIA BIO INC.
147 Hamelin Street
Winnipeg, Manitoba
Canada R3T 3Z1

Tel: (204) 478-1023
Fax: (204) 452-7721
Email: [illegible]ventia.com
Web: www.viventia.com



September 21, 2015

Tracey Braun
Environmental Approvals Branch
Manitoba Conservation and Water Stewardship
Box 80 - 123 Main Street
Winnipeg, MB R3C 1A5

Rec'd on Oct. 15/15 Raj.

Dear Ms. Braun:

**Re: Request for alternative method of HEPA filters disposal - Viventia's Environment Act License Number 1623 R**

Further to our discussion with Alvin Dyck and his letter dated June 24, 2015, we are submitting this letter to request your approval for an alternative method of disposing used HEPA filters arising from our process operations as part of any necessary repair or scheduled preventive maintenance.

Our company, Viventia Bio Inc., utilizes HEPA filters in various applications as listed below. We assessed the degree of microbiological contamination for each application as follows:

| Equipment | Risk of microbiological contamination |
|---|---|
| Biosafety cabinet | High |
| Laminar Flow | Nil to Low |
| Clean Room | Nil to Low |
| Depyrogenation oven | Low |
| Incubators | Low |

In our Environment Act Licence No. 1623R, clause 22(b) of the licence states:

*The Licencee shall dispose of HEPA filters, exposed to air from the Development, which are contaminated with:*

*b) microbiological organisms by either:*

*i) continuous exposure to formaldehyde gas at a concentration and for a sufficient time to decontaminate the filter, followed by landfilling or incineration; or*

*ii) by an alternative method approved by the Director.*

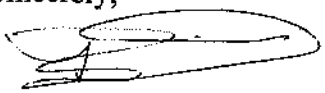
From the list of applications stated above, the HEPA filters from our biosafety cabinets, when disposal is required, shall be disposed as spelled out in clause b)i. As for other HEPA filters with low to negligible risk of microbiological contamination, we are requesting your approval to use an alternative method as stated below:

> *Steam autoclaving at a temperature of at least 121°C at a pressure of 15 psi for more than 1 hr and then dispose to garbage bin for landfilling through a garbage collection company.*

The above-mentioned method is adapted from the Guidelines for the Management of Biomedical Waste in Canada CCME EPC-WM-42E, dated February 1992. With this alternative, we do not expect any significant environmental effects.

I appreciate the effort that you and your staff will make in processing this request. Should you have any questions, I can be reached at (204) 478-1023 ext. 308 or by e-mail at rdillon@viventia.com.

Sincerely,



Rachelle Dillon
Environmental, Health & Safety Officer
Viventia Bio Inc.

cc. Alvin Dyck, Environment Officer, Environmental Compliance and Enforcement

## Beshada, Eshetu (CWS)

**From:** Ferdinand Dela Cruz [mailto:FDelaCruz@viventia.com]
**Sent:** April-08-16 12:56 PM
**To:** Beshada, Eshetu (CWS)
**Cc:** Rachelle Dillon
**Subject:** RE: File 3459 - Viventia Bio Inc.- Notice of Alteration

Hello Mr. Beshada,

Sorry for the delayed response. We couldn't reply as soon as possible because we have to verify the previous information we have for Item 2. We would like to answer your queries as follows:

1. **Confirm if there is any protocol in place to segregate HEPA filters that are from the biosafety cabinets and other HEPA filters with low to negligible risk of microbiological contamination.**

   We have standard operating procedures (SOPs) in place to deal with used HEPA filters from every pieces of equipment, although, there is no stated protocol "to segregate" the HEPA filters since it is remote to replace filters from every piece of equipment at the same time. In our operation, HEPA filters from biosafety cabinets and other HEPA filters are seldom replaced (except for incubator HEPA filters) due to their long lifespan based on our experience. Our installed HEPA filters are regularly integrity tested/re-certified/maintained and majority exceed the 10-year maximum frequency of replacement (typical manufacturer's recommended frequency of replacement is in between 5 to 10 years).

   We have specific Preventative Maintenance SOPs for each equipment which incorporate the disposal method for HEPA filters installed. Our standard operating procedures can be summarized as follows:

   (1) ***Biosafety Cabinet***: SOP 4.1.21 rev 04 Certification and Maintenance of Biological Safety Cabinets, Laminar Flow Hoods and Fume Hoods states that "decontamination of biosafety cabinets is to be performed" when required (ie. decommissioning or replacement). We follow clause 22(b)(i) of our Environmental Act License No. 1623R when disposing HEPA filters or decommissioning biosafety cabinets. We get outside contract help from licensed decontamination company such as Con-Test.

   (2) ***Laminar Flow:*** SOP 9.4.1 rev 02 Treatment and Disposal of Biological Materials and Waste Products. We consider laminar flow HEPA filter as having nil to low microbiological contamination. However, for safety and environmental reasons we still consider it as biological solid waste. Therefore, it will be treated as per SOP 9.4.1 by autoclave sterilization.

   (3) ***Clean Room:*** SOP 11.2.18 rev 02 Replacement of HEPA filters for Biopharm Pilot Plant and Fermentation Suite. Cleanroom HEPA filters are considered bio-waste as per our SOP and will be treated as per SOP 9.4.1.

   (4) ***Depyrogenation oven:*** SOP 11.3.4 rev 02 Maintenance of Depyrogenation Oven Model DCC-1406. HEPA filter for this equipment is classified as biological material with low degree of microbiological contamination. To be treated as per SOP 9.4.1.

   (5) ***Incubator:*** SOP 9.4.1 rev 02 Treatment and Disposal of Biological Materials and Waste Products. Incubator HEPA filters are considered as biological solid waste and will be treated according to this SOP.

2. **Provide the bacterial destruction capacity/rate of the proposed autoclave.**

   The proposed autoclave to be used is the Amsco Eagle 3000 Vacamatic Sterilizer with chamber size 24"x36"x48".

   In late December 2015 to early January 2016, we executed a Performance Qualification (PQ) protocol to challenge the destructive effectiveness of the autoclave using biological indicators (3M Attest Rapid Readout Biological Indicator P/N 1292; population, mean/strip = 1.7 X $10^5$ CFU). The PQ involved six cycles of sterilization process at ≥ 121 degrees Celsius for 30 minutes for each testing.

The PQ results show that all biological indicators in the six repeated testing did not show any growth after sterilization. We concluded that the autoclave is sufficient to kill not less than $1.7x10^5$ population of *Bacillus Stearothermophilus* which meet the ANSI/AAMI/ISO 11138-3:2006 standard for steam sterilization process.

If you have further questions, please let me know.

Thank you,

**Ferdinand Dela Cruz, CET, EIT**
Manager, Engineering and Metrology
Viventia Bio Inc
147 Hamelin Street
Winnipeg, MB
Canada R3T 3Z1
(204) 471-2782
(204) 452-7126 Ext. 364
fdelacruz@viventia.com