Administration of the New Substances program - Processing of submissions

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1. Purpose

- The purpose of this document is to provide an overview of the processes applied by the New Substances (NS) program when administrating submissions received in accordance with the *Canadian Environmental Protection Act, 1999 Canadian Environmental Protection Act, 1999 (CEPA)*, hereinafter referred to as the Act, the *Service Fees Act* (SFA), and the following regulations:

- *New Substances Notification Regulations (Chemicals and Polymers)*
- *New Substances Notification Regulations (Organisms)*
- *Masked Name Regulations*
- *New Substances Fees Regulations*

For the purposes of this document, the term **notifier** includes:

- Any person who manufactures or imports a new substance (chemical, polymer or living organism), or who intends to do so, and who provides, in accordance with paragraph 81(1)(a) or 106 (1)(a) of the Act, the information required under the *New Substances Notification Regulations (Chemicals and Polymers)*, or the *New Substances Notification Regulations (Organisms) (referred to as the Regulations in this document);* including technical contacts;
- Any person who acts as the Canadian agent on behalf of the foreign importer or manufacturer of the new substance;
- Requestors of confidential searches and masked names; and
- A Third Party Information Supplier submitting confidential business information pursuant to a submission.

2. Scope

The intent of this document is to provide guidance on topics primarily related to the administrative processes of the NS program. In the case of a discrepancy between this document and Acts or Regulations, the Acts or Regulations take precedence.

This document applies to the following types of submissions:

- New Substances Notifications (NSN) for chemicals, polymers (including biochemicals, biopolymers and nanomaterials)

- NSNs for living organisms
- Masked Name Requests
- Confidential Search Requests to Manufacture or Import
- Pre-notification Consultations
- Re-evaluations
- Notices of Excess Quantity
- Notices of Manufacture or Import

3. Communicating with the New Substances program

Inquiries can be directed to the following:

By email

substances@ec.gc.ca

By phone

1-800-567-1999 (Toll Free in Canada) or 1-819-938-3232 (Outside of Canada)

General inquiries:

The NS program's email account is monitored daily, except weekends and statutory holidays. An automatic reply is generated for all emails received. The automatic email reply indicates the timeframe within which the NS program anticipates responding. The target timeframe takes into account current workload capacity, and may be adjusted throughout the calendar year.

The NS program is jointly administered by Environment and Climate Change Canada (ECCC) and Health Canada (HC). Throughout the submission process, NS program officers may communicate directly with the notifier using their ECCC or HC email accounts or by phone. This facilitates obtaining direct responses in a timely manner while a submission is being processed.

4. Before filing a submission

It is the responsibility of the notifier to be familiar with the Acts and Regulations which govern new substances, as identified in the "Purpose" section of the document. The most current versions of these documents are available through the hyperlinks included in the "Purpose" section, or by accessing the Department of Justice's webpages for Acts and Regulations.

For NSNs, detailed information about the notification and testing of new chemicals and polymers, as well as the notification and testing of new living organisms is available in the following documents located on the New Substances program website:

- Guidance document for the New Substances Notification Regulations (Chemical and Polymers)
- Guidelines for the Notification and Testing of New Substances: Organisms
- Supplementary Guidance Document for the Notification and Testing of New Substances: Organisms Used in Cell and Gene Therapy under Schedule 1 of the *New Substances Notification Regulations (Organisms)*

If a notifier is unable to supply all of the required information because a foreign supplier considers this information confidential, the first or original notifier must ensure that the Third Party Information Supplier subsequently submits the confidential information directly to the NS program.

4.1 Consider requesting a Pre-notification Consultation

The NS program offers the opportunity to consult during the planning or preparation of a NSN. A Pre-notification Consultation (PNC) is a free service meant to discuss how a notifier can meet the information and data requirements required by Regulations (for example, acceptability of waivers, test protocols, alternative data, organism identification). Notifiers may use PNCs to help ensure their NSN is complete, reducing the likelihood that the NS program will request missing information and reject the NSN as incomplete.

Notifiers may request a PNC by completing a PNC form along with relevant data and information.

If a notifier is requesting the review of a NSN for a living organism, the PNC form does not need to be submitted; however, the notifier should include an NSN form completed to the best of their ability and indicate clearly in their cover letter that they are submitting the draft for review as a PNC request.

If a teleconference call is requested, in order to ensure an efficient and effective consultation, notifiers should submit the PNC package to the NS program a minimum of 30 days prior to the desired meeting date. Notifiers should provide available teleconference dates and times and a brief agenda.

The NS program will provide feedback in writing based on the information received in the PNC package. The professional opinions of the NS program, expressed during the PNC, are not an official commitment, since technical conclusions may differ after the NS program conducts a more in-depth assessment on the complete NSN.

For PNC requests for chemicals and polymers, the NS program strives to respond in writing within 30 calendar days of receipt of a complete PNC package.

For PNC requests for organisms, the NS program strives to respond in writing within 45 calendar days of receipt of a complete PNC package.

Important tip

Taking advantage of the PNC service is encouraged and considered a best practice by the NS program, especially for submissions that will include alternative data or waiver requests, and for notifiers submitting an NSN for a living organism for the first time.

4.2 Check for common errors in NSNs

Over many years of processing NSNs, the NS program has identified common issues/errors that cause delays in the processing of NSNs. The following list provides general guidance to help notifiers file a complete NSN and avoid common issues/errors.

- Refer to the relevant sections of the appropriate Guidance document for details about what is expected to be submitted in an NSN submission:
    - Guidance document for the New Substances Notification Regulations (Chemical and Polymers)
    - Guidelines for the Notification and Testing of New Substances: Organisms
    - Supplementary Guidance Document for the Notification and Testing of New Substances: Organisms Used in Cell and Gene Therapy under Schedule 1 of the *New Substances Notification Regulations (Organisms)*

- If applicable, request a PNC to get advice from the NS program about the acceptability of technical data, alternative data, surrogate data, or waiver requests.

- Use the most up-to-date version of the NSN form. Complete the NSN form carefully, paying attention to data codes and check boxes, and ensure that all required administrative information and signatures are provided.

- Provide a separate attachment for each referenced document, and title all attachments starting with their attachment number as listed on the NSN followed by the filename. Consistently refer to each attachment when needed by its attachment number or full filename throughout your submission. Provide attachments as searchable PDFs when possible.

- Clearly state the test substance's identity and purity on all relevant test reports and other attachments. Alternatively, other identification codes (including internal identifiers and anonymized samples codes used by contract laboratories) present in the test reports can be cross-referenced in the NSN form.

- Ensure full test reports are provided for all data requirements.

- For chemicals and polymers (including biochemicals, biopolymers and nanomaterials), use Part E of the NSN form as a guide to provide all required exposure information in as much detail as possible.

- Ensure each block for the required schedule on the NSN form is answered—that is, if the answer is “none”—please enter “none”. Sections cannot be left blank and “not applicable” is not an acceptable answer.

- Review the schedule requirements carefully, and ensure that each requirement of the submitted schedule is addressed in the NSN.

5. How the New Substances program processes a submission

In general, submissions are processed in four main stages:

5.1 Receipt

Submissions are not processed on weekends or designated statutory holidays.

Submissions will move to the Screening stage following the Receipt stage. The NS program does not inform notifiers when their submission has moved to the Screening stage.

5.2 Screening

All submissions are screened to confirm receipt of the required regulatory and administrative information, including the authorization of the applicable prescribed fees. An in-depth assessment of the provided information is not part of Screening.

During Screening, if all required information has not been provided, the NS program will contact the notifier using the email provided in the submission to request the missing information. When a notice of missing information is sent to a notifier, it will always indicate a response due date. For NSN submissions, the notice of missing information will request that the information be provided within 30 calendar days. The notifier should contact the NS program if more time is required to provide the missing information.

Failure to provide the missing information may result in the submission being rejected as incomplete. The NS program will issue a notice to the notifier when a submission is rejected. When a submission is rejected as a result of being incomplete, a new submission is required in accordance with the Regulations prior to the importation or manufacture of the substance.

The NS program will try to include all missing information identified during Screening in a single request; however, more than one request may be necessary. The assessment

start date, against which the performance standard is measured, is based on the receipt date of the information which rendered the submission complete.

The NS program confirms when the submission contains all required information. Once the submission is considered complete, the following actions are taken:

a) An acknowledgement email is sent to the notifier, which provides the assessment start date, the assessment end date and information on payment of appropriate fees; and
b) The submission is moved to the Assessment stage.

Important tips

It is important that the notifier respond as quickly and as thoroughly as possible to the NS program's notices of missing information. A response due date will be provided in every notice.

Failure to respond by the due date may result in the rejection of the submission; should the submission be refiled, it will be assigned a new file number. References to information in previous submissions that were rejected or withdrawn will not be accepted in a new submission.

5.3 Assessment

The NS program may need to request information or clarifications in order to complete the assessment and will contact the notifier by email.

5.4 Decision issuance

All submissions types that have passed through the Assessment stage will move to the Decision issuance stage. The NS program does not notify notifiers when their submission has moved to the Decision issuance stage.

6. Fees, refunds and fee remissions

6.1 Fees

In accordance with the *Service Fees Act (SFA)*, the NS program charges fees for some regulatory services associated with the *New Substances Notification Regulations (Chemicals and Polymers)* and *Masked Name Regulations*, and some non-regulatory services such as confidential search requests. Fees are not currently charged for regulatory services associated with living organisms, biochemicals, biopolymers, or research and development substances. Substances intended for use solely in products regulated under other Acts of Parliament (for example the *Food and Drugs Act*),

Significant New Activity Notifications or re-evaluations of previously assessed NSNs are also not subject to fees.

See the fee table for applicable fees.

Full authorization of payment of the appropriate fees is required during the Screening stage, prior to the Assessment stage. All information required to process the correct fees must be provided with the submission.

- The name and contact information of a person in the notifier's organization who is authorized to be contacted when payment is due; or
- All necessary information required to process the payment through a credit card.

The NS program charges fees for the delivery of regulatory and non-regulatory services for which performance standards have been established (See Section 7).

6.2 Fees for rejected or withdrawn submissions

Submissions deemed to be incomplete during Screening or Assessment may be rejected if a Notice of missing information is sent to the notifier and:

- A response is not received by the response due date; or
- The provided response is inadequate/incomplete.

During the Screening stage:

When a submission is found to be incomplete during the Screening stage, and is subsequently rejected before the Assessment stage has been initiated, no fees will be charged to the notifier.

Where a submission is withdrawn by the notifier before or during the Screening stage, no fees will be charged to the notifier.

During the Assessment stage:

When a submission is found to be incomplete during the Assessment stage, and is subsequently rejected during the Assessment stage (that is the missing information is not provided by the notifier), no refund of the fees will be made to the notifier. Furthermore, full fees (new payment) will be required if the submission is refiled at a later date.

When a submission is withdrawn by the notifier during the Assessment stage, no refund of fees will be made to the notifier. Furthermore, full fees will be required if the submission is refiled.

6.3 Fee remissions

When the performance standard is not met, the notifier is entitled to a fee remission.

The NS program processes fee remissions in accordance with the ECCC Remission Policy, and the New Substances Program Remissions Approach. Notifiers do not have to request a fee remission when a performance standard is not met. When a performance standard is not met, the NS program will inform the notifier by email that they are owed a fee remission and will process the appropriate fee remission automatically within 3 months of the email.

6.4 Refunds

A refund is the return of the fee to the notifier in the case of an administrative error (for example, overpayment of fees).

7. Performance standards

The performance standards for the NS program are timelines in which it aims to deliver services to notifiers. Performance standards for NSNs are based on the assessment period for the schedule of the Regulations, while performance standards for masked name requests and confidential search requests are set out in the New Substances Program Remissions Approach.

Notifiers may use this table to identify the performance standards and services associated with submissions. The NSN assessment periods are summarized in the New Substances Program Remissions Approach.

Performance standards for processing submissions

Type of submission	Performance standards in calendar days	Service to be delivered via email
New Substances Notifications	Equal to the Assessment period of the schedule in the Regulations	Assessment outcome letter confirming the assessment decision
Significant New Activity Notifications	90 days or as prescribed in the SNAc Notice, for chemicals and polymers 120 days or as prescribed in the SNAc Notice, for organisms	Assessment outcome letter confirming the assessment decision
Confidential Search Requests	15	Communication of search results, or that the search cannot be completed

Masked Name Requests	60	Initial communication of the review outcome for the Masked Name

Important notes

The start date against which the performance standard is measured is the date specified in the notice of acknowledgement email sent when Screening is completed.

When the notifier is advised that information is missing during Screening, the start date against which the performance standard is measured is based on the receipt date of the information which rendered the submission complete, as opposed to the date the initial submission was received.

8. Submission types

The forms to submit a NSN, the New Substances Fees, Masked Name Requests and Confidential Search Requests are available in fillable PDFs.

8.1 New Substance Notifications

The NSN forms serve as an aid for complying with the *New Substances Notification Regulations (Chemicals and Polymers)*, the *New Substances Notification Regulations (Organisms),* the *Masked Name Regulations* and the *New Substances Fees Regulations*. Notifiers may reproduce the forms or sections of forms as often as required.

The NS program recommends that completed NSN submissions be filed electronically via Environment and Climate Change Canada's Single Window Information Manager (SWIM), which is a free and secure online portal.

Although submissions are accepted in paper format (which is not recommended), or via email, filing electronically through the SWIM portal benefits both the notifier and the NS program by:

- Enabling efficient processing and potentially faster response times;
- Ensuring clearly legible information and reducing the likelihood of processing errors;
- Ensuring the secure submission of information;
- Reducing the risk of misdirection and delivery errors; and
- Reducing environmental impacts and monetary costs associated with the handling of paper-based submissions.

SWIM supports the following document types: Word (doc, docx), Excel (xls, xlsx), JPG, i5z and PDF, with a maximum size of 100 MB per file.

Emails sent to substances@ec.gc.ca have a maximum size of 25 MB per email.

To reduce duplication efforts when notifiers also have notification obligations under other regulations enabled by the *Food & Drugs Act*, an information sharing agreement exists between the NS program and the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada that allows the NS program to access Clinical Trial Applications (CTA) or New Drug Submissions (NDS). If there is overlap between the information and data provided in a CTA or NDS and the information and data required in an NSN, the notifier can simply refer to the CTA or NDS in the relevant section of the NSN. When a CTA or NDS is cited, it is necessary to reference the appropriate sections and page numbers of the CTA or NDS documents. For more information on this information sharing agreement, see Section 1.1 of the Supplementary Guidance Document for the Notification and Testing of New Substances: Organisms Used in Cell and Gene Therapy under Schedule 1 of the *New Substances Notification Regulations (Organisms)*, respectively.

Important tips

Using the ECCC Single Window Information Manager (SWIM) portal is secure, and is considered a best practice.

Information regarding how to enroll and access the SWIM portal is outlined on the ECCC website.

8.1.1 NSN assessment

The NS program uses two types of information requests to request information or clarification during the Assessment stage for NSN submissions.

1. Notices of missing information

   A notice of missing information is sent to the notifier when information required by the Regulations is found to be missing, incomplete, incorrect or scientifically unacceptable. Notices of missing information will identify the required information to be provided and will include a response due date of 30 calendar days by which the requested information is to be provided to the NS program. The notice will explain that the assessment period has been stopped and will restart on Day 1 once the required information is provided by the due date. The notifier should contact the NS program if more time is required to provide the missing information.

   Failure to provide a complete response by the due date may result in the submission being rejected as incomplete. A new submission, including new fees,

will be required whenever an existing submission is rejected as being incomplete during the Assessment stage.

Where the required missing information is provided by the response due date, the start date against which the applicable performance standard is measured is based on the receipt date of the information which rendered the submission complete.

2. Notices of clarification

A notice of clarification is sent to the notifier when data or information required by the Regulations requires further clarification. Clarification requests will identify the required information to be provided and will include a response due date of no more than 7 calendar days, by which the requested information is to be provided to the NS program.

The information requested in a clarification request will not preclude the completion of the assessment; however, the information may affect the final assessment decision and the nature of any risk management measures that may be imposed.

All NSNs are eligible to have their assessment periods extended when additional time is required by the NS program to complete an assessment. The notifier will be issued a notice of extension of the assessment period at or before the end of the initial assessment period when an extension is required.

8.1.2 NSN assessment outcomes

There are three outcomes for an NSN assessment:

1. The substance is not suspected of being toxic or capable of becoming toxic under section 64 of the Act;
2. There is suspicion that a significant new activity may result in the substance becoming toxic under section 64 of the Act;
3. The substance is suspected to be toxic or capable of becoming toxic under section 64 the Act, and one of the following risk management measures is implemented:
    - 3.1 A ministerial condition to restrict conditions on the manufacture and/or importation of the substance;
    - 3.2 Request additional information; or
    - 3.3 A ministerial prohibition to prohibit manufacture and/or import of the substance.

When a substance is suspected of being toxic or capable of becoming toxic, risk management measures may be applied to mitigate any risk to human health or the environment. Notifiers will be advised, prior to the end of the assessment period, that

there are concerns with the substance. Usually the assessment period is extended, which provides time to develop the risk management measure and obtain ministerial approval. The notifier will be advised of the extension of the assessment period and of proposed risk management measures prior to the end of the assessment period.

Risk management measures must be imposed by the Minister before the expiration of the assessment period. A copy of the ministerial correspondence and notice will be e-mailed to the notifier. When a ministerial condition or prohibition is issued or varied, the notice must be published in the *Canada Gazette* describing the action and the substance to which it applies. A substance that is subject to ministerial condition(s) imposed pursuant to sections 84(1)(a) or 109(1)(a) of the Act cannot be added to the DSL.

8.1.3 NSN decision issuance

An email from the NS program will communicate at least one of the following outcomes:

a) The assessment decision;
b) Early termination of the prescribed assessment period.

Where the communication of the assessment decision is made in advance of the assessment period end date, the notifier must follow the instructions set out in the email regarding the substance until the assessment period end date has passed.

8.2 Significant New Activity notifications

A new substance assessment takes into consideration potential risks concerning the notified activities as well as any other possible activities involving the substance. When there is suspicion that a significant new activity may result in the substance becoming toxic, the significant new activity (SNAc) provisions of the Act can be applied to a new substance with the publication of a SNAc Notice in the *Canada Gazette*, Part I. A SNAc Notice is published within 90 days of the end of the assessment period. Typically, the notifier is informed of the development of a SNAc Notice prior to the end of the assessment period.

A SNAc Notice applies to anyone using the substance. Any person wishing to engage in a significant new activity in relation to the substance is required to submit a Significant New Activity Notification (SNAN) to the Minister containing all of the information prescribed in the Notice prior to using the substance for the proposed activity. After the complete information is received, the Ministers will conduct a risk assessment of the substance in relation to the proposed significant new activity within the timelines set out in the Notice.

Where applicable, the notifier is required to provide:

- the subsequent Schedules of information under the Regulations, if necessary;

- the prescribed additional information in subsection 7(2), 7(3), 11(2) or 11(3) of the Regulations in the case of high release or significant public exposure; and
- the appropriate notice to fulfill the DSL listing criteria.

The substance may become eligible for addition to the DSL once the above-mentioned information has been received, accepted and assessed. Until the substance is added to the DSL, other notifiers must continue to notify the manufacture or import of the new substance as specified by the Regulations.

The SNAc provisions of the Act can also be applied to a substance on the DSL with the publication of a SNAc Order in the *Canada Gazette,* Part II. When a substance subject to a SNAc Notice is added to the DSL, this SNAc Notice no longer applies. To maintain the reporting obligations on the substance, the SNAc requirements are added to the DSL with the publication of a SNAc Order.

Because the information requirements of each SNAc Notice or Order are unique, no standard form exists for submitting SNANs. However, notifiers may use existing NSN forms to structure their SNAN, if convenient. After a complete SNAN is received, the NS program will assess the information within the time period specified in the SNAc Notice or SNAc Order (typically 90 days for chemicals and polymers and 120 days for organisms). From the assessment of this information, SNAc requirements may be varied or rescinded, or other risk management measures may be imposed, if necessary.

8.3 Masked name requests

Where the explicit chemical name of a new substance, or the explicit biological name of a living organism, would result in the release of confidential business information, a request may be made to have the substance identified by a name developed in accordance with the *Masked Name Regulations*. The masked name of the substance or living organism would then be used in any relevant publications, such as the Domestic Substances List (DSL), Non-domestic Substances List (NDSL), or New substances risk assessment summaries.

When a masked name request is made, one of the following forms should be provided:

- NSN (Chemicals and Polymers) form
- NSN (micro-organisms) form
- NSN reporting form for organisms other than a micro-organism
- Domestic Substances Nomination form, if applicable.
- Non-domestic Substances List Nomination form, if applicable

Notifiers should consult the Guidance document for the New Substances Notification Regulations (Chemical and Polymers) or the Guidelines for the Notification and Testing of New Substances: Organisms to ensure the proper information is submitted in the request for a masked name.

Notifiers will receive separate acknowledgement emails for the processing of masked name request and their NSN submission. This is because the performance standard for the masked name request is separate from and does not affect the NSN assessment period.

The NS program will work closely with the notifier to arrive at an acceptable masked name that complies with the requirements of the *Masked Name Regulations.*

8.3.1 Masked name assessment outcomes

For masked name requests, the conclusion of the Assessment stage determines whether the proposed masked name is acceptable.

8.3.2 Masked name decision issuance

An email from the NS program will communicate one of the following outcomes:

a) The approval of the masked name proposed in the notifier's request;
b) The rejection of the masked name proposed in the notifier's request, including steps to communicate further with the NS program to develop an acceptable name.

8.4 Confidential search requests

Substances listed on a confidential part of the DSL or NDSL are published with confidential accession numbers and using masked names that comply with the *Masked Name Regulations*. Any person who intends to manufacture or import a substance that they believe to be listed on the confidential portion of either of these lists may seek confirmation to that effect from the NS program by providing a Confidential Search Request form to manufacture or import the substance.

After the notifier has provided a Confidential Search Request, the NS program will search the confidential parts of the DSL and NDSL, and will respond indicating whether or not the substance is on either of the lists.

8.4.1 Confidential search assessment outcomes

For confidential search requests, the conclusion of the Assessment stage is the result of the search.

8.4.2 Confidential search decision issuance

An email from the NS program will communicate one of the following results of the search:

a) The substance is listed on the confidential portion of the DSL;

b) The substance is listed on the confidential portion of the NDSL;
c) The substance is not listed on the confidential portions of the DSL or NDSL;
d) The search cannot be completed.

9 Post-assessment submission types

9.1 Correction of information

Under subsections 81(11) and 106 (11) of the Act, any notifier who has provided information in support of a NSN and later finds that the information is incorrect or erroneous must immediately notify the NS program of that fact and submit the necessary correction to their NSN. This requirement relates only to the correction of information that existed at the time the NSN was submitted.

9.2 Section 70 of the Act – Information that suggests that a substance is toxic or capable of becoming toxic

Information generated after a NSN was submitted which reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic must be provided to the NS program under the provisions of section 70 of the Act. This information must be provided unless the notifier has knowledge that the NS program already has the information.

9.3 Re-evaluations

When a notifier provides information under the Correction of Information provisions or under section 70 of the Act, the NS program reviews the information to determine whether a re-evaluation of the new substance is warranted.

If a re-evaluation is deemed unnecessary, the NS program informs the notifier of this decision by email. If a re-evaluation is deemed necessary, the NS program sends a notice of acknowledgement email to the notifier signifying that their submission has moved to Assessment.

There are no prescribed assessment periods associated with re-evaluations. However, the NS program strives to complete the Assessment stage and proceed to the Decision issuance stage within the assessment period of the associated schedule of the Regulations.

9.4 Notice of Excess Quantity

Under subsection 81(14) of the Act, a notifier who has met the requirements to manufacture or import a substance, other than research and development, contained site-limited intermediate or contained export-only substances, is required to submit a Notice of Excess Quantity (NOEQ) within 30 days of exceeding manufacture or import trigger quantities.

The NS program strives to process a Notice of Excess Quantity (NOEQ) within 10 calendar days of receipt.

9.5 Notice of Manufacture or Import

This type of notice is an alternative to the requirement for the submission of a NOEQ so that a substance may be eligible for listing on the DSL without requiring the tracking of manufacture or import quantities.

The NS program strives to process a Notice of Manufacture or Import (NOMI) within 10 calendar days of receipt. A NOEQ is not required if an acceptable NOMI is submitted.

9.6 Additions to the Domestic Substances List

Pursuant to section 87 of the Act, a substance must be added to the DSL and, if listed on the NDSL, deleted from that list, within 120 days after specific conditions are met. For more information on the NS program's responsibilities and conditions to be met for addition to the DSL, please consult the Guidance document for the New Substances Notification Regulations (Chemical and Polymers).

Pursuant to section 112 of the Act, a living organism may be added to the DSL within 120 days after specific conditions are met. For more information on the NS program's responsibilities and conditions to be met for addition to the DSL, please consult the Guidelines for the Notification and Testing of New Substances: Organisms.