

# Environment Act Licence

Manitoba  
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# Loi sur l'environnement Licence

Licence No./Licence n° 1623 R

Issue Date/Date de délivrance January 26, 1993

Revised: April 24, 2002

**IN ACCORDANCE WITH THE MANITOBA ENVIRONMENT ACT (C.C.S.M. c. E125)  
THIS LICENCE IS ISSUED PURSUANT TO SECTIONS 10(1) AND 14(2) TO:**

**VIVENTIA BIOTECH INC.; "the Licencee"**

for the operation of the Development being a research, development and clinical trial level manufacturing pharmaceutical facility which handles and processes natural products of fermentation, recombinant DNA technology and implements other genetic engineering techniques, including all related activities, located at 147 Hamelin Street in the City of Winnipeg, in accordance with the Proposal dated March 10, 1992, and the Notice of Alteration dated May 27, 1998, and subject to the following specifications, limits, terms and conditions:

**DEFINITIONS**

In this Licence,

**"accredited laboratory"** means an analytical facility accredited by the Standard Council of Canada (SCC), or accredited by another accrediting agency recognized by Manitoba Conservation to be equivalent to the SCC, or be able to demonstrate, upon request, that it has the quality assurance/quality control (QA/QC) procedures in place equivalent to accreditation based on the international standard ISO/IEC 17025, or otherwise approved by the Director;

**"affected area"** means a geographical area, beyond the boundary of the property on which the Development is located;

**"biological solid waste material"** includes materials which may be contaminated during operational procedures through contact with biota e.g.: HEPA filters, etc.;

**"Director"** means an employee so designated pursuant to The Environment Act;

**"HEPA filter"** means a high efficiency particulate air filter exhibiting a minimum efficiency of 99.97% when tested at an aerosol of 0.3 micrometres diameter;

**"NIH"** means National Institutes of Health;

**"noise nuisance"** means a continuous or repeated noise in an affected area, which is offensive, obnoxious, troublesome, annoying, unpleasant or disagreeable to a person:

- a) residing in an affected area;
- b) working in an affected area; or
- c) present at a location in an affected area which is normally open to the members of the public;

**\*\*A COPY OF THIS LICENCE MUST BE KEPT ON SITE AT THE DEVELOPMENT AT ALL TIMES\*\***

if the noise

- d) is the subject of at least 5 written complaints, received by the Director in a form satisfactory to the Director, and within a 90 day period, from 5 different persons falling within clauses a), b), or c), who do not live in the same household;

**"odour nuisance"** means a continuous or repeated odour, smell or aroma, in an affected area, which is offensive, obnoxious, troublesome, annoying, unpleasant, or disagreeable to a person:

- a) residing in an affected area;
- b) working in an affected area; or
- c) present at a location in an affected area which is normally open to the members of the public;

if the odour, smell or aroma

- d) is the subject of at least 5 written complaints, received by the Director in a form satisfactory to the Director, and within a 90 day period, from 5 different persons falling within clauses a), b), or c), who do not live in the same household;

**"opacity"** means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background;

**"particulate matter"** means any finely divided liquid or solid matter other than water droplets;

**"particulate residue"** means that part or portion of an atmospheric emission which is deposited onto a surface;

**"point source"** means any point of emission from the Development where pollutants are emitted to the atmosphere by means of a stack;

**"QA/QC"** means quality assurance/quality control;

**"stack"** means a duct, pipe, chimney, vent, opening or other structure through which pollutants are emitted to the atmosphere;

**"Standard Methods for the Examination of Water and Wastewater"** means the most recent edition of Standard Methods for the Examination of Water and Wastewater published jointly by the American Public Health Association, the American Waterworks Association and the Water Environment Federation;

**"VOC"** means volatile organic compound;

**"volatile organic compound"** means any organic substance, mixture of organic substances, or the organic components of any mixture of organic and inorganic substances that participates in atmospheric photochemical reactions excluding methane, carbon monoxide, carbon dioxide, carbonic acid, metallic carbides and carbonates, ammonium carbonate and other compounds which may be exempt by the Director;

**"solvent"** means any non-aqueous substance, either organic or inorganic, that is used in any process for purposes of cleaning, concentrating, purifying, dissolving, dispersing, suspending or otherwise altering the physical properties of any material used or produced at the Development; and

"waste(s)" means waste products of any kind whatsoever or the run-off from such waste products and includes both liquid and solid materials.

### GENERAL TERMS AND CONDITIONS

This Section of the Licence contains requirements intended to provide guidance to the Licencee in implementing practices to ensure that the environment is maintained in such a manner as to sustain a high quality of life, including social and economic development, recreation and leisure for present and future Manitobans.

1. The Licencee shall implement a high standard of equipment maintenance and good housekeeping and operational practices with respect to the Development, at all times.
2. The Licencee shall reduce the production and dissemination of wastes by initiating and maintaining waste reduction and waste recycling programs.
3. The Licencee shall, upon the request of the Director and in addition to any of the limits, terms or conditions specified in this Licence:
  - a) sample, monitor, analyze and/or investigate specific areas of concern regarding any segment, component or aspect of pollutant storage, containment, treatment, handling, disposal or emission systems, for such pollutants or ambient quality, aquatic toxicity, leachate characteristics and discharge or emission rates, whether to land, water or air, for such duration and at such frequencies as may be specified;
  - b) determine the environmental impact associated with the release of any pollutants from the said Development; or
  - c) provide the Director, within such time as may be specified, with such reports, drawings, specifications, analytical data, descriptions of sampling and analytical procedures being used, bioassay data, flow rate measurements and such other information as may from time to time be requested.
4. The Licencee shall, unless otherwise specified in this Licence:
  - a) carry out all preservations and analyses on liquid samples in accordance with the methods prescribed in the most current edition of Standard Methods for the Examination of Water and Wastewater or in accordance with equivalent preservation and analytical methodologies approved by the Director;
  - b) carry out all sampling of, and preservation and analyses on, soil and air samples in accordance with methodologies approved by the Director;
  - c) ensure that all analytical determinations are undertaken by an accredited laboratory; and
  - d) report the results to the Director within 60 days of the samples being taken.
5. The Licencee shall carry out any remedial measures, modifications, or alterations, as deemed necessary by the Director, in respect to matters authorized under this Licence.
6. The Licencee shall provide to the Director, upon request, all information required under this Licence, in writing and in such form and content (including number of copies), as may be specified by the Director.

### **LIMITS, TERMS AND CONDITIONS**

7. The Licencee shall not emit from the Development:
  - a) particulate matter in any air emission that:
    - i) exceeds 0.23 grams per dry standard cubic metre calculated at 25 degrees Celsius and 760 millimetres of mercury, corrected to 12 percent carbon dioxide for processes involving combustion, from any point source of the Development;
    - ii) exhibits a visible plume with an opacity of greater than 5 percent at any point beyond the property line of the Development; or
    - iii) results in the deposition of visible particulate residue at any time beyond the property line of the Development; or
  - b) particulate matter from any point source with an opacity that equals or exceeds:
    - i) 20 percent as the average of any 24 consecutive opacity observations taken at 15 second intervals;
    - ii) 20 percent for more than 16 individual opacity observations within any 1 hour period; or
    - iii) 40 percent for any individual opacity observation.
8. The Licencee shall not cause or permit a noise nuisance to be created as a result of the construction, operation, or alteration of the Development, and shall take such steps as the Director may require to eliminate or mitigate a noise nuisance.
9. The Licencee shall not cause or permit an odour nuisance to be created as a result of the construction, operation, or alteration of the Development, and shall take such steps as the Director may require to eliminate or mitigate an odour nuisance.

### **Respecting Air Emissions – Sampling, Analysis, Reporting**

10. The Licencee, upon written request from the Director, shall provide a stack or stacks including all necessary sampling facilities for the sampling of air emissions at the Development. The stack or stacks shall be provided:
  - a) at a location(s) and within a time frame satisfactory to the Director; and
  - b) to the specifications and in accordance with the most recent version of Manitoba Conservation Guideline, *Guideline for Stack Sampling Facilities*, unless otherwise approved by the Director.
11. The Licencee, upon a written request from the Director, shall submit a detailed plan which is acceptable to and approved by the Director, for the sampling and analysis of potential air pollutants, released as stationary point and fugitive emissions, including any compounds determined by the Director. The plan shall identify the rationale for the sampling; the ways and means by which the sampling program will be implemented including any special measures or methods which would be necessitated by influencing factors such as unfavourable weather conditions, the need for large or additional sample volumes, the need for multiple sampling runs; the methods used for the sampling and the analysis for each compound; the detection level to be attained; a comprehensive QA/QC program, and other items as may be identified by the Director.
12. The Licencee shall perform all stack sampling in accordance with the most recent version of Manitoba Conservation Report No. 96-07, *Interim Stack Sampling Performance Protocol*, unless otherwise approved by the Director.

13. The Licencee shall arrange the scheduling of the sampling program submitted pursuant to Clause 11 of this Licence such that a representative of Manitoba Conservation is available to monitor and audit the implementation of the sampling program.
14. The Licencee, within a timeframe to be determined by the Director, shall complete the sampling of emissions according to the approved plan submitted pursuant to Clause 11 of this Licence.
15. The Licencee, within 60 days of the receipt of the analytical results of the sampling plan pursuant to Clause 11 of this Licence, shall submit a report for the approval of the Director containing at minimum:
  - a) the raw data collected;
  - b) a discussion of the sampling and analytical portions of the program including any anomalies of sampling and analysis; and
  - c) a discussion of the significance of the data gathered with specific attention to:
    - i) the significance for potential acute and chronic impacts to health or environment from exposure to concentrations of the compounds detected;
    - ii) the need for risk assessment of the impact of emissions;
    - iii) the need for the establishment of ambient air monitoring stations;
    - iv) the need for dispersion modeling of emissions;
    - v) results and conclusions of the QA/QC program; and
    - vi) other issues as may be determined by the Director.
16. The Licencee, upon the written request of and in a timeframe stipulated by the Director, shall comply with any air emission or ambient air quality criteria specified by the Director for any pollutant of concern to the Director which has been identified pursuant to Clauses 3, 11, or 17 of this Licence.
17. The Licencee shall, when requested by the Director, conduct a sampling program and analyse air emissions at the Development as per the requirements of Clauses 11 to 15 of this Licence for all or any of the following:
  - a) total VOC's;
  - b) chloroform;
  - c) methanol;
  - d) ethanol; and
  - e) compounds derived from 17 b), c) or d).Samples are to be collected using methods approved by the Director, and analysis is to be performed in a manner approved by the Director.
18. The Licencee shall submit a copy of the sampling report complete with analytical results as specified pursuant to Clause 17, to the Director within 60 days of the completion of the sampling program.

#### **Respecting Solvent Management and Use**

19. The Licencee shall report to the Director in writing, the use of any solvent(s) at the Development, other than those listed in Clause 17 b), c) or d), when the combined usage of such solvents exceeds 205 litres in any 12 month period.
20. The Licencee shall notify the Director of an intended alteration of process, which may affect in any manner a waste discharge or emission, prior to implementing such alteration.

21. The Licencee shall submit, on an annual basis by the last day of February of each year, a written report to the Director containing the following information for each solvent used at the Development:
- a) identification of solvent;
  - b) amount (litres) acquired in the report period;
  - c) total amount (litres) acquired in the calendar year;
  - d) total amount in 21 c) directed to a sewer;
  - e) total amount in 21 c) incorporated in solid waste; and
  - f) disposition of solvent reclaimed.

#### **Respecting HEPA Filter Disposal**

22. The Licencee shall dispose of HEPA filters, exposed to air from the Development, which are contaminated with:
- a) anti-neoplastic chemicals by incineration in an incinerator approved for bio-medical waste;
  - b) microbiological organisms by either:
    - i) continuous exposure to formaldehyde gas at a concentration and for a sufficient time to de-contaminate the filter, followed by landfilling or incineration; or
    - ii) by an alternative method approved by the Director.

#### **Respecting Biosafety Practices**

23. The Licencee shall implement and comply with the most current applicable guidelines as recommended by Health and Welfare Canada and Medical Research Council of Canada including, but not limited to, *Laboratory Biosafety Guidelines*.
24. The Licencee shall provide to the Director, within thirty (30) days of receipt, a copy of any report from an inspecting authority regarding compliance or non-compliance with the guidelines referenced in Clause 23.
25. The Licencee shall comply with all current Medical Research Council of Canada *Laboratory Biosafety Guidelines*, during the research and development, pilot scale and production stages of the Development. Compliance is to be based on classification of organism as per the NIH guideline and scale of operation.
26. The Licencee shall comply with all current Health and Welfare Canada, Drugs Directorate guidelines, during both the research and development and the pilot scale production stages of the Development. Compliance is to be based on classification of organism as per the NIH guidelines and the scale of operation.

#### **Respecting Waste Biosolids Management**

27. The Licencee shall maintain a record of validation for the effectiveness of the biomass steam sterilization process. The validation shall apply to the most resistant stage of organism present. Records shall be maintained at the Development for at least two (2) years, and be made available to the Director upon request.
28. The Licencee shall dispose of biological solid waste material as per current Medical Research Council of Canada *Laboratory Biosafety Guidelines*.

**Respecting Emergency Response Planning**

29. The Licencee shall review and maintain as needed, the emergency response plan approved by the Director, and submit any alterations of this plan to the Director for approval. This plan must include, but is not limited to, items which will address: measures implemented for spill prevention and containment; security; personnel training and response arrangements.

**REVIEW AND REVOCATION**

- A. This Licence replaces Licence No. 1623 which is hereby rescinded.
- B. If, in the opinion of the Director, the Licencee has exceeded or is exceeding or has or is failing to meet the specifications, limits, terms, or conditions set out in this Licence, the Director may, temporarily or permanently, revoke this Licence.
- C. If, in the opinion of the Director, new evidence warrants a change in the specifications, limits, terms or conditions of this Licence, the Director may require the filing of a new proposal pursuant to Section 10 of The Environment Act.



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**Larry Strachan, P. Eng.  
Director  
Environment Act**

**Client File No.: 3459.00**