



Conservation and Water Stewardship

Environmental Stewardship Division
Environmental Approvals Branch
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www.gov.mb.ca/conservation/eal

CLIENT FILE NO.: 5748.00

May 19, 2015

Lisa Winning, M.Sc., Environmental Associate
Emergent BioSolutions
155 Innovation Drive
Winnipeg, MB R3T 5Y3

Dear Ms. Winning:

Enclosed is **Environment Act Licence No. 3138** dated May 19, 2015 issued to **Cangene Corporation** for the continued operation of the Development being a biopharmaceutical manufacturing facility, operating as Emergent BioSolutions Inc. at 155 Innovation Drive in Winnipeg, Manitoba, in accordance with the Proposal dated October 9, 2014.

In addition to the enclosed Licence requirements, please be reminded that all other applicable federal, provincial and municipal regulations and by-laws must be complied with. A Notice of Alteration must be filed with the Director for approval prior to any alteration to the Development as licensed.

For further information on the administration and application of the Licence, please feel free to contact Yvonne Hawryliuk, Environment Officer at 204-945-5305.

Pursuant to Section 27 of *The Environment Act*, this licensing decision may be appealed by any person who is affected by the issuance of this Licence to the Minister of Conservation and Water Stewardship within 30 days of the date of the Licence.

Yours truly,

“original signed by”

Tracey Braun, M.Sc.
Director
Environment Act

c: Don Labossiere, Director; Environmental Compliance and Enforcement
Donna Smiley and Yvonne Hawryliuk, Environmental Compliance and Enforcement (**email**)
Public Registries

NOTE: Confirmation of Receipt of this Licence No. 3138 (by the Licensee only) is required by the Director of Environmental Approvals. Please acknowledge receipt by signing in the space below and provide a copy (letter only) to the Department by June 2, 2015.

On behalf of Cangene Corporation

Date

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

LICENCE

Licence No. / Licence n° 3138

Issue Date / Date de délivrance May 19, 2015

In accordance with *The Environment Act* (C.C.S.M. c. E125) /
Conformément à la *Loi sur l'environnement* (C.P.L.M. c. E125)

Pursuant to Section 10(1) / Conformément au Paragraphe 10(1)

THIS LICENCE IS ISSUED TO:/CETTE LICENCE EST DONNÉE À :

CANGENE CORPORATION DOING BUSINESS AS
EMERGENT BIOSOLUTIONS INC.
"the Licencee"

for the continued operation of the Development being a biopharmaceutical manufacturing facility, operating as Emergent BioSolutions Inc. at 155 Innovation Drive in Winnipeg, Manitoba, in accordance with the Proposal dated October 9, 2014 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 and Water Stewardship 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, excluding the property of the Development;

"**approved**" means approved by the Director or assigned Environment Officer in writing;

"**approved facility**" means a facility operating in accordance with the requirements of *The Environment Act* and the Regulations thereunder;

"Closure Plan" means a plan indicating the actions to be taken for the closure of the Development;

"dangerous good" means a product, substance or organism as defined in *The Dangerous Goods Handling and Transportation Act*, or any amendments thereto;

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

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

"fugitive emissions" means particulate matter escaping from sources within the development property into the atmosphere other than through any of the emission stacks or vents;

"hazardous waste" means a product, substance or organism as defined in *The Dangerous Goods Handling and Transportation Act*, or any amendments thereto;

"noise nuisance" means an unwanted sound, in an affected area, which is annoying, troublesome, 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 members of the public;

if the unwanted sound

- d) is the subject of at least five 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; or
- e) is the subject of at least one written complaint, received by the Director in a form satisfactory to the Director, from a person falling within clauses a), b), or c) and the Director is of the opinion that if the unwanted sound had occurred in a more densely populated area there would have been at least 5 written complaints received within a 90-day period, from 5 different persons 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 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; or
- e) is the subject of at least one written complaint, received by the Director in a form satisfactory to the Director, from a person falling within clauses a), b), or c) and the Director is of the opinion that if the odour, smell or aroma had occurred in a more densely populated area there would have been at least 5 written complaints received within a 90-day period, from 5 different persons 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;

"operator" means the company or person who is responsible for the day-to-day maintenance and operation of the Development;

"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 a Development where pollutants are emitted to the atmosphere by means of a stack;

"pollutant" means a pollutant as defined in *The Environment Act*;

"Post Closure Plan" means a plan indicating the actions to be taken for the care, maintenance, and monitoring of the Development after closure, that will prevent, mitigate, or minimize the threat to public health and the environment;

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

"solid waste" means solid waste as defined in *Manitoba Regulation 150/91*, or any future amendments thereto, respecting waste disposal grounds, excluding waste rock;

"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; and

"wastewater" means any liquid containing a pollutant as defined in *The Environment Act*, associated with or resulting from the Development which is discharged into the environment.

GENERAL TERMS AND CONDITIONS

This Section of the Licence contains terms and conditions 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 submit all information required to be provided to the Director or Environment Officer under this Licence, in writing, in such form (including number of copies), and of such content as may be required by the Director or Environment Officer, and each submission shall be clearly labeled with the Licence Number and Client File Number associated with this Licence.
4. In addition to any of the limits, terms and conditions specified in this Licence, the Licencee shall, upon the request of the Director:
 - 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, for such duration and at such frequencies as may be specified;
 - b) determine the environmental impact associated with the release of any pollutant(s) from the Development;
 - c) conduct specific investigations in response to the data gathered during environmental monitoring programs; or
 - d) 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.
5. 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) have all analytical determinations undertaken by an accredited laboratory; and

- d) report the results to the Director, in writing and in an electronic format acceptable to the Director, within 60 days of the samples being taken.
6. The Licencee shall designate an employee, within 60 days of the date of issuance of this Licence, as the Licencee's Environmental Coordinator, whose job description will include assisting the Licencee in complying with the limits, terms and conditions in this Licence and assisting Senior Management of the Licencee to manage environmental issues at the Development. The name of the Environmental Coordinator shall be submitted in writing to the Director within 14 days of appointment and any subsequent appointment.

SPECIFICATIONS, LIMITS, TERMS, AND CONDITIONS

Respecting Air Emissions – Limits

7. The Licencee shall not emit particulate matter from the Development such that:
 - a) particulate matter:
 - 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) opacity from any point source of the Development 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 Pollution Control Equipment

10. The Licencee shall direct all air streams that contain a pollutant(s) of concern to the Director to a pollution control device which has been designed for and

demonstrated to be capable of reducing, altering, eliminating or otherwise treating the pollutant(s).

11. The Licencee shall prepare, within 90 days of the issuance of this Licence, and maintain the following manuals which shall be kept at the Development and available for review upon request by an Environment Officer:
 - a) a standard operating procedural manual and a maintenance schedule for each air emission pollution control device based on the manufacturer's specifications and recommendations;
 - b) an updated standard operating procedural manual and a maintenance procedure for each air emission pollution control device within 120 days of the addition, elimination or change regarding any air emission control device; and
 - c) a copy of the manufacturing operational and maintenance manual.
12. The Licencee shall not operate any process directing an emission to an air pollution control device at the Development unless:
 - a) the operating and maintenance measures and status of the device are in full compliance with the procedures and timetables as per Clause 11;
 - b) all emissions from the process are directed to the fully operational air pollution control device;
 - c) all discharges of treated emissions from the air pollution control devices are immediately directed to a stack;
 - d) the emissions do not contain concentrations of pollutants which:
 - i) are in violation of any other applicable legal instrument including an Act, Regulation or by-law;
 - ii) otherwise create a significant negative environmental or health impact in the affected area.
13. The Licencee shall maintain a log book of the most recent 24 month period to record any downtime of an air pollution control device due to either the breakdown or maintenance of that air pollution control device. The log book shall be kept at the Development and shall be available upon request for inspection by an Environment Officer. The log book shall record, at minimum, the following information:
 - a) identification of the air pollution control device and the process(es) it serves;
 - b) time/date of log entry;
 - c) nature of event;
 - d) time and duration of event;
 - e) action taken
 - f) the accumulated downtime of this air pollution control device for the events for each calendar year; and
 - g) signature of the Environmental Coordinator.
14. The Licencee shall handle, store and dispose of all pollutants collected by the air pollution control equipment in a manner suitable to their characterization as type of

waste or dangerous good. A record that characterizes the pollutant and the manner it was disposed of shall be kept at the Development and available for review upon request by an Environment Officer.

Respecting Air Emission Monitoring

15. 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.
16. 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.
17. 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.
18. The Licencee shall arrange the scheduling of the sampling program approved pursuant to Clause 16 of this Licence such that a representative of Manitoba Conservation and Water Stewardship is available to monitor and audit the implementation of the sampling program.
19. The Licencee shall submit a report, for the approval of the Director, of the completed sampling and analysis plan approved pursuant to Clause 16 of this Licence, within 60 days of the receipt of the analytical results of that sampling plan. The report shall contain 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.
20. The Licencee, upon the written request of and in a time frame 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 Clause 4, 7, 10, or 19 of this Licence.

Respecting Chemical Storage and Spill Containment

21. The Licencee shall provide containment for all vessels containing chemicals in each area of the development where the chemicals are stored, loaded, transferred, used or otherwise handled, in compliance with the National Fire Code of Canada (2010), or any future amendment thereof, such that any product leakage or spillage and any contaminated liquid generated is contained within the Development and contamination of groundwater and surface water is prevented.
22. The Licencee shall, in a manner approved by the Director, remove and dispose of all spilled dangerous goods.

Respecting Dangerous Goods and Hazardous Wastes

23. The Licencee shall store, handle and dispose of all dangerous goods and hazardous wastes used or generated at the Development in accordance with the provisions of *The Manitoba Dangerous Goods Handling and Transportation Act* (C.C.S.M. c. D12).
24. The Licencee shall comply with all the applicable requirements of:
 - a) Manitoba Regulation 188/2001, or any future amendment thereof, respecting the Storage and Handling of Petroleum Products and Allied Products;
 - b) *The Dangerous Goods Handling and Transportation Act*, and regulations issued thereunder, respecting the handling, transport, storage and disposal of any dangerous goods brought onto or generated at the Development; and
 - c) the Office of the Fire Commissioner – Province of Manitoba.
25. The Licencee shall not receive at the Development any hazardous waste from any generator off site of the Development.

Respecting Wastewater

26. The Licencee shall not discharge wastewater beyond the boundaries of the Development except any discharge which is directed to the City of Winnipeg wastewater collection system in accordance with the requirements of the City of Winnipeg.

Respecting Solid Waste

27. The Licencee shall dispose of all solid waste generated at the Development only at a waste disposal ground operating under the authority of a permit issued pursuant to *Manitoba Regulation 150/91* or any future amendment thereof, or a Licence issued pursuant to *The Environment Act*.

Respecting Emergencies

28. The Licencee shall, in the case of physical or mechanical equipment breakdown or process upset where such breakdown or process upset results or may result in the release of a pollutant in an amount or concentration or at a level or rate of release, that causes or may cause a significant adverse effect, immediately report the event by calling the 24-hour environmental incident reporting line at 204-944-4888 (toll-free 1-855-944-4888). The report shall indicate the nature of the event, the time and estimated duration of the event and the reason for the event.
29. The Licencee shall, following the reporting of an event pursuant to Clause 28
- identify the repairs required to the mechanical equipment;
 - undertake all repairs to minimize unauthorized discharges of a pollutant;
 - complete the repairs in accordance with any written instructions of the Director; and
 - submit a report to the Director about the causes of breakdown and measures taken, within one week of the repairs being done.
30. The Licencee shall prepare, within 90 days of the date of issuance of this Licence, and maintain an emergency response contingency plan in accordance with the Canadian Centre for Occupational Health and Safety "Emergency Response Planning Guide" or other emergency planning guidelines acceptable to the Director.

Closure and Post Closure

31. Within one year prior to imminent closure of the Development, the Licencee shall submit, for the approval of the Director, a formal detailed Closure and Post Closure Plan for the Development.
32. The Licencee shall implement and maintain the approved Closure and Post Closure Plan.

REVIEW AND REVOCATION

- A. 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.
- B. If, in the opinion of the Director, new evidence warrants a change in the specifications, limits, terms or conditions set out in this Licence, the Director may require the filing of a new proposal pursuant to *The Environment Act*.

“original signed by”

Tracey Braun, M.Sc.
Director
The Environment Act

Client File No.: 5748.00

rescinded