

AMENDED ENVIRONMENTAL COMPLIANCE APPROVAL

NUMBER 9323-BH7NCA

Issue Date: December 16, 2019

Bles Biochemicals Incorporated
60 Pacific Court, No. 8
London, Ontario
N5V 3K4

Site Location: 60 Pacific Court
London City, County of Middlesex
N5V 3K4

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 pharmaceutical facility producing bovine lipid extract surfactant, consisting of the following processes and support units:

- chemical preparation;
- surfactant extraction;
- surfactant purification;
- rotary evaporation;
- quality control testing;

including the *Equipment* and any other ancillary and support processes and activities, operating at a *Facility Production Limit* of up to **1,050 kilograms of bovine lipid extract surfactant 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 Jakub Wrobel / O2E Inc. Environmental Consultants and dated March 30, 2017 submitted in support of the application, that documents all sources of noise emissions and *Noise Control Measures* present at the *Facility*, as updated in accordance with Condition 5 of this *Approval*;

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. "*Approval*" means this entire Environmental Compliance Approval and any *Schedules* to it;

6. "*Basic Comprehensive User Guide*" means the *Ministry* document titled "Basic Comprehensive Certificates of Approval (Air) User Guide" dated March 2011, as amended;

7. "*Company*" means Bles Biochemicals Incorporated 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*;

8. "*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;

9. "*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*;

10. "*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*;

11. "*District Manager*" means the District Manager of the appropriate local district office of the *Ministry*, where the *Facility* is geographically located;

12. "*Emission Summary Table*" means a table described in paragraph 14 of subsection 26 (1) of *O. Reg. 419/05*;
13. "*Environmental Assessment Act*" means the Environmental Assessment Act, R.S.O. 1990, c.E.18, as amended;
14. "*EPA*" means the Environmental Protection Act, R.S.O. 1990, c.E.19, as amended;
15. "*Equipment*" means equipment or processes described in the *ESDM Report*, this *Approval* and in the *Schedules* referred to herein and any other equipment or processes;
16. "*Equipment with Specific Operational Limits*" means 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*;
17. "*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*;
18. "*Exhausted*" means the capacity of the activated carbon control unit to adsorb emissions is reached and the *Equipment* is no longer able to effectively reduce emissions;
19. "*Facility*" means the entire operation located on the property where the *Equipment* is located;
20. "*Facility Production Limit*" means the production limit placed by the *Director* on the main product(s) or raw materials used by the *Facility*;
21. "*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;
22. "*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;
23. "*Ministry*" means the ministry of the *Minister*;
24. "*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*;

25. "*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;
26. "*O. Reg. 419/05*" means Ontario Regulation 419/05, Air Pollution – Local Air Quality, as amended;
27. "*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 Jeff Campbell / O2E Inc. and dated May 14, 2019 submitted in support of the application, and includes any changes to the report made up to the date of issuance of this *Approval*;
28. "*Point of Impingement*" has the same meaning as in section 2 of *O. Reg. 419/05*;
29. "*Point of Reception*" means Point of Reception as defined by *Publication NPC-300*;
30. "*Procedure Document*" means *Ministry* guidance document titled "Procedure for Preparing an Emission Summary and Dispersion Modelling Report" dated February 2017, as amended;
31. "*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*;
32. "*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;
33. "*Publication NPC-233*" means the *Ministry* Publication NPC-233, "Information to be Submitted for Approval of Stationary Sources of Sound", October, 1995, as amended;
34. "*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;
35. "*Schedules*" means the following schedules attached to this *Approval* and forming part of this *Approval* namely:
 - Schedule A - Supporting Documentation;

36. "*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
37. "*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.

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 ensure that the noise emissions from the *Facility* comply with the limits set out in *Ministry Publication NPC-300*;
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*.

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 the control media in the activated carbon control unit is replaced before it is *Exhausted*.

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. 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 May 22, 2019, signed by Harold Nigh, Director and submitted by the *Company*;
2. Emission Summary and Dispersion Modelling Report, prepared by Jeff Campbell, O2E Inc. and dated May 14, 2019;
3. *Acoustic Assessment Report*, dated March 30, 2017, prepared by O2E Inc. Environmental Consultants, and signed by Jakub Wrobel;
4. Additional information provided by Jeff Campbell, O2E Inc. in emails dated October 16, 2019 and October 23, 2019.

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. **REVOCACTION OF PREVIOUS APPROVALS**

Condition No. 10 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). 2121-4KTNPD issued on May 30, 2000

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

*** 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 16th day of
December, 2019

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

KS/
c: District Manager, MECP London - District
Jeff Campbell, O2E Inc.