



Guidance for responding to the
Notice with respect to certain micro-organisms (the Notice)

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This document provides guidance for responding to the *Notice with respect to certain micro-organisms* published in the Canada Gazette, Part I, on September 23, 2017, pursuant to paragraph 71(1)(b) of the *Canadian Environmental Protection Act, 1999* (the Act). It is meant to be used with its companion piece, the FAQ, which provides more details and guidance with regards to information gathering activities.

In case of discrepancy between this document and the notice or the Act, the official versions of the notice and the Act take precedence.

1. Overview

1.1. Purpose of the Notice

The *Notice with respect to certain micro-organisms* applies to 11 micro-organisms. The scope of the notice will allow the Government of Canada to capture up-to-date and critical information on commercial status, downstream use and yearly market fluctuations between 2013 and 2016 to help inform future risk management activities. Information gathered from this notice will help identify micro-organisms that are in commerce, or that are expected to be of higher concern based on their commercial status and that need further regulatory attention at this time.

Clarification on substance ATCC 22342 listed in Schedule 1 of the Notice:

Recent studies have shown that the ATCC 22342 listed on the Domestic Substances List (DSL) is a strain of *Aspergillus niger* and not *Aspergillus awamori*. Hence, this strain number may also be associated to the substance name *Aspergillus niger*.

1.2. Information to which you may reasonably be expected to have access

You are required to provide information that your company possesses or to which you may be reasonably expected to have access. For more information about this section click [here](#).

Suppliers who wish to protect their formulations from their clients can submit the information directly to the Government of Canada by submitting a [blind submission](#).

Tip: You are not required to conduct tests to comply with the notice.

1.3. Request for confidentiality

Pursuant to section 313 of the Act, any person who provides information in response to the notice may submit, a written request that it be treated as confidential.



If you provide information in response to the notice, and request that the information be treated as confidential, you will be asked for the reason for requesting confidentiality based on the following criteria:

- a) the information is a trade secret;
- b) it is information of a financial, commercial, scientific or technical nature that you treat consistently in a confidential manner;
- c) disclosure of the information could reasonably be expected to result in material financial loss or gain, or could reasonably be expected to prejudice your competitive position; or
- d) disclosure of the information could reasonably be expected to interfere with contractual or other negotiations you are conducting.

You should make a request for confidentiality only for information that is truly confidential. For more information on the treatment of Confidential Business Information, please [contact us](#).

1.4. **Blind Submissions**

To determine whether you meet the reporting criteria of the notice, and in order to fill out your response, you may request information from a supplier of imported mixtures, products or manufactured items. The supplier may be reluctant to provide it to you if it is Confidential Business Information. In such a case, you and your supplier can agree to both participate in a joint response, where each party submits part of the information directly to the [Substances Management Coordinator](#), allowing you to meet your reporting obligation, while protecting the supplier's trade secrets. Blind submissions can also be initiated by a supplier who knows/suspects that a customer should report, based on quantities purchased. In any case, a cover letter or note should be provided with each part of the blind submission indicating that the supplier's submission completes the customer's submission. Both parties must agree to this approach.

The Substances Management Coordinator makes the necessary connection between the two submissions, while keeping all information confidential.

More guidance on this topic is available [here](#).

1.5. **Information previously submitted**

As indicated in section 7 of Schedule 2 of the notice, if any of the information required under the notice was previously submitted to the Government of Canada, it may be relied on as your response to any question of the Notice if the information previously submitted is applicable to the calendar year for which you are responding to the notice.



If this applies to you, the previously submitted information is **not** required to be resubmitted; you must simply provide the following information as an attachment to your submission:

- the strain identification number of the substance(s) to which the submitted information relates,
- the date on which the information was submitted,
- the name of the person who submitted the information, and
- the program or government official title to which the information was submitted.

Example: During a voluntary data collection initiative, you provided 2010 data to the Minister of the Environment for a substance listed in Schedule 1 of the notice, and the data is still applicable for the 2016 calendar year. You should reference the previously submitted information in response to the applicable section(s) of Schedule 2, and attach the information specified in section 7 of Schedule 2.

2. Reporting Criteria

To determine whether you are required to respond, the following factors must be considered:

- Calendar year
- Type of activity
- Exclusions

The notice applies to those who, during the 2016 calendar year:

- **Manufactured** a substance listed in Schedule 1 of the notice;
- **Imported** a substance listed in Schedule 1 of the notice, whether the substance is alone, in a mixture or product.

Manufacture applies only to the research or industrial production of the animate substance listed on Schedule 1, whether it is intended to be part of a product or not.

It is important to note that for the purpose of the notice, making a mixture, product or manufactured item containing a reportable substance would **NOT** be considered “manufacture”. In this case, the activity is considered “use”, which is not a reportable activity under the notice. However, your activity with the substance may still be of interest to the Government and you can provide this information on a voluntary basis via the Declaration of Stakeholder Interest.



Click here for information about importers.

Tip: For this notice, you do not have to differentiate between mixture and product since the reporting criteria are consistent for both.

If your company owns more than one facility, you must meet the reporting criteria on a company-wide basis. Your response for each question should be an amalgamated response that includes information from **all facilities** owned by the company.

2.1 Exclusions

There are several exclusions that apply to the notice, which are found in Schedule 2 of the notice.

The notice does not apply to a substance listed in Schedule 1, whether alone, in a mixture, or in a product, that:

- (a) was in transit through Canada;
- (b) was, or was contained in, a hazardous waste or hazardous recyclable material within the meaning of the [Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations](#) and was imported pursuant to a permit referred to in these Regulations;
- (c) was, or was contained in, a pest control product registered under the [Pest Control Products Act](#);
- (d) was, or was contained in, a fertilizer or supplement imported or manufactured in accordance with the [Fertilizers Act](#);
- (e) was, or was contained in, a feed imported or manufactured in accordance with the [Feeds Act](#);
- (f) was mixed with, or attached to, a seed registered imported or manufactured in accordance with the [Seeds Act](#);
- (g) was, or was contained in, a veterinary biologic imported or manufactured in accordance with the [Health of Animals Act](#); or
- (h) was a research and development substance not introduced outside a contained facility, if the containment of the substance was in accordance with either the *Canadian Biosafety Standards* or Appendix K of the *NIH Guidelines* and if the substance:
 - i. was imported to the contained facility in a quantity that, at the time of the import, was less than 50 mL or 50 g;



- ii. was, subject to subparagraphs (iii) and (iv), manufactured and present at any one time in the contained facility in a quantity of less than 1 000 L, unless the substance requires containment level 2, 3 or 4 as identified in the *Canadian Biosafety Standards and Guidelines*¹;
- iii. was manufactured and present at any one time in the contained facility in a quantity of less than 250 L and requires containment level 2 as identified in the *Canadian Biosafety Standards and Guidelines*; or
- iv. was a human pathogen and was manufactured and present at any one time in the contained facility in a quantity of less than 250 L and requires containment level 3 or 4 as identified in the *Canadian Biosafety Standards and Guidelines*, and if an import permit or an approval in writing to transfer has been granted in respect of the substance under the *Human Pathogens and Toxins Regulations*.

3. Reportable Codes

When submitting your response to the notice, you will be required to consider two sets of codes:

- North American Industry Classification System (NAICS) codes
- Use Codes

3.1 North American Industry Classification System (NAICS) codes

You are required to provide the applicable NAICS codes that best describe the activities with each substance. The code(s) will provide general information on the number and types of sectors involved with the substances listed in the notice.

The [NAICS 2017](#) list of codes is available at the Statistics Canada web site.

3.2 Use Codes

You are required to select the use codes that apply to the activity involving each reportable micro-organism.

¹ “*Canadian Biosafety Standards and Guidelines*” means the *Canadian Biosafety Standards and Guidelines*, 1st Edition, published in 2013 by the Public Health Agency of Canada and the Canadian Food Inspection Agency, as amended from time to time.



Code	Description
1	Absorbent or adsorbent
2	Bioenergy, biofuel production or biomass conversion
3	Biodegradation
4	Biological waste treatment
5	Bioremediation
6	Catalyst, accelerator, initiator, activator
7	Climate control
8	Composting
9	Cosmetic product or preparation of cosmetic products
10	Custodial, cleaning and other related products
10.1	Bathroom, toilet and shower cleaners
10.2	Dust control
10.3	Floor cleaners, floor care, carpet care
10.4	General all-purpose cleaners
10.5	Industrial cleaners
10.6	Laundry and dishwashing cleaners
11	Drain cleaning or degreasing
12	Drilling mud additive, oil recovery agent or oil well treatment agent
13	Environmental probes
14	Fertilizer
15	Enzyme or chemical production
16	Flocculating, precipitating or clarifying agent
17	Food production or food processing
18	Fragrance, perfume or deodorizer
19	Fuel or fuel additive



20	Forestry, wood products or wood treatment
21	Industrial gas production
22	Leather or tanning
23	Livestock feed
24	Mineral leaching
25	Metallurgical
26	Mining
27	Natural health products, human biologics or medical devices
28	Organic chemicals, industrial
29	Organic chemicals, specialty
30	Organo metallic chemicals
31	Oxidizing agent
32	Paint and coating
33	Paint flocculants, degraders
34	Pest control
35	Pet care
36	Petroleum processing
37	Pharmaceutical preparation
38	Photosensitive agent (fluorescent agent, brightener or ultraviolet absorber)
39	Polymer additive
40	Pigment, dye and printing ink
41	Plastics
42	Plating and surface finishing
43	Preservative
44	Processing aid
45	Pulp and paper processing
46	Research and development



47	Refined petroleum and coal agent
48	Rubber products
49	Septic tank or recreational vehicle tank additive
50	Sequestering agent
51	Stripper, etcher, discharge printing agent or de-inker
52	Surfactant (detergent, emulsifier, wetting agent or dispersant)
53	Soap and cleaning products or mixtures
54	Textile processing
55	Wastewater treatment
56	Waste treatment
57	Water conditioners, pond treatment or aquarium treatment
58	Wax separation
99	Use(s) other than those listed above (specify)

4. Sections to be completed – Schedule 2 of the notice

If you determine that you meet the reporting criteria of the notice, you must complete the sections of Schedule 2 applicable to your activity with each reportable substance.

4.1 Examples where reporting criteria are not met

Example 1:

During the calendar year 2016, you imported 2 tubes (6 ml/each) of pure culture of *Pseudomonas aeruginosa* (ATCC 700371) for research and development purposes, to a contained facility that is in accordance with a containment level 2 – as identified in the *Canadian Biosafety Standards and Guidelines*. The substance was not introduced outside of the facility and was present at any one time in the facility in quantities below 250 L. You are **not** required to report information under the notice - as described under section 4 of Schedule 2 of the exclusions section.

Example 2:

During the calendar years 2013 and 2014, you manufactured *Enterobacter aerogenes* (ATCC 13048) for wastewater treatment applications. Since 2015 you have ceased all



activities pertaining to *Enterobacter aerogenes* (ATCC 13048) due to a lack of demand from your customers. You are **not** required to provide information under the notice as you did not manufacture or import the substance in 2016.

4.2 Example where reporting criteria are met

Example 3:

During the calendar years 2013 to 2016, you manufactured *Bacillus cereus* (ATCC 14579).

During calendar year of 2016, you manufactured a total of 550 kg of *Bacillus cereus* (ATCC 14579) in two batches at different concentrations with applicable NAICS codes 562998 and 453910.

The first batch you manufactured resulted in a total quantity of 250 kg of the micro-organism, at a concentration of 10^4 cfu/g. The total quantity was sold to “Canadian customer #1” for the production of Bioremidx² – a product used in drain cleaning (use code: 11).

The second batch you manufactured resulted in a total quantity of 200 kg of that same micro-organism, at a concentration of 10^3 cfu/g. 100 kg was sold to “Canadian customer #2” for the production of Zyliminate³ – a pet odor removal product (use code: 35) – and the remaining 100 kg was sold to “American customer” for the same application.

You are legally required to report to the notice using the online Excel reporting template which can be downloaded via [Environment and Climate Change Canada’s Single Window](#)’s CMP reporting module. Using an Excel template different from the one your company downloaded from Single Window will result in the rejection of your submission.

For **Example 3**, the following information should be provided in your submission:

Table 1: Information pertaining to paragraph 6(1)(a), (b) and (c) of Schedule 2 of the notice.

Strain identification number	Was the substance manufactured or imported, whether alone, in a mixture or in a product in:				Quantity (L or kg)* manufactured or imported in 2016	
	2013	2014	2015	2016	Imported	Manufactured
ATCC 14579	Yes	Yes	Yes	Yes	0 kg	450 kg

² The trade name Bioremidx is a fictitious example.

³ The trade name Zyliminate is a fictitious example.



*: "L" means Liters and "kg" means kilograms

Table 2: Information pertaining to paragraph 6(1)(d) of Schedule 2 of the notice.

Strain identification number	Applicable NAICS code(s)
ATCC 14579	562998
ATCC 14579	453910

Table 3: Information pertaining to paragraph 6(1)(e) of Schedule 2 of the notice.

Strain identification number	Use code(s)	Concentration or range of concentration reported in cfu/mL* or cfu/g**	Physical state of mixture or product	Trade name or common name	Substance is intended for use in commercial activities?	Substance is intended for use in consumer activities?
ATCC 14579	11	10 ⁴ cfu/g	Powder	Bioremidex	Yes	No
ATCC 14579	35	10 ³ cfu/g	Powder	Zyliminate	Yes	No

*: cfu/mL means colony forming units (cfu) per millimeter (mL)

** : cfu/g means colony forming units (cfu) per gram (mL)

Table 4: Information pertaining to paragraph 6(1)(f) of Schedule 2 of the notice.

Strain identification number	Person	Quantity (L or kg)*
ATCC 14579	Canadian customer #1	250 kg
ATCC 14579	Canadian customer #2	100 kg

*: "L" means Liters and "kg" means kilograms

In that example, you are not required to report the information pertaining to "American customer" as that person is not located in Canada.

Example 4 :

During the calendar year 2016, you imported 50 000 L of a mixture containing *Aspergillus awamori* (ATCC 22342) and *Bacillus subtilis* (11685-3).

You are required to report to the notice.

The mixture had a concentration of 10⁴ cfu/mL of *Aspergillus awamori* (ATCC 22342) and 10³ cfu/mL of *Bacillus subtilis* (11685-3), its trade name was Bio-degradation mixture⁴ and its applicable NAICS code was 325110. You used a total of 40 000 L for biodegradation applications (use code: 3) and sold the remaining 10 000 L to "Canadian customer #1" for the same application.

⁴ Trade name Bio-degradation mixture is a fictitious example.



You are legally required to report to the notice using the online Excel reporting template which can be downloaded via [Environment and Climate Change Canada's Single Window's](#) CMP reporting module. Using an Excel template different from the one your company downloaded from Single Window will result in the rejection of your submission.

For **Example 4**, the following information should be provided in your submission:

Table 5: Information pertaining to paragraph 6(1)(a), (b) and (c) of Schedule 2 of the notice.

Strain identification number	Was the substance manufactured or imported, whether alone, in a mixture or in a product in:				Quantity (L or kg)* manufactured or imported in 2016	
	2013	2014	2015	2016	Imported	Manufactured
ATCC 22342	No	No	No	Yes	50 000 L	0 L
11685-3	No	No	No	Yes	50 000 L	0 L

Table 6: Information pertaining to paragraph 6(1)(d) of Schedule 2 of the notice.

Strain identification number	Applicable NAICS code(s)
ATCC 22342	325110
11685-3	325110

Table 7: Information pertaining to paragraph 6(1)(e) of Schedule 2 of the notice.

Strain identification number	Use code(s)	Concentration or range of concentration reported in cfu/mL* or cfu/g**	Physical state of mixture or product	Trade name or common name	Substance is intended for use in commercial activities?	Substance is intended for use in consumer activities?
ATCC 22342	3	10 ⁴ cfu/mL	Liquid	Bio-degradation mixture	Yes	No
11685-3	3	10 ³ cfu/mL	Liquid	Bio-degradation mixture	Yes	No

* : cfu/mL means colony forming units (cfu) per millimeter (mL).

** : cfu/g means colony forming units (cfu) per gram (mL).

Table 8: Information pertaining to paragraph 6(1)(f) of Schedule 2 of the notice.

Strain identification number	Person	Quantity (L or kg)*
ATCC 22342	Canadian customer	10 000,00 L
11685-3	Canadian customer	10 000,00 L

* : "L" means Liters and "kg" means kilograms



5. Companies that do not meet the reporting criteria of the notice

If you have determined that you do not meet the reporting criteria of the mandatory notice, you are not legally obligated to respond.

In situations where you do not meet the reporting requirements, the Government of Canada encourages you to provide information on a voluntary basis. One of the following two options may be applicable :

- **Declaration of Stakeholder Interest:** This option applies to you if you do not meet the criteria to respond to the notice, but you have a past, current or future interest in a reportable substance. In such a case, you may identify yourself as an interested stakeholder by completing a [Declaration of Stakeholder Interest](#) online. You may also use this approach to provide the department with information you consider relevant regarding any substances of interest. When completing this form, you should:
 - identify the substances of interest to you, and
 - specify your activity or potential activity with the substance (e.g.: import, export, manufacture, or use)

For example, if you had no activity with the reportable substance(s) or had activity below the quantity threshold, and/or the activity took place during a calendar year not specified in the notice, you are encouraged to provide any information you consider relevant for the alternate calendar year by completing a Declaration of Stakeholder Interest.

Interested stakeholders may be contacted for further information regarding their interest in a reportable substance.

- **Declaration of Non-Engagement:** This option is available to you if you have no activity and no commercial interest in any of the reportable substances identified in a notice. If this applies, you may choose to complete a [Declaration of Non-Engagement](#) online.

Tip: Via the online reporting tool, if you reported information as part of the section 71 notice, you can also submit information via a Declaration of Stakeholder Interest for any other reportable substances. On the other hand, submitting a Declaration of non-engagement indicates you have no involvement with any reportable substance and therefore the option to submit under the section 71 notice will not be available.



6. Submission of Voluntary Information

Interested stakeholders are encouraged to voluntarily submit additional information that is deemed beneficial on a reportable substance, through a [Declaration of Stakeholder Interest](#) using the online reporting system via [Environment and Climate Change Canada's Single Window](#).

Voluntary data supplementing a response to the notice can be submitted online in any “Notes” fields of the Excel reporting template within the Environment and Climate Change Canada's Single Window reporting system. The online reporting tool also allows you to upload documents.

When providing voluntary information, please clearly indicate if any of the information is confidential and provide the calendar year for which it applies.

7. Single Window - Online Reporting Tool

[ECCC's Single Window](#) is an online data reporting system. Those reporting to the CMP can use the system to provide responses to CEPA Notices (e.g., Section 71) and New Substances notifications as well as calls for voluntary data. Foreign suppliers and authorized third parties can also use the system to provide data. Refer to the [Single Window guidance document](#) for details on how to create and manage an account.

Once you have created an account, you will be logged into [Single Window](#) as a new user. You will then proceed to set up your profile. After that you must link your profile to your organization. Note that if the organization does not exist in the system, you will need to create it.

Tip: if the organization does not exist in the system, you will need to create it.

If you meet the reporting criteria of the notice, you must provide your response online, by uploading your completed Excel template. This Excel template is available for download via Single Window.

Refer to the “[CMP Online Reporting – How-To Guide](#)” for general guidance and step by step instructions on how to complete your online submission. While each notice response may be unique, this guide addresses all functionalities needed to complete any submission for the CMP.



8. Reporting Deadline

Responses to the notice must be provided no later than **January 23, 2018, 3 p.m., Eastern Daylight Saving Time**, and must be completed using the Excel reporting template available through Environment and Climate Change Canada's Single Window. The Excel template must be completed, then uploaded to your Single Window account and finally "Submitted" to transmit the data. It is very important to make sure that you have received a "Confirmation of Submission" email from **eccc.substances.eccc@canada.ca**.

9. Deadlines for complying with the Notice

Requests for additional time to comply with the notice must be submitted in writing. The request should include:

- a) the company name;
- b) contact information; and
- c) the reason for the request.

It is important to note that you must request an extension of time in writing before **January 23, 2018, 3 p.m., Eastern Daylight Saving Time**. No extensions will be granted after the deadline has expired. It is recommended that any request for an extension be submitted at least **five (5)** business days before **the deadline to respond**, so that a request can be processed by the Minister of the Environment before expiry of the deadline.

Requests for an extension of time should be sent to the Minister of the Environment, to the attention of the [Substances Management Coordinator](#).

10. Questions

Inquiries concerning the notice may be directed to the [Substances Management Information Line](#).

Indicate in the subject line "Micro-Organisms Notice Inquiry"