

AMENDED ENVIRONMENTAL COMPLIANCE APPROVAL

NUMBER 8276-BFJK8D

Issue Date: May 13, 2020

Sanofi Pasteur Limited/Sanofi Pasteur Limitee
1755 Steeles Avenue West
North York, Ontario
M2R 3T4

Site Location: 1755 Steeles Avenue West
Toronto City, Ontario

You have applied under section 20.2 of Part II.1 of the Environmental Protection Act , R.S.O. 1990, c. E. 19 (Environmental Protection Act) for approval of:

Description Section

A human vaccine manufacturing and research facility, consisting of the following processes and support units:

- process and laboratory fume hoods;
- cooling towers;
- natural gas fired boilers;
- one (1) natural gas fired co-generation unit, rated at 3.2 Megawatts, equipped with a steam injection system, consisting of a combustion gas turbine (CGT) having a heat input of 34.9 Gigajoules per hour, and a heat recovery steam generator (HRSG), having a heat input of 15.0 Gigajoules per hour;
- one (1) natural gas fired co-generation unit, rated at 5.7 Megawatts, equipped with a steam injection system, consisting of a combustion gas turbine (CGT) having a heat input of 59.9 Gigajoules per hour, and a heat recovery steam generator (HRSG), having a heat input of 30.55 Gigajoules per hour;

including the *Equipment* and any other ancillary and support processes and activities, operating at a *Facility Production Limit* of up to 100 million vials of human vaccines per year discharging to the air as described in the *Original ESDM Report*.

For the purpose of this environmental compliance approval, the following definitions apply:

1. "ACB list" means the document entitled "Air Contaminants Benchmarks (ACB)

List: Standards, guidelines and screening levels for assessing point of impingement concentrations of air contaminants”, as amended from time to time and published by the *Ministry* and available on a Government website;

2. "*Acceptable Point of Impingement Concentration*" means a concentration accepted by the *Ministry* as not likely to cause an adverse effect for a *Compound of Concern* that,
 - a. is not identified in the *ACB list*, or
 - b. is identified in the *ACB list* as belonging to the category “Benchmark 2” and has a concentration at a *Point of Impingement* that exceeds the concentration set out for the contaminant in that document.
With respect to the *Original ESDM Report*, the *Acceptable Point of Impingement Concentration* for a *Compound of Concern* mentioned above is the concentration set out in the *Original ESDM Report*;
3. "*Acoustic Assessment Report*" means the report, prepared in accordance with *Publication NPC-233* and Appendix A of the *Basic Comprehensive User Guide*, by Alexandra Davidson and Michael Medal, Aercoustics Engineering Ltd. and dated July 24, 2019, and submitted in support of the application, that documents all sources of noise emissions and *Noise Control Measures* present at the *Facility* and includes all up-dated *Acoustic Assessment Reports* as required by the Documentation Requirements conditions of this *Approval* to demonstrate continued compliance with the *Performance Limits* following the implementation of any *Modification*;
4. "*Acoustic Assessment Summary Table*" means a table prepared in accordance with the *Basic Comprehensive User Guide* summarising the results of the *Acoustic Assessment Report*, as updated in accordance with Condition 5 of this *Approval*;
5. "*Acoustic Audit*" means an investigative procedure consisting of measurements and/or acoustic modelling of all sources of noise emissions due to the operation of the *Facility* assessed to determine compliance with the Performance Limits for the *Facility* regarding noise emissions, completed in accordance with the procedures set in *Publication NPC-103* and reported in accordance with *Publication NPC-233*;
6. "*Acoustic Audit Report*" means a report presenting the results of an *Acoustic Audit*, prepared in accordance with *Publication NPC-233*;
7. "*Acoustical Consultant*" means a person currently active in the field of environmental acoustics and noise/vibration control, who is familiar with *Ministry* noise guidelines and procedures and has a combination of formal university education, training and experience necessary to assess noise emissions from a *Facility*;
8. "*Approval*" means this entire Environmental Compliance Approval and any

Schedules to it;

9. "*Basic Comprehensive User Guide*" means the *Ministry* document titled "Basic Comprehensive Certificates of Approval (Air) User Guide" dated March 2011, as amended;
10. "*Co-Generation Units*" means the 3.2 Megawatt Co-Generation Unit and the 5.7 Megawatt Co-Generation Unit, including the combustion gas turbines (CGT) and the Heat Recovery Steam Generators (HRSG) described in the *Original ESDM Report*, this *Approval* and in the *Supporting Documentation* referred to herein and any other equipment or processes.
11. "*Company*" means Sanofi Pasteur Limited/Sanofi Pasteur Limitee that is responsible for the construction or operation of the *Facility* and includes any successors and assigns in accordance with section 19 of the *EPA*;
12. "*Compound of Concern*" means a contaminant described in paragraph 4 subsection 26 (1) of *O. Reg. 419/05*, namely, a contaminant that is discharged from the *Facility* in an amount that is not negligible;
13. "*Description Section*" means the section on page one of this *Approval* describing the *Company's* operations and the *Equipment* located at the *Facility* and specifying the *Facility Production Limit* for the *Facility*;
14. "*Director*" means a person appointed for the purpose of section 20.3 of the *EPA* by the *Minister* pursuant to section 5 of the *EPA*;
15. "*District Manager*" means the District Manager of the appropriate local district office of the *Ministry*, where the *Facility* is geographically located;
16. "*Emergency Diesel Generators*" means all the emergency diesel generators described in the *Original ESDM Report*, this *Approval* and in the *Supporting Documentation* referred to herein and any other equipment or processes.
17. "*Emission Summary Table*" means a table described in paragraph 14 of subsection 26 (1) of *O. Reg. 419/05*;
18. "*Environmental Assessment Act*" means the Environmental Assessment Act, R.S.O. 1990, c.E.18, as amended;
19. "*EPA*" means the Environmental Protection Act, R.S.O. 1990, c.E.19, as amended;
20. "*Equipment*" means equipment or processes described in the *ESDM Report*, the *Acoustic Assessment Report*, this *Approval* and in the *Schedules* referred to herein and any other equipment or processes;
21. "*Equipment with Specific Operational Limits*" means the *Co-Generation Units* and any *Equipment* related to the thermal oxidation of waste or waste derived fuels, fume incinerators or any other *Equipment* that is specifically referenced in any

published *Ministry* document that outlines specific operational guidance that must be considered by the *Director* in issuing an *Approval*;

22. "*ESDM Report*" means the most current Emission Summary and Dispersion Modelling Report that describes the *Facility*. The *ESDM Report* is based on the *Original ESDM Report* and is updated after the issuance of this *Approval* in accordance with section 26 of *O. Reg. 419/05* and the *Procedure Document*;
23. "*Facility*" means the entire operation located on the property where the *Equipment* is located;
24. "*Facility Production Limit*" means the production limit placed by the *Director* on the main product(s) or raw materials used by the *Facility*;
25. "*Heat Output*" means the total useful heat energy recovered from the combustion turbine as heat, expressed in megawatts;
26. "*Log*" means a document that contains a record of each change that is required to be made to the *ESDM Report* and *Acoustic Assessment Report*, including the date on which the change occurred. For example, a record would have to be made of a more accurate emission rate for a source of contaminant, more accurate meteorological data, a more accurate value of a parameter that is related to a source of contaminant, a change to a *Point of Impingement* and all changes to information associated with a *Modification* to the *Facility* that satisfies Condition 2;
27. "*Lower Heating Value*" means the energy released during combustion of the fuel, excluding the latent heat content of the water vapour component of the products of combustion, expressed in megajoules per cubic metre at standard temperature and pressure, or megajoules per kilogram;
28. "*Manager*" means the Manager, Technology Standards Section, Technical Assessment and Standards Development Branch, or any other person who represents and carries out the duties of the Manager, Technology Standards Section, Technical Assessment and Standards Development Branch, as those duties relate to the conditions of this *Approval*;
29. "*Minister*" means the Minister of the Environment, Conservation and Parks or such other member of the Executive Council as may be assigned the administration of the *EPA* under the Executive Council Act;
30. "*Ministry*" means the ministry of the *Minister*;
31. "*Modification*" means any construction, alteration, extension or replacement of any plant, structure, equipment, apparatus, mechanism or thing, or alteration of a process or rate of production at the *Facility* that may discharge or alter the rate or manner of discharge of a *Compound of Concern* to the air or discharge or alter noise or vibration emissions from the *Facility*;

32. "*Noise Abatement Action Plan*" means the noise abatement program developed by the *Company*, submitted to the *Director* and *District Manager* and approved by the *Director*, designed to achieve compliance with the sound level limits set in *Publication NPC-300*, as applicable;
33. "*Noise Control Measures*" means measures to reduce the noise emissions from the *Facility* and/or *Equipment* including, but not limited to, silencers, acoustic louvres, enclosures, absorptive treatment, plenums and barriers. It also means the *Noise Control Measures* as detailed in the *Acoustic Assessment Report* dated July 24, 2019 and signed by Alexandra Davidson and Michael Medal, Aercoustics Engineering Ltd. and in the updated *Acoustic Assessment Report* required in Condition 14 of this *Approval*;
34. "*O. Reg. 419/05*" means Ontario Regulation 419/05, Air Pollution – Local Air Quality, as amended;
35. "*Original ESDM Report*" means the Emission Summary and Dispersion Modelling Report which was prepared in accordance with section 26 of *O. Reg. 419/05* and the *Procedure Document* by Dillon Consulting Limited and dated July 24, 2019, submitted in support of the application, and includes any changes to the report made up to the date of issuance of this *Approval*;
36. "*Point of Impingement*" has the same meaning as in section 2 of *O. Reg. 419/05*;
37. "*Point of Reception*" means Point of Reception as defined by *Publication NPC-300*;
38. "*Power Output*" means the electricity and shaft power production of the combustion turbine, expressed in megawatts;
39. "*Pre-test Information*" means the information outlined in Section 1. of the Source Testing Code;
40. "*Procedure Document*" means *Ministry* guidance document titled "Procedure for Preparing an Emission Summary and Dispersion Modelling Report" dated February 2017, as amended;
41. "*Processes with Significant Environmental Aspects*" means the *Equipment* which, during regular operation, would discharge one or more contaminants into the air in an amount which is not considered as negligible in accordance with section 26 (1) 4 of *O. Reg. 419/05* and the *Procedure Document*;
42. "*Publication NPC-207*" means the *Ministry* draft technical publication "Impulse Vibration in Residential Buildings", November 1983, supplementing the Model Municipal Noise Control By-Law, Final Report, published by the *Ministry*, August 1978, as amended;
43. "*Publication NPC-233*" means the *Ministry* Publication NPC-233, "Information to

be Submitted for Approval of Stationary Sources of Sound", October, 1995, as amended;

44. "*Publication NPC-300*" means the *Ministry* Publication NPC-300, "Environmental Noise Guideline, Stationary and Transportation Sources – Approval and Planning, Publication NPC-300", August 2013, as amended;
45. "*Revised Noise Abatement Action Plan*" means the updated *Noise Abatement Action Plan* developed by the *Company*, submitted to the *Director* and *District Manager* and approved by the *Director*, designed to manage and achieve compliance with the sound level limits set in *Publication NPC-300*.
46. "*Schedules*" means the following schedules attached to this *Approval* and forming part of this *Approval* namely:
 - Schedule A - Supporting Documentation;
 - Schedule B - Emission Limits;
 - Schedule C - *Source Testing* Procedures; and
 - Schedule D - *Thermal Efficiency* Verification.
47. "*Source Testing*" means site-specific sampling and testing to measure emissions resulting from operating the targeted sources under operating conditions that will derive an emission rate that, for the relevant averaging period of the contaminant, is at least as high as the maximum emission rate that the source of contaminant is reasonably capable of, within the approved operating range of the Targeted Sources which satisfies paragraph 1 of subsection 11(1) of O. Reg. 419/05;
48. "*Source Testing Code*" means the Ontario Source Testing Code, dated June 2010, prepared by the *Ministry*, as amended;
49. "*Thermal Efficiency*" means the fraction of the total energy input into the *Co-Generation Units* which is transformed into useful energy output expressed as a percentage on a lower heating value basis.
50. "*Toxicologist*" means a qualified professional currently active in the field of risk assessment and toxicology that has a combination of formal university education, training and experience necessary to assess contaminants; and
51. "*Written Summary Form*" means the electronic questionnaire form, available on the *Ministry* website, and supporting documentation, that documents the activities undertaken at the *Facility* in the previous calendar year.

You are hereby notified that this environmental compliance approval is issued to you subject to the terms and conditions outlined below:

TERMS AND CONDITIONS

1. GENERAL

1. Except as otherwise provided by this *Approval*, the *Facility* shall be designed, developed, built, operated and maintained in accordance with the terms and conditions of this *Approval* and in accordance with the following *Schedules* attached hereto:
 - Schedule A - Supporting Documentation
 - Schedule B - Emission Limits;
 - Schedule C - *Source Testing* Procedures; and
 - Schedule D - *Thermal Efficiency* Verification.

2. LIMITED OPERATIONAL FLEXIBILITY

1. Pursuant to section 20.6 (1) of the *EPA* and subject to Conditions 2.2 and 2.3 of this *Approval*, future construction, alterations, extensions or replacements are approved in this *Approval* if the future construction, alterations, extensions or replacements are *Modifications* to the *Facility* that:
 - a. are within the scope of the operations of the *Facility* as described in the *Description Section* of this *Approval*;
 - b. do not result in an increase of the *Facility Production Limit* above the level specified in the *Description Section* of this *Approval*; and
 - c. result in compliance with the performance limits as specified in Condition 4.
2. Condition 2.1 does not apply to,
 - a. the addition of any new *Equipment with Specific Operational Limits* or to the *Modification* of any existing *Equipment with Specific Operational Limits* at the *Facility*; or
 - b. *Modifications* to the *Facility* that would be subject to the *Environmental Assessment Act*.
3. Condition 2.1 of this *Approval* shall expire ten (10) years from the date of this *Approval*, unless this *Approval* is revoked prior to the expiry date. The *Company* may apply for renewal of Condition 2.1 of this *Approval* by including an *ESDM Report* and an *Acoustic Assessment Report* that describes the *Facility* as of the date of the renewal application.

3. REQUIREMENT TO REQUEST AN ACCEPTABLE POINT OF IMPINGEMENT CONCENTRATION

1. Prior to making a *Modification* to the *Facility* that satisfies Condition 2.1.a. and 2.1.b., the *Company* shall prepare a proposed update to the *ESDM Report* to reflect the proposed *Modification*.

2. The *Company* shall request approval of an *Acceptable Point of Impingement Concentration* for a *Compound of Concern* if the *Compound of Concern* is not identified in the *ACB list* as belonging to the category “Benchmark 1” and a proposed update to an *ESDM Report* indicates that one of the following changes with respect to the concentration of the *Compound of Concern* may occur:
 - a. The *Compound of Concern* was not a *Compound of Concern* in the previous version of the *ESDM Report* and
 - i. the concentration of the *Compound of Concern* exceeds the concentration set out for the contaminant in the *ACB list*; or
 - ii. the *Compound of Concern* is not identified in the *ACB list*; or
 - b. The concentration of the *Compound of Concern* in the updated *ESDM Report* exceeds the higher of,
 - i. the most recent *Acceptable Point of Impingement Concentration*, and
 - ii. the concentration set out for the contaminant in the *ACB list*, if the contaminant is identified in that document.
3. The request required by Condition 3.2 shall propose a concentration for the *Compound of Concern* and shall contain an assessment, performed by a *Toxicologist*, of the likelihood of the proposed concentration causing an adverse effect at *Points of Impingement*.
4. If the request required by Condition 3.2 is a result of a proposed *Modification* described in Condition 3.1, the *Company* shall submit the request, in writing, to the *Director* at least 30 days prior to commencing to make the *Modification*. The *Director* shall provide written confirmation of receipt of this request to the *Company*.
5. If a request is required to be made under Condition 3.2 in respect of a proposed *Modification* described in Condition 3.1, the *Company* shall not make the *Modification* mentioned in Condition 3.1 unless the request is approved in writing by the *Director*.
6. If the *Director* notifies the *Company* in writing that the *Director* does not approve the request, the *Company* shall,
 - a. revise and resubmit the request; or
 - b. notify the *Director* that it will not be making the *Modification*.
7. The re-submission mentioned in Condition 3.6 shall be deemed a new submission under Condition 3.2.

8. If the *Director* approves the request, the *Company* shall update the *ESDM Report* to reflect the *Modification*.
9. Condition 3 does not apply if Condition 2.1 has expired.

4. PERFORMANCE LIMITS

1. Subject to Condition 4.2, the *Company* shall not discharge or cause or permit the discharge of a *Compound of Concern* into the air if,
 - a. the *Compound of Concern* is identified in the *ACB list* as belonging to the category "Benchmark 1" and the discharge results in the concentration at a *Point of Impingement* exceeding the Benchmark 1 concentration; or
 - b. the *Compound of Concern* is not identified in the *ACB list* as belonging to the category "Benchmark 1" and the discharge results in the concentration at a *Point of Impingement* exceeding the higher of,
 - i. if an *Acceptable Point of Impingement Concentration* exists, the most recent *Acceptable Point of Impingement Concentration*, and
 - ii. the concentration set out for the contaminant in the *ACB list*, if the contaminant is identified in that document.
2. Condition 4.1 does not apply if the benchmark set out in the *ACB list* has a 10-minute averaging period and no ambient monitor indicates an exceedance at a *Point of Impingement* where human activities regularly occur at a time when those activities regularly occur.
3. The *Company* shall:
 - a. implement the new *Equipment and Noise Control Measures*, and ensure that the *Facility/Equipment* shall be operated and maintained as outlined in the *Acoustic Assessment Report*;
 - b. ensure, subsequent to the implementation of the new *Equipment and Noise Control Measures*, that the noise emissions from the *Facility* comply with the limits set out in *Ministry Publication NPC-300*;
 - c. ensure that the *Noise Control Measures* are properly maintained to ensure that the acoustical performance of the *Noise Control Measures* does not deteriorate and complies with the requirements of the *Acoustic Assessment Report*.
4. The *Company* shall ensure that the vibration emissions from the *Facility* comply with the limits set out in *Ministry Publication NPC-207*.
5. The *Company* shall operate any *Equipment with Specific Operational Limits* approved by this *Approval* in accordance with the *Original ESDM Report* and

Condition 10 in this *Approval*.

5. DOCUMENTATION REQUIREMENTS

1. The *Company* shall maintain an up-to-date *Log*.
2. No later than March 31 in each year, the *Company* shall update the *Acoustic Assessment Report* and shall update the *ESDM Report* in accordance with section 26 of *O. Reg. 419/05* so that the information in the reports is accurate as of December 31 in the previous year.
3. The *Company* shall make the *Emission Summary Table* (see section 27 of *O. Reg. 419/05*) and *Acoustic Assessment Summary Table* available for examination by any person, without charge, by posting it on the Internet or by making it available during regular business hours at the *Facility*.
4. The *Company* shall, within three (3) months after the expiry of Condition 2.1 of this *Approval*, update the *ESDM Report* and the *Acoustic Assessment Report* such that the information in the reports is accurate as of the date that Condition 2.1 of this *Approval* expired.
5. Conditions 5.1 and 5.2 do not apply if Condition 2.1 has expired.

6. REPORTING REQUIREMENTS

1. Subject to Condition 6.2, the *Company* shall provide the *Director* no later than June 30 of each year, a *Written Summary Form* to be submitted through the *Ministry's* website that shall include the following:
 - a. a declaration of whether the *Facility* was in compliance with section 9 of the *EPA, O. Reg. 419/05* and the conditions of this *Approval*;
 - b. a summary of each *Modification* satisfying Condition 2.1.a. and 2.1.b. that took place in the previous calendar year that resulted in a change in the previously calculated concentration at a *Point of Impingement* for any *Compound of Concern* or resulted in a change in the sound levels reported in the *Acoustic Assessment Summary Table* at any *Point of Reception*.
2. Condition 6.1 does not apply if Condition 2.1 has expired.

7. OPERATION AND MAINTENANCE

1. The *Company* shall prepare and implement, not later than three (3) months from the date of this *Approval*, operating procedures and maintenance programs for all *Processes with Significant Environmental Aspects*, which shall specify as a minimum:
 - a. frequency of inspections and scheduled preventative maintenance;
 - b. procedures to prevent upset conditions;

- c. procedures to minimize all fugitive emissions;
 - d. procedures to prevent and/or minimize odorous emissions;
 - e. procedures to prevent and/or minimize noise emissions; and
 - f. procedures for record keeping activities relating to the operation and maintenance programs.
2. The *Company* shall ensure that all *Processes with Significant Environmental Aspects* are operated and maintained in accordance with this *Approval*, the operating procedures and maintenance programs.
 3. The *Company* shall ensure that only one of the *Emergency Diesel Generators* are tested at any given time.

8. COMPLAINTS RECORDING AND REPORTING

1. If at any time, the *Company* receives an environmental complaint from the public regarding the operation of the *Equipment* approved by this *Approval*, the *Company* shall take the following steps:
 - a. Record and number each complaint, either electronically or in a log book. The record shall include the following information: the time and date of the complaint and incident to which the complaint relates, the nature of the complaint, wind direction at the time and date of the incident to which the complaint relates and, if known, the address of the complainant.
 - b. Notify the *District Manager* of the complaint within two (2) business days after the complaint is received, or in a manner acceptable to the *District Manager*.
 - c. Initiate appropriate steps to determine all possible causes of the complaint, and take the necessary actions to appropriately deal with the cause of the subject matter of the complaint.
 - d. Complete and retain on-site a report written within one (1) week of the complaint date. The report shall list the actions taken to appropriately deal with the cause of the complaint and set out steps to be taken to avoid the recurrence of similar incidents.

9. RECORD KEEPING REQUIREMENTS

1. Any information requested by any employee in or agent of the *Ministry* concerning the *Facility* and its operation under this *Approval*, including, but not limited to, any records required to be kept by this *Approval*, shall be provided to the employee in or agent of the *Ministry*, upon request, in a timely manner.

2. Unless otherwise specified in this *Approval*, the *Company* shall retain, for a minimum of five (5) years from the date of their creation all reports, records and information described in this *Approval*, including,
 - a. a copy of the *Original ESDM Report* and each updated version;
 - b. a copy of each version of the *Acoustic Assessment Report*;
 - c. supporting information used in the emission rate calculations performed in the *ESDM Reports* and *Acoustic Assessment Reports*;
 - d. the records in the *Log*;
 - e. copies of each *Written Summary Form* provided to the *Ministry* under Condition 6.1 of this *Approval*;
 - f. records of maintenance, repair and inspection of *Equipment* related to all *Processes with Significant Environmental Aspects*; and
 - g. all records related to environmental complaints made by the public as required by Condition 8 of this *Approval*.

10. **EQUIPMENT WITH SPECIFIC REQUIREMENTS**

1. The *Company* shall ensure that the *5.7 Megawatt Co-Generation Unit* is designed and operated to comply, at all times, with the following performance requirements:
 - a. The concentrations of nitrogen oxides and carbon monoxide, in the undiluted gas emitted from the *5.7 Megawatt Co-Generation Unit* stack are not greater than the limits specified in Schedule B attached to this *Approval*.
 - b. The *Thermal Efficiency* of the *5.7 Megawatt Co-Generation Unit* is not less than the *Thermal Efficiency* specified in Schedule B of this *Approval*.
2. The *Company* shall perform *Source Testing*, in accordance with the procedures outlined in Schedule C every three (3) calendar years, to determine the rate of emission of Nitrogen Oxides from the *Co-Generation Units*.
3. The *Company* shall perform a test in conjunction with the above *Source Testing* to determine the *Thermal Efficiency* of the *Co-Generation Units*. The *Company* shall, as a minimum:
 - a. determine the parameters described in Schedule D, during the *Thermal Efficiency* testing for both *Co-Generation Units*;
 - b. calculate the *Thermal Efficiency* of the *Co-Generation Units* according to the formula described in Schedule D;

- c. prepare a summary of the results of the *Thermal Efficiency* testing no later than three (3) months after completing the test. The summary shall indicate the *Thermal Efficiency* of the *Co-Generation Units* and include all parameters described in Schedule D;
- d. if the measured *Thermal Efficiency* is less than the anticipated *Thermal Efficiency* specified in Schedule B of this *Approval* (with a tolerance of 0.05 multiplied by the anticipated *Thermal Efficiency*), notify the *Ministry* so that the concentration limits specified in Schedule B of this *Approval* can be revised accordingly.

11. UPDATED ACOUSTIC ASSESSMENT REPORT

1. The *Company* shall submit, not later than twelve (12) months from the date of this *Approval*, an updated *Acoustic Assessment Report*, to the *District Manager* and the *Director*, for approval by the *Director*. The updated *Acoustic Assessment Report* shall incorporate the associated *Revised Noise Abatement Action Plan* including:
 - a. a detailed description of the proposed *Noise Control Measures*, including individual acoustical performance specifications, such as octave band insertion losses and transmission losses and acoustic barrier dimensions, to reduce the noise emissions from the *Facility* to comply with the sound level limits set in *Publication NPC-300*; and
 - b. a detailed timetable for implementation of the *Noise Control Measures* acceptable to *District Manager*.

12. ACOUSTIC AUDIT

1. The *Company* shall carry out *Acoustic Audit* measurements on the actual noise emissions due to the operation of the *Facility*. The *Company* shall:
 - a. carry out *Acoustic Audit* measurements in accordance with the procedures in *Ministry Publication NPC-103*; and
 - b. submit an *Acoustic Audit Report* on the results of the *Acoustic Audit*, prepared by an *Independent Acoustical Consultant*, in accordance with the requirements of *Ministry Publication NPC-233*, to the *District Manager* and the *Director*, not later than three (3) months after the implementation of the *Revised Noise Abatement Action Plan*.
2. The *Director*:
 - a. may not accept the results of the *Acoustic Audit* if the requirements of *Ministry Publication NPC-233* were not followed; and
 - b. may require the *Company* to repeat the *Acoustic Audit* if the results of the *Acoustic Audit* are found unacceptable to the *Director*.

13. REVOCATION OF PREVIOUS APPROVALS

1. This *Approval* replaces and revokes all Certificates of Approval (Air) issued under section 9 *EPA* and Environmental Compliance Approvals issued under Part II.1 *EPA* to the *Facility* in regards to the activities mentioned in subsection 9(1) of the *EPA* and dated prior to the date of this *Approval*.

SCHEDULE A

Supporting Documentation

1. Environmental Compliance Approval Application, dated July 5, 2019, signed by Murray Fulmer and submitted by the *Company*;
2. Emission Summary and Dispersion Modelling Report, prepared by Dillon Consulting Limited and dated July 24, 2019;
3. *Acoustic Assessment Report*, dated July 24, 2019 and signed by Alexandra Davidson and Michael Medal, Aercoustics Engineering Ltd.; and
4. The letters (e-mails) dated September 13, 2019 and April 17, 2020, provided by Alexandra Davidson and Michael Medal, Aercoustics Engineering Ltd., and the letter (e-mail) dated April 27, 2020 and provided by Murray Fulmer, Deputy Director for Environment & Sustainability, Sanofi Pasteur Limited/Sanofi Pasteur Limitee.

SCHEDULE B

Emission Limits

Equipment	Parameter	Limit
5.7 MW Co-generation Unit	Nitrogen Oxides	47 ppmv (2)
	Carbon Monoxide	60 ppmv
	<i>Thermal Efficiency</i>	39 percent

(1) "Nitrogen oxides" means oxides of nitrogen, including nitric oxide (NO) and nitrogen dioxide (NO₂).

(2) "ppmv" means parts per million by volume on a dry basis normalized to 15 per cent oxygen.

SCHEDULE C

SOURCE TESTING PROCEDURES

1. The *Company* shall submit, not later than two (2) months prior to the *Source*

Testing, to the *Manager* a *Pre-Test Plan* for the *Source Testing* required under this *Approval*. The *Company* shall finalize the *Pre-Test Plan* in consultation with the *Manager*.

2. The *Company* shall not commence the *Source Testing* required under this *Approval* until the *Manager* has approved the *Pre-Test Plan*.
3. The *Company* shall notify the *Manager*, the *District Manager* and the *Director* in writing of the location, date and time of any impending *Source Testing* required by this *Approval*, at least fifteen (15) days prior to the *Source Testing*.
4. The *Company* shall submit a report (electronic format) on the *Source Testing* to the *Manager*, the *District Manager* and the *Director* not later than three (3) months after completing the *Source Testing*. The report shall be in the format described in the *Source Testing Code*, and shall also include, but not be limited to:
 - a. an executive summary;
 - b. an identification of the applicable North American Industry Classification System code (NAICS) for the *Facility*;
 - c. records of operating conditions at the time of *Source Testing*, including but not limited to the following:
 - i. production data and equipment operating rate as a percentage of maximum capacity;
 - ii. *Facility*/process information related to the operation of the targeted sources; including all records produced by the continuous monitoring systems;
 - iii. description of the emission sources controlled by the targeted sources at the time of testing;
 - d. results of *Source Testing*, including the emission rate, emission concentration, and relevant emission factor of the subject test contaminants from the targeted sources;
 - e. a tabular comparison of calculated emission rates and emission factors based on *Source Testing* results for the subject test contaminants to relevant estimates described in the *ESDM Report*;
 - f. the results of dispersion calculations using the results of *Source Testing* to estimate emissions from the targeted sources in accordance with O. Reg. 419 or Schedule "C" (for odour),

indicating the maximum concentrations of the subject test contaminants at the Point of Impingement and at the most impacted *Sensitive Receptor* (for odour).

5. The *Director* may not accept the results of the *Source Testing* if:
 - a. the *Source Testing Code* or the requirement of the *Manager* were not followed;
 - b. the *Company* did not notify the *Manager*, the *District Manager* and *Director* of the *Source Testing*; or
 - c. the *Company* failed to provide a complete report on the *Source Testing*.
6. If the *Director* does not accept the result of the *Source Testing*, the *Director* may require re-testing. If re-testing is required, the *Pre-Test Plan* strategies need to be revised and submitted to the *Manager* for approval. The actions taken to minimize the possibility of the *Source Testing* results not being accepted by the *Director* must be noted in the revision.
7. The *Company* shall update their *ESDM Report* in accordance with Section 26 of *O. Reg. 419/05* and the *Procedure Document* with the results from the *Source Testing* if any of the calculated emission factors or calculated emission rates are higher than the predicted rates in the *ESDM report*, not later than three (3) months after the submission of the *Source Testing* report and make these records available for review by staff of the *Ministry* upon request.

SCHEDULE D

THERMAL EFFICIENCY VERIFICATION

PARAMETERS:

1. Power Output (megaWatts);
2. Heat Output (megaWatts);
3. Fuel Flow Rate (in cubic metres per second at standard temperature and pressure, or kilograms per second) ;
4. Lower Heating Value of the Fuel (megajoules per cubic metre);
5. Ambient air temperature (degree of Celsius);
6. barometric pressure (kilopascal);
7. relative humidity (per cent);

8. Date, time and duration of test.

FORMULA

Thermal Efficiency = (Power Output + Heat Output) x 100% / Fuel Flow Rate / Lower Heating Value.

Thermal Efficiency testing should be conducted at maximum rating or at the maximum load achievable at the time of testing and shall employ an average time of not less than three hours.

The reasons for the imposition of these terms and conditions are as follows:

1. GENERAL

Condition No. 1 is included to require the *Approval* holder to build, operate and maintain the *Facility* in accordance with the Supporting Documentation in Schedule A considered by the *Director* in issuing this *Approval*.

2. LIMITED OPERATIONAL FLEXIBILITY, REQUIREMENT TO REQUEST AN ACCEPTABLE POINT OF IMPINGEMENT CONCENTRATION AND PERFORMANCE LIMITS

Conditions No. 2, 3 and 4 are included to limit and define the *Modifications* permitted by this *Approval*, and to set out the circumstances in which the *Company* shall request approval of an *Acceptable Point of Impingement Concentration* prior to making *Modifications*. The holder of the *Approval* is approved for operational flexibility for the *Facility* that is consistent with the description of the operations included with the application up to the *Facility Production Limit*. In return for the operational flexibility, the *Approval* places performance based limits that cannot be exceeded under the terms of this *Approval*. *Approval* holders will still have to obtain other relevant approvals required to operate the *Facility*, including requirements under other environmental legislation such as the *Environmental Assessment Act*.

3. DOCUMENTATION REQUIREMENTS

Condition No. 5 is included to require the *Company* to maintain ongoing documentation that demonstrates compliance with the performance limits as specified in Condition 4 of this *Approval* and allows the *Ministry* to monitor ongoing compliance with these performance limits. The *Company* is required to have an up to date *ESDM Report* and *Acoustic Assessment Report* that describe the *Facility* at all times and make the *Emission Summary Table* and *Acoustic Assessment Summary Table* from these reports available to the public on an ongoing basis in order to maintain public communication with regard to the emissions from the *Facility*.

4. REPORTING REQUIREMENTS

Condition No. 6 is included to require the *Company* to provide a yearly *Written Summary Form* to the *Ministry*, to assist the *Ministry* with the review of the site's compliance with the *EPA*, the regulations and this *Approval*.

5. OPERATION AND MAINTENANCE

Condition No. 7 is included to require the *Company* to properly operate and maintain the *Processes with Significant Environmental Aspects* to minimize the impact to the environment from these processes.

6. COMPLAINTS RECORDING AND REPORTING PROCEDURE

Condition No. 8 is included to require the *Company* to respond to any environmental complaints regarding the operation of the *Equipment*, according to a procedure that includes methods for preventing recurrence of similar incidents and a requirement to prepare and retain a written report.

7. RECORD KEEPING REQUIREMENTS

Condition No. 9 is included to require the *Company* to retain all documentation related to this *Approval* and provide access to employees in or agents of the *Ministry*, upon request, so that the *Ministry* can determine if a more detailed review of compliance with the performance limits as specified in Condition 4 of this *Approval* is necessary.

8. EQUIPMENT WITH SPECIFIC OPERATIONAL LIMITS

Condition No. 10 is included to provide the minimum performance requirement considered necessary to prevent an adverse effect resulting from the operation of the operation of the *Co-Generation Units*, and to require the *Company* to gather accurate information so that the environmental impact and subsequent compliance with the *EPA*, the regulations and this *Approval* can be verified.

9. UPDATED ACOUSTIC ASSESSMENT REPORT

Condition No. 11 is included to require the *Company* to submit an updated *Acoustic Assessment Report* incorporating a *Revised Noise Abatement Action Plan* to reduce the noise emissions from the *Facility* to comply with the applicable limits set in the *Ministry's Noise Guidelines*

10. ACOUSTIC AUDIT

Condition No. 12.1 is included to require the *Company* to gather accurate information so that the environmental impact and subsequent compliance with the *EPA*, the regulations and this *Approval* can be verified.

Condition No. 12.2 is included to ensure that the *Acoustic Audit* is carried out in accordance with procedures set in the *Ministry's Noise Guidelines*.

11. REVOCATION OF PREVIOUS APPROVALS

Condition No. 13 is included to identify that this *Approval* replaces all Section 9 Certificate(s) of Approval and Part II.1 Approvals in regards to the activities mentioned in subsection 9(1) of the *EPA* and dated prior to the date of this

Approval.

Upon issuance of the environmental compliance approval, I hereby revoke Approval No(s). 1890-A39SB3 issued on March 21, 2017.

In accordance with Section 139 of the Environmental Protection Act, you may by written Notice served upon me, the Environmental Review Tribunal and in accordance with Section 47 of the Environmental Bill of Rights, 1993, the Minister of the Environment, Conservation and Parks, within 15 days after receipt of this Notice, require a hearing by the Tribunal. The Minister of the Environment, Conservation and Parks will place notice of your appeal on the Environmental Registry. Section 142 of the Environmental Protection Act provides that the Notice requiring the hearing shall state:

- a. The portions of the environmental compliance approval or each term or condition in the environmental compliance approval in respect of which the hearing is required, and;
- b. The grounds on which you intend to rely at the hearing in relation to each portion appealed.

Pursuant to subsection 139(3) of the Environmental Protection Act, a hearing may not be required with respect to any terms and conditions in this environmental compliance approval, if the terms and conditions are substantially the same as those contained in an approval that is amended or revoked by this environmental compliance approval.

The Notice should also include:

1. The name of the appellant;
2. The address of the appellant;
3. The environmental compliance approval number;
4. The date of the environmental compliance approval;
5. The name of the Director, and;
6. The municipality or municipalities within which the project is to be engaged in.

And the Notice should be signed and dated by the appellant.

This Notice must be served upon:

The Secretary* Environmental Review Tribunal 655 Bay Street, Suite 1500 Toronto, Ontario M5G 1E5	AND	The Minister of the Environment, Conservation and Parks 777 Bay Street, 5th Floor Toronto, Ontario M7A 2J3	AND	The Director appointed for the purposes of Part II.1 of the Environmental Protection Act Ministry of the Environment, Conservation and Parks 135 St. Clair Avenue West, 1st Floor Toronto, Ontario M4V 1P5
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*** Further information on the Environmental Review Tribunal's requirements for an appeal**

can be obtained directly from the Tribunal at: Tel: (416) 212-6349, Fax: (416) 326-5370 or www.ert.gov.on.ca

This instrument is subject to Section 38 of the Environmental Bill of Rights, 1993, that allows residents of Ontario to seek leave to appeal the decision on this instrument. Residents of Ontario may seek leave to appeal within 15 days from the date this decision is placed on the Environmental Registry. By accessing the Environmental Registry at <https://ero.ontario.ca/>, you can determine when the leave to appeal period ends.

The above noted activity is approved under s.20.3 of Part II.1 of the Environmental Protection Act.

DATED AT TORONTO this 13th day of May, 2020

Rudolf Wan, P.Eng.
Director
appointed for the purposes of Part
II.1 of the *Environmental
Protection Act*

QN/
c: District Manager, MECP Toronto - District
Jillian Hicks-McClary, Dillon Consulting Limited