



New Substances Program Advisory Note 2006-05

Updates to the *Guidelines for the Notification and Testing of New Substances: Organisms*

This Advisory note is to inform manufacturers and importers of living organisms and other stakeholders of revisions to the *Guidelines for the Notification and Testing of New Substances: Organisms*. These changes and updates are in part the result of the coming into force of the *New Substances Notification Regulations (Organisms)* on October 31, 2005.

Background

The *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)] were published in the *Canada Gazette*, Part II on September 21, 2005 and came into force on October 31, 2005.

The NSNR (Organisms) differ from the provisions of the *New Substances Notification Regulations* that were applicable to living organisms in three respects. This addendum to the *Guidelines for the Notification and Testing of New Substances: Organisms* (Guidelines), was developed in order to update the references made to the provisions and schedules of the previous *New Substances Notification Regulations* to the provisions and schedules of the NSNR (Organisms). Other consultation recommendations of a program nature resulting from the multi-stakeholder consultations on the chemical and polymer provisions have also been incorporated.

Changes incorporated into the NSNR (Organisms)

1. Retention of Information (section 7 of the NSNR (Organisms))

All persons who provide information to the Minister of the Environment pursuant to s. 106 of the *Canadian Environmental Protection Act, 1999* and the NSNR (Organisms) are now required under section 7 of the NSNR (Organisms) to keep a copy of that information and any supporting data at the person's principal place of business in Canada, or at the principal place of business in Canada of a representative of that person, for a period of five years after the end of the year in which the information is provided.

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2. Certification Requirements (paragraph 8(1)(e) of the NSNR (Organisms))

Paragraph 8(1)(e) of the NSNR (Organisms) requires a certification that the information provided under the NSNR (Organisms) is accurate and complete, dated and signed by the manufacturer or importer if they are resident in Canada, or, if not, by the person authorized to act on their behalf.

3. Transitional Provisions (Parts 29.14, 29.15, 29.19 and 29.2 of the previous NSNR)

There are no longer transitional provisions for organisms first manufactured or imported between January 1, 1987 and June 30, 1994.

Changes to the Guidelines

1. Addendum 1 to the Guidelines

Attached to this Advisory note is "Addendum 1 to the *Guidelines for the Notification and Testing of New Substances: Organisms*". This Addendum updates the references made to the previous regulations that are found in the current Guidelines to the NSNR (Organisms).

2. Sections 2.6 and 2.7 of the Guidelines

Sections 2.6 and 2.7 of the Guidelines describing the transitional provisions for organisms first manufactured or imported between January 1, 1987 and ending on June 30, 1994 are no longer applicable.

3. Appendix 3 to the Guidelines

Attached to this Advisory note is a revised version of Appendix 3 of the Guidelines providing a New Substances Notification Reporting Form for Organisms other than Micro-organisms, and a New Substances Notification Reporting Form for Micro-organisms.

4. Subsections 9.1.1 and 9.2.2 of the Guidelines

Subsections 9.1.1 and 9.2.2 of the Guidelines describing a Notice of Interruption and the ability to pause the clock on a notification assessment period are no longer applicable. If during the assessment period the information within the New Substances Notification (NSN) package is found to be incomplete or erroneous, the NSN package will be deemed incomplete and the assessment period will be restarted on day 1 once a complete NSN package has been submitted.

5. Withdrawing an NSN Package (New to Section 9 of the Guideline)

A notifier may request to withdraw an NSN package if it is determined that the organism has been previously notified by the same company, the organism is on the DSL or the notifier no longer intends to import or manufacture the organism. Withdrawal requests will normally not be accepted if the notifier has been informed of a proposed decision to take control measures or issue a Significant New Activity Notice, unless a control measure of Significant New Activity Notice addressing the concern is already in place.

Contact Information

New Substances Notification Information Line

Telephone: 1-800-567-1999 (toll-free in Canada)
1-819-953-7156 (outside of Canada)

Facsimile: 1-819-953-7155

E-mail: nsn-info@ec.gc.ca

For additional information or documentation regarding the NSNR (Organisms), please visit the New Substances Web Site at http://www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

Original Signed by

Bernard Madé
Director
New Substances Division
Environment Canada

Signed on August 21, 2006

Addendum 1: Update of references made in the *Guidelines for the Notification and Testing of New Substances: Organisms*

Reference in the current Guideline	Replace with New Reference
New Substances Notification Regulations (NSNR)*	New Substances Notification Regulations (Organisms) [NSNR (Organisms)]
Section 1	No equivalent section
Subsection 2(1)	Subsection 1(1)
Subsection 2(2)	No equivalent subsection
Subsections 3(1) and 3(2)	Subsections 2(1) and 2(2)
Part I and Part II	NSNR (Chemicals and Polymers)
Part II.1	NSNR (Organisms)
Paragraphs 29.1(a),(b),(c) and (d)	Paragraphs 2(3)(a),(b),(c) and (d)
Subsections 29.11(1),(2),(3),(4),(5) and (6)	Subsections 3(1),(2),(3),(4),(5) and (6)
Subsection 29.11(7)	Addressed in Paragraphs 3(2)(a) and (c)
Paragraphs 29.12(a),(b) and (c)	Paragraphs 5(a),(b) and (c)
Paragraphs 29.13(a),(b) and (c)	Paragraphs 6(a),(b) and (c)
Sections 29.14 and 29.15	No equivalent subsection
Section 29.16	Subsection 2(4) and section 4
Section 29.17	Paragraph 5(d)
Section 29.18	Paragraph 6(d)
Sections 29.19 and 29.2	No equivalent subsection
Part III	Section 8
Paragraphs 30(1)(a), (b) and (c)	Paragraphs 8(1)(a),(c) and (d)
Subsections 30(2) and (3)	Subsections 8(2) and (3)
Subsection 30(4)	Paragraph 8(1)(b)
Schedule XV	Schedule 1
Schedule XVI	Schedule 2
Schedule XVII	Schedule 3
Schedule XVIII	Schedule 4
Schedule XIX	Schedule 5

* References made in section 1.3 of the Guideline continue to refer to the provisions for living organisms in the previous NSNR and not the NSNR (Organisms)