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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

New Substances Notification Regulations (Chemicals and Polymers)

P.C. 2005-1484 August 31, 2005

Whereas, pursuant to subsection 332(1) (see footnote a) of the *Canadian Environmental Protection Act, 1999* (see footnote b), the Minister of the Environment published in the *Canada Gazette*, Part I, on October 30, 2004, a copy of the proposed *New Substances Notification Regulations (Chemicals and Polymers)*, substantially in the annexed form, and persons were given an opportunity to file comments with respect to the proposed Regulations or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to subsection 89(1) of the *Canadian Environmental Protection Act, 1999* (see footnote c), hereby makes the annexed *New Substances Notification Regulations (Chemicals and Polymers)*.

NEW SUBSTANCES NOTIFICATION REGULATIONS (CHEMICALS AND POLYMERS)

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NEW SUBSTANCES NOTIFICATION REGULATIONS (CHEMICALS AND POLYMERS)

INTERPRETATION

Definitions	**1.** (1) The following definitions apply in these Regulations.
"Act" « *Loi* »	"Act" means the *Canadian Environmental Protection Act, 1999*.
"animal" « *animal* »	"animal" includes a part of an animal, but does not include an animal or a part of an animal that exists primarily as a single cell and is without the organization that characterizes tissues or organs.
"anionic polymer" « *polymère anionique* »	"anionic polymer" means a polymer that has one or more monomer units that are covalently bound and bear a net negative charge.
"biochemical" « *substance biochimique* »	"biochemical" means a chemical that is produced by a micro-organism or a protein or a nucleic acid derived from a plant or an animal.
"biopolymer" « *biopolymère* »	"biopolymer" means a polymer that is produced by a micro-organism or a protein or a nucleic acid derived from a plant or an animal.
"CAS registry number" « *numéro d'enregistrement CAS* »	"CAS registry number" means the identification number assigned to a substance by the Chemical Abstracts Service Division of the American chemical Society.
"cationic polymer" « *polymère cationique* »	"cationic polymer" means a polymer that has one or more monomer units that are covalently bound and bear a net positive charge.
"chemical" « *substance chimique* »	"chemical" means a substance that is not a polymer.
"consumed" « *consommée* »	"consumed", in respect of a substance, means destroyed or completely converted to another substance.
"contained" « *confinée* »	"contained", in respect of a site-limited intermediate substance or an export-only substance, means an absolute release limit of 1 kg per day per site to the aquatic environment after wastewater treatment.

"DSL" « *liste intérieure* »	"DSL" means the Domestic Substances List maintained by the Minister under subsection 66(1) of the Act, as amended from time to time.
"material safety data sheet" « *fiche signalétique* »	"material safety data sheet", in respect of a substance, has the same meaning as in subsection 11(1) of the *Hazardous Products Act*.
"micro-organism" « *micro-organisme* »	"micro-organism" means a microscopic organism that is (*a*) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which includes yeasts; (*b*) a virus, virus-like particle or sub-viral particle; (*c*) a cultured cell of an organism not referred to in paragraph (*a*) or (*b*), other than a cell used to propagate the organism; or (*d*) any culture other than a pure culture.
"monomer unit" « *unité monomère* »	"monomer unit" means the reacted form of a monomer in a polymer.
"NDSL" « *liste extérieure* »	"NDSL" means the Non-domestic Substances List maintained by the Minister under subsection 66(2) of the Act, as amended from time to time.
"plant" « *végétaux* »	"plant" includes a part of a plant, but does not include a plant or part of a plant that exists primarily as a single cell and is without the organization that characterizes tissues or organs.
"polymer" « *polymère* »	"polymer" means a substance that consists of (*a*) molecules characterized by the sequence of one or more types of monomer units; (*b*) greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants; (*c*) less than 50% by weight of molecules of the same molecular weight; and (*d*) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units.
"reactant" « *réactif* »	"reactant", in respect of a polymer, means a substance that is used in the manufacture of the polymer and becomes part of its chemical composition, and includes a monomer.
"reactive functional group" « *groupe fonctionnel réactif* »	"reactive functional group" means atoms or an associated group of atoms in a substance that are intended or may reasonably be expected to undergo facile chemical reaction.
"reduced regulatory requirement polymer" « *polymère à exigences réglementaires réduites* »	"reduced regulatory requirement polymer" means one of the polymers described in section 9.

"research and development substance" « *destinée à la recherche et au développement* »	"research and development substance" means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following: (*a*) to create or improve a product or process; (*b*) to determine the technical viability or performance characteristics of a product or process; or (*c*) to evaluate the substance prior to its commercialization, by pilot plant trials, production trials, including scale-up, or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.
"site-limited intermediate substance" « *intermédiaire limitée au site* »	"site-limited intermediate substance" means a substance that is consumed in a chemical reaction used for the manufacture of another substance and that is (*a*) manufactured and consumed at the site of manufacture; (*b*) manufactured at one site and transported to a second site where it is consumed; or (*c*) imported and transported directly to the site where it is consumed.
"test marketing" « *test de marché* »	"test marketing", in respect of a product, means the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective.
Meaning of "substance"	(2) For greater certainty, "substance" has the meaning given that word by subsection 3(1) and section 80 of the Act.
Government agencies	(3) The definition of "government" in subsection 3(1) of the Act does not apply to the expression "government agencies" wherever it appears in these Regulations.

PURPOSE AND SCOPE

Purpose

2. (1) These Regulations set out the information that a person must provide to the Minister of the Environment under subsection 81(1) of the Act before manufacturing or importing a chemical or polymer that is not on the DSL. The information is required so that the Minister may determine whether the chemical or polymer is toxic or capable of becoming toxic within the meaning of section 64 of the Act. These Regulations set out the periods within which the Minister of the Environment and the Minister of Health must assess the information received and the conditions under which the Minister of the Environment must add a chemical or polymer to the DSL under section 87 of the Act.

Contents

(2) The Regulations are divided into 4 Parts: Parts 1 and 2 set out the information requirements; Part 3, administrative matters; Part 4, the obligations of the Ministers. Schedules 1 to 6 and 9 to 11 set out information to be provided, Schedule 7, the types of polymers, Schedule 8, reactants and Schedule 12, flowcharts giving an overview of all the information requirements.

Avoiding regulatory duplication

3. (1) For greater certainty, these Regulations do not apply in respect of a substance that is manufactured or imported for a use that is regulated under any other Act or regulations listed in Schedule 2 to the Act.

Transit

(2) These Regulations also do not apply in respect of a substance that is loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there is a change of carrier during transit.

Maximum exempt quantities

4. For the purposes of paragraph 81(6)(*e*) of the Act, a substance is exempt from the application of subsection 81(1) of the Act if it is manufactured or imported in a quantity that does not exceed the quantity that first triggers a requirement to provide information under these Regulations.

PART 1

REQUIRED INFORMATION FOR RESEARCH AND DEVELOPMENT, CONTAINED SITE-LIMITED INTERMEDIATE OR CONTAINED EXPORT-ONLY SUBSTANCES

Chemicals and Biochemicals

Quantity greater than 1 000 kg	**5.** (1) Every person that manufactures or imports a chemical referred to in one of the following paragraphs must provide to the Minister the information specified in Schedule 1 at least 30 days before the day on which the quantity of the chemical exceeds 1 000 kg in a calendar year: (*a*) a chemical that is a research and development substance; (*b*) a chemical that is a contained site-limited intermediate substance; or (*c*) a chemical that is a contained export-only substance.
Biochemical research and development substance	(2) If the chemical is a biochemical research and development substance, the person must provide, with the Schedule 1 information, the information specified in items 1 and 2 of Schedule 2.
Biochemical site-limited intermediate or export-only substance	(3) If the chemical is a biochemical contained site-limited intermediate substance that is not manufactured and consumed at the site of manufacture or is a biochemical contained export-only substance, the person must provide, with the Schedule 1 information, the information specified in items 1 to 4 of Schedule 2 and (*a*) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2; and (*b*) if the biochemical possesses enzymatic capability, the information specified in items 7 to 13 of Schedule 2.
Biochemical site-limited intermediate substance manufactured and consumed at the site of manufacture	(4) If the chemical is a biochemical contained site-limited intermediate substance that is manufactured and consumed at the site of manufacture, the person must provide, with the Schedule 1 information, the information specified in items 1, 2 and 4 of Schedule 2.
Quantity greater than 10 000 kg	(5) The person must notify the Minister at least 30 days before the day on which the quantity of the chemical manufactured or imported exceeds 10 000 kg in any calendar year and, at that time, update the information previously provided under this section or indicate that there has been no change in the information.

Polymers and Biopolymers

Quantity greater than 10 000 kg	**6.** (1) Every person that manufactures or imports a polymer referred to in one of the following paragraphs must provide to the Minister the information specified in Schedule 3 at least 30 days before the day on which the quantity of the polymer exceeds 10 000 kg in a calendar year: (*a*) a polymer that is a research and development substance; (*b*) a polymer that is a contained site-limited intermediate substance; or (*c*) a polymer that is a contained export-only substance.
Biopolymer research and development substance	(2) If the polymer is a biopolymer research and development substance, the person must provide, with the Schedule 3 information, the information specified in items 1 and 2 of Schedule 2.
Biopolymer site-limited intermediate or export-only substance	(3) If the polymer is a biopolymer contained site-limited intermediate substance that is not manufactured and consumed at the site of manufacture or is a biopolymer contained export-only substance, the person must provide, with the Schedule 3 information, the information specified in items 1 to 4 of Schedule 2 and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of that Schedule.
Biopolymer site-limited intermediate substance manufactured and consumed at the site of manufacture	(4) If the polymer is a biopolymer contained site-limited intermediate substance that is manufactured and consumed at the site of manufacture, the person must provide, with the Schedule 3 information, the information specified in items 1, 2 and 4 of Schedule 2.

PART 2

REQUIRED INFORMATION FOR CHEMICALS AND POLYMERS OTHER THAN RESEARCH AND DEVELOPMENT, CONTAINED SITE-LIMITED INTERMEDIATE AND CONTAINED EXPORT-ONLY SUBSTANCES

Chemicals and Biochemicals on the NDSL

Manufacture or import: quantities greater than 1 000 kg and 10 000 kg

7. (1) Every person that manufactures or imports a chemical that is on the NDSL — other than a chemical referred to in section 5 — must provide to the Minister

(*a*) at least 30 days before the day on which the quantity of the chemical exceeds 1 000 kg in a calendar year,

(i) the information specified in Schedule 4, and

(ii) if the chemical is a biochemical, the information specified in items 1 to 3 of Schedule 2; and

(*b*) at least 60 days before the day on which the quantity of the chemical exceeds 10 000 kg in a calendar year,

(i) the information specified in Schedule 5, and

(ii) if the chemical is a biochemical, the information specified in items 1 to 4 of Schedule 2 and

(A) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2, and

(B) if the biochemical possesses enzymatic capability, the information specified in items 7 to 13 of Schedule 2.

Quantity greater than 50 000 kg and exceeding 3 kg released per day

(2) If the quantity of the chemical exceeds 50 000 kg in a calendar year — and the chemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment — the person must, in addition to the information referred to in subsection (1), provide to the Minister the following information in respect of the chemical, at least 75 days before the day on which the quantity exceeds 50 000 kg:

(*a*) for chemicals having a water solubility of greater than or equal to 200 µg/L,

(i) adsorption-desorption screening test data, and

(ii) the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis; and

(*b*) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days duration, using the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation, plus

(i) the age, sex, number, species, strain and source of the animals tested,

(ii) the route by which the chemical is administered and the conditions under which

the test is conducted, and
(iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle.

Quantity greater than 50 000 kg and significant exposure

(3) If the quantity of the chemical exceeds 50 000 kg in a calendar year and if the public may be significantly exposed to the chemical in a product, the person must, in addition to the information referred to in subsection (1), provide to the Minister the following information in respect of the chemical, at least 75 days before the day on which the quantity exceeds 50 000 kg:
(*a*) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days duration, using the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation, plus
(i) the age, sex, number, species, strain and source of the animals tested,
(ii) the route by which the chemical is administered and the conditions under which the test is conducted, and
(iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle; and
(*b*) the data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the chemical or its metabolites, permits an assessment of *in vivo* clastogenicity.

Chemicals and Biochemicals Not on the NDSL

Manufacture or import: quantities greater than 100 kg, 1 000 kg and 10 000 kg

8. (1) Every person that manufactures or imports a chemical that is not on the NDSL — other than a chemical referred to in section 5 — must provide to the Minister
(*a*) at least 5 days before the day on which the quantity of the chemical exceeds 100 kg in a calendar year,
(i) the information specified in Schedule 4, and
(ii) if the chemical is a biochemical, the information specified in items 1 to 3 of Schedule 2;
(*b*) at least 60 days before the day on which the quantity of the chemical exceeds 1 000 kg in a calendar year,
(i) the information specified in Schedule 5, and
(ii) if the chemical is a biochemical, the information specified in items 1 to 4 of

Schedule 2 and

(A) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2, and

(B) if the biochemical possesses enzymatic capability, the information specified in items 7 to 13 of Schedule 2; and

(*c*) at least 75 days before the day on which the quantity of the chemical exceeds 10 000 kg in a calendar year,

(i) the information specified in Schedule 6 and

(ii) if the chemical is a biochemical, the information specified in items 1 to 4 of Schedule 2 and

(A) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2, and

(B) if the biochemical possesses enzymatic capability, the information specified in items 7 to 13 of Schedule 2.

Notification

(2) The person that has submitted the information referred to in subparagraph (1)(*b*)(i) together with the information referred to in item 10 of Schedule 5 respecting a chemical or biochemical that is subsequently added to the NDSL must notify the Minister, in writing, that the chemical or biochemical is specified on the NDSL.

Reduced Regulatory Requirement Polymers

Description

9. A reduced regulatory requirement polymer is

(*a*) a polymer that is not one of the types listed in items 1 to 4 of Schedule 7 and that has a number average molecular weight greater than 10 000 daltons, with less than 2% of its components having molecular weights of less than 500 daltons and less than 5% of its components having molecular weights of less than 1 000 daltons;

(*b*) a polymer that is not one of the types listed in Schedule 7 and that has a number average molecular weight greater than 1 000 daltons and equal to or less than 10 000 daltons, with less than 10% of its components having molecular weights of less than 500 daltons and less than 25% of its components having molecular weights of less than 1 000 daltons; or

(*c*) a polymer that is a polyester manufactured solely from reactants listed in Schedule 8, or an anhydrous form of those reactants, other than the reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid.

Polymers and Biopolymers — General Requirements

Quantity greater than 1 000 kg	**10.** Every person that manufactures or imports a polymer — other than a polymer referred to in section 6 — must provide to the Minister, at least 30 days before the day on which the quantity of the polymer exceeds 1 000 kg in a calendar year, (*a*) the information specified in Schedule 9; and (*b*) if the polymer is a biopolymer, the information specified in items 1 to 3 of Schedule 2.

Polymers and Biopolymers on the NDSL or All of Whose Reactants Are on the DSL or NDSL

Quantity greater than 10 000 kg	**11.** (1) Subject to subsections (4) and (5), every person that manufactures or imports either a polymer that is on the NDSL or a polymer all of whose reactants are on the DSL or NDSL must provide to the Minister, at least 60 days before the day on which the quantity of the polymer exceeds 10 000 kg in a calendar year, (*a*) the information specified in Schedule 10; and (*b*) if the polymer is a biopolymer, the information specified in items 1 to 4 of Schedule 2, and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of that Schedule.
Quantity greater than 50 000 kg and 3 kg released per day	(2) If the quantity of the polymer exceeds 50 000 kg in a calendar year — and the polymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment — the person must, in addition to the information referred to in subsection (1), provide to the Minister the following information in respect of the polymer, at least 60 days before the day on which the quantity exceeds 50 000 kg: (*a*) the data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days duration, using the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation, plus (i) the age, sex, number, species, strain and source of the animals tested, (ii) the route by which the polymer is administered and the conditions under which the test is conducted, and (iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle; and (*b*) the mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutation or chromosomal aberrations in mammalian cells.

Quantity greater than 50 000 kg and significant exposure	(3) If the quantity of the polymer exceeds 50 000 kg in a calendar year and if the public may be significantly exposed to the polymer in a product, the person must, in addition to the information referred to in subsection (1), provide to the Minister the following information in respect of the polymer, at least 60 days before the day on which the quantity exceeds 50 000 kg: (*a*) the data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days duration, using the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation, plus (i) the age, sex, number, species, strain and source of the animals tested, (ii) the route by which the polymer is administered and the conditions under which the test is conducted, and (iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle; (*b*) the mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutation; and (*c*) the data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* clastogenicity.
Exception	(4) The information referred to in this section is not required if the polymer is referred to in section 6 or is a reduced regulatory requirement polymer.
Exception: Information in Schedule 10	(5) The information referred to in subsections (2) and (3) and item 4 of Schedule 10 is not required if the polymer does not meet the criteria for a reduced regulatory requirement polymer solely owing to the presence of any of the following functional groups: (*a*) aldehydes whose functional group equivalent weight is less than or equal to 1 000 daltons; (*b*) vinyl ethers whose functional group equivalent weight is less than or equal to 5 000 daltons; or (*c*) sulphonic acids whose functional group equivalent weight is less than or equal to 5 000 daltons.

Polymers and Biopolymers Not on the NDSL

Quantity greater than 10 000 kg

12. (1) Subject to subsections (2) and (3), every person that manufactures or imports a polymer that is not on the NDSL must provide to the Minister, at least 60 days before the day on which the quantity of the polymer exceeds 10 000 kg in a calendar year,
(*a*) the information specified in Schedule 11; and
(*b*) if the polymer is a biopolymer, the information specified in items 1 to 4 of Schedule 2, and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of that Schedule.

Exception

(2) The information is, however, not required if the polymer is referred to in section 6 or is a reduced regulatory requirement polymer or a polymer all of whose reactants are on the DSL or the NDSL.

Exception: Information in Schedule 11

(3) Despite paragraph (1)(*a*), the information referred to in items 5 to 10 of Schedule 11 is not required if the polymer does not meet the criteria for a reduced regulatory requirement polymer solely owing to the presence of any of the following functional groups:
(*a*) aldehydes whose functional group equivalent weight is less than or equal to 1 000 daltons;
(*b*) vinyl ethers whose functional group equivalent weight is less than or equal to 5 000 daltons; or
(*c*) sulphonic acids whose functional group equivalent weight is less than or equal to 5 000 daltons.

PART 3

ADMINISTRATIVE MATTERS

Retention of Information

Five years

13. A person that is required to provide information to the Minister under these Regulations must 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. The information and the supporting data must be kept for a period of five years after the year in which the information is provided.

Administrative Requirements

Information and certification

14. (1) Any information to be provided to the Minister under these Regulations must include all of the following:
(*a*) the name, civic and postal addresses and telephone number, as well as the fax number and e-mail address, if any, of the manufacturer or importer of the substance;
(*b*) the name, title, civic and postal addresses and telephone number, as well as the fax number and e-mail address, if any, of the person authorized to act on behalf of the manufacturer or importer of the substance, if any;
(*c*) an indication of whether the substance will be manufactured in or imported into Canada and the civic address of the site of manufacture in Canada of the substance or, if known, the port of entry into Canada of the substance, as the case may be; and
(*d*) a certification that the information 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.

Recipient

(2) Two copies of any information provided under these Regulations must be sent in English or French to the Minister, care of the Director, New Substances Branch, Department of the Environment, Ottawa, Ontario K1A 0H3.

Agent

(3) If a person that provides the information under these Regulations is not resident in Canada, they must identify, under paragraph (1)(*b*), a person resident in Canada that is authorized to act on their behalf to whom any notice or correspondence may be sent and that is required to keep the information and any supporting data under section 13.

Testing Requirements

Conditions and test procedures

15. (1) The conditions to be met and test procedures to be followed in developing test data for a substance in order to comply with the information requirements of section 81 of the Act — or requests for information under paragraph 84(1)(*c*) of the Act — must be consistent with the conditions and procedures set out in the "OECD Test Guidelines" that are current at the time the test data are developed. The Guidelines are set out in Annex 1 of the OECD *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the Organisation for Economic Co-operation and Development on May 12, 1981.

Laboratory practices

(2) Subject to subsection (3), the laboratory practices to be followed in developing data for the following tests must comply with the practices set out in the "Principles of Good Laboratory Practice" that are current at the time the test data are developed. The Principles are set out in Annex 2 of the OECD *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the Organisation for Economic Co-operation and Development on May 12, 1981:
(*a*) acute mammalian toxicity tests;
(*b*) repeated-dose mammalian toxicity tests;
(*c*) genotoxicity tests;
(*d*) tests to assess skin irritation;
(*e*) skin sensitization tests;
(*f*) acute fish, daphnia or algae toxicity tests; and
(*g*) biodegradation tests.

Consistency

(3) If the test was commenced or completed before the day on which these Regulations come into force, the laboratory practices must be consistent with those referred to in subsection (2).

PART 4

OBLIGATIONS OF THE MINISTER OF THE ENVIRONMENT AND THE MINISTER OF HEALTH

Assessment Periods

Research and development, site-limited intermediate and export-only substances

16. (1) For the purposes of subsection 83(1) of the Act, the period within which the Ministers must assess the information respecting research and development, contained site-limited intermediate and contained export-only substances provided under section 5 or 6 is 30 days after receiving it.

Chemicals and biochemicals

(2) For the purposes of subsection 83(1) of the Act, the periods within which the Ministers must assess the information respecting chemicals and biochemicals provided under section 7 or 8 are as follows:
(*a*) 5 days after receiving the information referred to in paragraph 8(1)(*a*);
(*b*) 30 days after receiving the information referred to in paragraph 7(1)(*a*);
(*c*) subject to subsection (3), 60 days after receiving the information referred to in paragraph 7(1)(*b*) or 8(1)(*b*); and
(*d*) 75 days after receiving the information referred to in subsection 7(2) or (3) or paragraph 8(1)(*c*).

Addition on the NDSL

(3) If a chemical or biochemical is added to the NDSL after the Minister of the Environment's receipt of the information referred to in subparagraph 8(1)(*b*)(i), together with the information referred to in item 10 of Schedule 5, but the Minister has not received the information referred to in paragraph 8(1)(*c*), the period within which the Ministers must assess the information referred to in paragraph 7(1)(*b*) respecting that chemical or biochemical is 60 days after receipt of the notification referred to in subsection 8(2).

Polymers and biopolymers

(4) For the purposes of subsection 83(1) of the Act, the periods within which the Ministers must assess the information respecting polymers and biopolymers provided under any of sections 10 to 12 are as follows:
(*a*) 30 days after receiving the information referred to in section 10; and
(*b*) 60 days after receiving the information referred to in section 11 or 12.

Additions to the DSL — Chemicals and Biochemicals

Prescribed quantity

17. (1) With respect to the obligation of the Minister of the Environment to add a substance to the DSL, other than research and development, contained site-limited intermediate and contained export-only substances, the quantity of a chemical or a biochemical prescribed for the purposes of subparagraph 87(1)(*b*)(iii) of the Act is
(*a*) in the case of a chemical or a biochemical not on the NDSL, a quantity that exceeds 10 000 kg in any calendar year; and
(*b*) in the case of a chemical or a biochemical that is on the NDSL, a quantity that exceeds in any calendar year
- (i) 50 000 kg if
  - (A) the chemical or biochemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment, or
  - (B) the public may be significantly exposed to the chemical or biochemical in a product, or
- (ii) 10 000 kg, in any other case.

Prescribed information

(2) With respect to the obligation of the Minister of the Environment to add a substance to the DSL, the information that is prescribed with respect to a chemical or a biochemical for the purposes of paragraph 87(5)(*a*) of the Act is

(*a*) a notice from the person who provides the information, stating that the person has manufactured or imported the chemical or biochemical;

(*b*) in the case of a biochemical, the information specified in items 1 to 4 of Schedule 2, and

(i) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2, and

(ii) if the biochemical possesses enzymatic capability, the information specified in items 7 to 13 of Schedule 2;

(*c*) if the chemical or biochemical is on the NDSL,

(i) the information specified in Schedules 4 and 5,

(ii) the information specified in paragraphs 7(2)(*a*) and (*b*) if the quantity of the chemical or biochemical exceeds 50 000 kg in a calendar year — and the chemical or biochemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment, and

(iii) the information specified in paragraphs 7(3)(*a*) and (*b*) if the quantity of the chemical or biochemical exceeds 50 000 kg in a calendar year and if the public may be significantly exposed to the chemical or biochemical in a product; and

(*d*) if the chemical or biochemical is not on the NDSL, the information specified in Schedules 4 to 6.

Additions to the DSL — Polymers and Biopolymers

Prescribed quantity

18. (1) With respect to the obligation of the Minister of the Environment to add a substance to the DSL, other than research and development, contained site-limited intermediate and contained export-only substances, the quantity of a polymer or a biopolymer prescribed for the purposes of subparagraph 87(1)(*b*)(iii) of the Act is

(*a*) in the case of a reduced regulatory requirement polymer, a quantity that exceeds 1 000 kg in any calendar year; and

(*b*) in the case of any other polymer or biopolymer, a quantity that exceeds in any calendar year

(i) 50 000 kg if the polymer or biopolymer is on the NDSL, or one that is not on the NDSL but all of its reactants are on the DSL or the

NDSL and

(A) that polymer or biopolymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment, or

(B) the public may be significantly exposed to that polymer or biopolymer in a product, or

(ii) 10 000 kg, in any other case.

Prescribed information

(2) With respect to the obligation of the Minister of the Environment to add a substance to the DSL, the information that is prescribed with respect to a polymer or a biopolymer for the purposes of paragraph 87(5)(*a*) of the Act is

(*a*) a notice from the person who provides the information, stating that the person has manufactured or imported the polymer or biopolymer;

(*b*) in the case of a reduced regulatory requirement polymer, the information specified in Schedule 9 and, if the reduced regulatory requirement polymer is a biopolymer, the information specified in items 1 to 3 of Schedule 2;

(*c*) in the case of a biopolymer, other than a reduced regulatory requirement polymer, the information specified in items 1 to 4 of Schedule 2, and, if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of that Schedule;

(*d*) if the polymer or biopolymer, other than a reduced regulatory requirement polymer, is on the NDSL, or one that is not on the NDSL but all of its reactants are on the DSL or the NDSL,

(i) the information specified in Schedules 9 and 10,

(ii) the information specified in paragraphs 11(2)(*a*) and (*b*) if the quantity of the polymer or biopolymer exceeds 50 000 kg in a calendar year and the polymer or biopolymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment, and

(iii) the information specified in paragraphs 11(3)(*a*) and (*b*) if the quantity of the polymer or biopolymer exceeds 50 000 kg in a calendar year and if the public may be significantly exposed to the polymer or biopolymer in a product; and

(*e*) if the polymer or biopolymer is not on the NDSL, other than a reduced regulatory requirement polymer or a polymer or biopolymer subject to paragraph (*d*), the information specified

in Schedules 9 and 11.

COMING INTO FORCE

Coming into force

19. These Regulations come into force 60 days after the day on which they are registered.

SCHEDULE 1
(Subsections 2(2) and 5(1) to (4))

INFORMATION RESPECTING CHEMICALS AND BIOCHEMICALS THAT ARE RESEARCH AND DEVELOPMENT SUBSTANCES, CONTAINED SITE-LIMITED INTERMEDIATE SUBSTANCES OR CONTAINED EXPORT-ONLY SUBSTANCES

1. The type of substance: research and development substance, contained site-limited intermediate substance or contained export-only substance.

2. The new substances pre-notification consultation number if it has been assigned and if known.

3. The chemical name of the chemical, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

4. The trade names of the chemical and the synonyms of its chemical name, if known.

5. The CAS registry number of the chemical, if such a number can be assigned.

6. The following identification information in respect of the chemical:

(*a*) its molecular formula;

(*b*) its structural formula;

(*c*) its gram molecular weight;

(*d*) the degree of purity in its technical grade composition, if applicable;

(*e*) known impurities present and their concentration by weight; and

(*f*) any additives, stabilizers and solvents present when the chemical is tested and their concentration by weight.

7. A material safety data sheet in respect of the chemical, if available.

8. The following exposure information respecting the chemical:

(*a*) the anticipated annual quantity to be manufactured, if applicable;

(*b*) the anticipated annual quantity to be imported, if applicable;

(*c*) the anticipated uses;

(*d*) its anticipated concentration in products and, if known, in end-use products;

(*e*) a description of the expected modes for its transportation and storage;

(*f*) a description of the size and type of container used for its transportation and storage;

(*g*) an identification of the components of the environment into which it is anticipated to be released;

(*h*) its anticipated releases into municipal wastewater systems;

(*i*) a description of the methods recommended for its destruction or disposal;

(*j*) whether the public is anticipated to be significantly exposed to the chemical in a product taking into account factors including its concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed; and

(*k*) for site-limited intermediate substances, the location of use.

9. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.

10. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the chemical and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

SCHEDULE 2

(Subsections 2(2), 5(2) to (4) and 6(2) to (4), subparagraphs 7(1)(a)(ii) and (b)(ii) and 8(1)(a)(ii), (b)(ii) and (c)(ii) and paragraphs 10(b), 11(1)(b), 12(1)(b), 17(2)(b) and 18(2)(b) and (c))

INFORMATION RESPECTING BIOCHEMICALS AND BIOPOLYMERS

1. The identification of the organism, hereinafter referred to as "production organism", and the organ, if applicable, from which the biochemical or biopolymer is isolated, including

(*a*) synonyms and common and superseded names, if known; and

(*b*) its source and history.

2. A description of any known adverse environmental or human health effects associated with exposure to the production organism.

3. The concentration of the viable production organism in the biochemical or biopolymer and, if known, in end-use products.

4. A description of the method used to separate the production organism from the biochemical or biopolymer.

5. The identification of the encoded products, if known.

6. A description of any known biological activity or adverse environmental or human health effects associated with the nucleic acid or with the encoded products specified under item 5.

7. A description of all known catalytic functions.

8. The Enzyme Commission (EC) number as designated by the nomenclature committee of the International Union of Biochemistry and Molecular Biology (IUBMB), if available.

9. The known substrate specificity for each of the catalytic functions specified under item 7.

10. The optimum pH and temperature for the substrates specified under item 9.

11. The catalytic constants K_m and K_{cat} and the conditions under which they were measured.

12. The known cofactors necessary for enzymatic activity.

13. The enzymatic activity per unit of weight of products and, if known, of end-use products.

SCHEDULE 3
(Subsection 2(2) and section 6)

INFORMATION RESPECTING POLYMERS AND BIOPOLYMERS THAT ARE RESEARCH AND DEVELOPMENT SUBSTANCES, CONTAINED SITE-LIMITED INTERMEDIATE SUBSTANCES OR CONTAINED EXPORT-ONLY SUBSTANCES

1. The type of substance: research and development substance, contained site-limited intermediate substance or contained export-only substance.

2. The new substances pre-notification consultation number if it has been assigned, and if known.

3. The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

4. The trade names of the polymer and the synonyms of its chemical name, if known.

5. The CAS registry number of the polymer, if such a number can be assigned.

6. The molecular formula of the polymer.

7. The structural formula of the polymer, if possible, or else a partial structural formula.

8. For contained site-limited intermediate substances and contained export-only substances:

(*a*) its number average molecular weight (Mn); and

(*b*) the maximum concentrations, expressed as a percentage, of all residual constituents having molecular weights of less than 500 daltons and of all residual constituents having molecular weights of less than 1 000 daltons.

9. For research and development substances, the target number average molecular weight (Mn) of the polymer.

10. The known impurities present and their concentration by weight.

11. The composition of the polymer including constituents — such as monomers and other reactants, additives, stabilizers and solvents — which constituents are present when the polymer is tested, and their concentration by weight.

12. A material safety data sheet in respect of the polymer, if available.

13. The physical state of the polymer.

14. Whether the polymer is formulated for dispersal in water.

15. The following exposure information respecting the polymer:

(*a*) the anticipated annual quantity to be manufactured, if applicable;

(*b*) the anticipated annual quantity to be imported, if applicable;

(*c*) the anticipated uses;

(*d*) its anticipated concentration in products and, if known, in end-use products;

(*e*) a description of the expected modes for its transportation and storage;

(*f*) a description of the size and type of container used for its transportation and storage;

(*g*) an identification of the components of the environment into which it is anticipated to be released;

(*h*) its anticipated releases into municipal wastewater systems;

(*i*) a description of the methods recommended for its destruction or disposal;

(*j*) whether the public is anticipated to be significantly exposed to the polymer in a product taking into account factors including its concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed; and

(*k*) for site-limited intermediate substances, the location of use.

16. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

17. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the polymer and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

SCHEDULE 4
(Subsection 2(2), subparagraphs 7(1)(a)(i), 8(1)(a)(i) and 17(2)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL (100 KG) OR ON THE NDSL (1 000 KG)

1. Whether the chemical is on the NDSL.

2. The new substances pre-notification consultation number if it has been assigned and if known.

3. The chemical name of the chemical, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

4. The trade names of the chemical and the synonyms of its chemical name, if known.

5. The CAS registry number of the chemical, if such a number can be assigned.

6. A material safety data sheet in respect of the chemical, if available.

7. The following exposure information respecting the chemical:

(*a*) the anticipated annual quantity to be manufactured, if applicable;

(*b*) the anticipated annual quantity to be imported, if applicable;

(*c*) the anticipated uses within Canada; and

(*d*) its anticipated concentration in products and, if known, in end-use products.

8. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.

9. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the chemical and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

SCHEDULE 5
(Subsection 2(2), subparagraphs 7(1)(b)(i) and 8(1)(b)(i), subsections 8(2) and 16(3), subparagraph 17(2)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL (1 000 KG) OR ON THE NDSL (10 000 KG)

1. The information specified in Schedule 4 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.

2. The following identification information in respect of the chemical:

(*a*) its molecular formula;

(*b*) its structural formula;

(*c*) its gram molecular weight;

(*d*) the degree of purity in its technical grade composition, if applicable;

(*e*) known impurities present and their concentration by weight; and

(*f*) any additives, stabilizers and solvents present when the chemical is tested and their concentration by weight.

3. The following physical and chemical data in respect of the chemical:

(*a*) its melting point or the temperature at which the chemical decomposes

(i) expressed in degrees Celsius if its melting point or the temperature at which it decomposes is -25°C or greater but not greater than 300°C, and

(ii) in any other case, expressed as "less than -25°C" or "greater than 300°C", as appropriate;

(*b*) its boiling point or the temperature at which the chemical decomposes

(i) expressed in degrees Celsius if its boiling point or the temperature at which it decomposes is -50°C or greater but not greater than 300°C, and

(ii) in any other case, expressed as "less than -50°C" or "greater than 300°C", as appropriate;

(*c*) its density;

(*d*) its vapour pressure if it has a standard boiling point of 0°C or greater;

(*e*) its water solubility; and

(*f*) for chemicals having a water solubility of less than or equal to 5 g/L, its octanol/water partition coefficient.

4. Ready biodegradation test data in respect of the chemical and, if known, identification of the products of biodegradation. *

5. Data from one acute fish, daphnia or algae toxicity test in respect of the chemical. *

6. Data from an oral, dermal or inhalation type of acute mammalian toxicity test in respect of the chemical, selected on the basis of the most significant route of potential human exposure to the chemical and the following information:

(*a*) the age, sex, number, species, strain and source of the animals tested;

(*b*) the route by which the chemical is administered and the conditions under which the test is conducted; and

(*c*) the dose of the chemical, the vehicle by means of which the chemical is administered and the concentration of the chemical in the vehicle. *

7. Mutagenicity data obtained from one *in vitro* test in respect of the chemical, with and without metabolic activation, for gene mutations. *

8. The following exposure information respecting the chemical:

(*a*) a description of the expected modes for its transportation and storage;

(*b*) a description of the size and type of container used for its transportation and storage;

(*c*) an identification of the components of the environment into which it is anticipated to be released;

(*d*) its anticipated releases into municipal wastewater systems;

(*e*) a description of the methods recommended for its destruction or disposal;

(*f*) whether it is anticipated to be used in products intended for use by or for children;

(*g*) the anticipated degree of direct human exposure to the chemical, including concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure; and

(*h*) if known, the three sites in Canada where the greatest quantity of the chemical, manufactured or imported by the person, is anticipated to be used or processed and the estimated quantity by site.

9. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.

10. If the chemical is on the NDSL, the following additional exposure information respecting the chemical:

(*a*) its historical and other likely uses;

(*b*) any factors that may limit environmental exposure;

(*c*) whether it is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and, if the release is less than or equal to 3 kg per day, per site, the data substantiating the quantity released; and

(*d*) whether the public is anticipated to be significantly exposed to the chemical in a product taking into account factors including the concentration of the chemical, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed.

Note: The asterisks (*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the *New Substances Notification Regulations (Chemicals and Polymers)*.

SCHEDULE 6
(Subsection 2(2), subparagraph 8(1)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL (10 000 KG)

1. The information specified in Schedules 4 and 5 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.

2. The following physical and chemical data in respect of the chemical:

(*a*) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the chemical;

(*b*) for chemicals having a water solubility of greater than or equal to 200 µg/L, adsorption-desorption screening test data; and

(*c*) for chemicals having a water solubility of greater than or equal to 200 µg/L, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

3. Data from the two tests mentioned in item 5 of Schedule 5 for which data was not submitted under that item, namely, the remaining two out of the following three tests: acute fish, daphnia and algae toxicity tests. *

4. Unless the chemical boils below 0°C and has been tested for acute inhalation toxicity under item 6 of Schedule 5, data from one of the remaining types of acute mammalian toxicity test of the chemical, namely, oral, dermal or inhalation, that was not completed for the submission of item 6 of Schedule 5 and that is selected on the basis of the most significant route of potential human exposure to the chemical. *

5. Information sufficient to assess skin irritation in respect of the chemical. *

6. Data from a skin sensitization test in respect of the chemical. *

7. Data from one repeated-dose mammalian toxicity test in respect of the chemical, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation. *

8. For the tests referred to in items 4 to 7, the following additional information:

(*a*) the age, sex, number, species, strain and source of the animals tested;

(*b*) the route by which the chemical is administered and the conditions under which the test is conducted; and

(*c*) the dose of the chemical, the vehicle by means of which the chemical is administered and the concentration of the chemical in the vehicle. *

9. Mutagenicity data obtained from one *in vitro* test in respect of the chemical, with and without metabolic activation, for chromosomal aberrations in mammalian cells. *

10. Mutagenicity data obtained from one *in vivo* mammalian test of the chemical for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the chemical or its metabolites, permits an assessment of *in vivo* mutagenicity. *

11. The following exposure information respecting the chemical:

(*a*) its historical and other likely uses; and

(*b*) any factors that may limit environmental exposure.

Note: The asterisks (*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the *New Substances Notification Regulations (Chemicals and Polymers)*.

SCHEDULE 7
(Subsection 2(2) and paragraphs 9(a) and (b))

TYPES OF POLYMERS

1. A cationic polymer or a polymer that is reasonably expected to become cationic in a natural aquatic environment, except

(*a*) a polymer whose cationic group has a combined equivalent weight greater than 5 000 daltons; or

(*b*) a polymer that is a solid material, that is not soluble or dispersible in water and that will be used only in the solid phase, such as polymers that can be used as ion exchange beads.

2. A polymer that is designed, or can be expected, to substantially degrade, decompose or depolymerize, including polymers that could substantially degrade, decompose or depolymerize after manufacture and use, even though they are not intended to do so. Degradation, decomposition and depolymerization refer to the types of changes that

convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light and microbial action.

3. A polymer that has, as an integral part of its composition, only one or none of the following atomic elements: carbon, hydrogen, nitrogen, oxygen, silicon and sulphur.

4. A polymer that has

(*a*) any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon;

(*b*) any monoatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminium, potassium ion or divalent calcium; or

(*c*) 0.2% or more by weight of any atomic element or combination of the following atomic elements: lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium.

5. A polymer

(*a*) that has reactive functional groups other than carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary"*, butenedioic acid groups, blocked isocyanates including ketoxime-blocked isocyanates, thiols, unconjugated nitrile groups, halogens excluding reactive halogen groups such as benzylic or allylic halides, and conjugated olefinic groups present in naturally occurring fats, oils and carboxylic acids, in combined equivalent weights of less than 5 000 daltons; or

(*b*) in which the only reactive functional groups present are part of acid halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxysilanes with alkoxy greater than C_2-alkoxysilanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, in combined equivalent weights of less than 1 000 daltons.

* Not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact.

SCHEDULE 8
(Subsection 2(2) and paragraph 9(c))

LIST OF REACTANTS AND THEIR CAS REGISTRY NUMBER

	CAS Registry Number	Name of Substance
1.	***Monobasic Acids and Natural Oils***	
	65-85-0	Benzoic acid

	111-14-8	Heptanoic acid
	112-05-0	Nonanoic acid
	142-62-1	Hexanoic acid
	143-07-7	Dodecanoic acid
	3302-10-1	Hexanoic acid, 3,3,5-trimethyl-
	8001-20-5	Tung oil *
	8001-21-6	Sunflower oil *
	8001-22-7	Soybean oil *
	8001-23-8	Safflower oil *
	8001-26-1	Linseed oil *
	8001-29-4	Cottonseed oil *
	8001-30-7	Corn oil *
	8001-31-8	Coconut oil *
	8002-50-4	Oils, menhaden *
	8016-35-1	Oils, oiticica *
	8023-79-8	Oils, palm kernel *
	8024-09-7	Oils, walnut *
	61788-47-4	Fatty acids, coco *
	61788-66-7	Fatty acids, vegetable oil *
	61789-44-4	Fatty acids, castor oil *
	61789-45-5	Fatty acids, dehydrated castor oil *
	61790-12-3	Fatty acids, tall-oil *
	67701-08-0	Fatty acids, C_{16-18} and C_{18}-unsaturated *
	67701-30-8	Glycerides, C_{16-18} and C_{18}-unsaturated *
	68132-21-8	Oils, perilla *
	68153-06-0	Oils, herring *
	68308-53-2	Fatty acids, soybean oil *
	68424-45-3	Fatty acids, linseed oil *
	68649-95-6	Linseed oil, oxidized *
	68953-27-5	Fatty acids, sunflower oil, conjugated *
	84625-38-7	Fatty acids, sunflower oil *
	91078-92-1	Oils, babassu palm *
	93165-34-5	Fatty acids, safflower oil *
	93334-41-9	Oils, sardine *
	120962-03-0	Oils, glyceridic, canola *

	128952-11-4	Oils, anchovy *
	N/A	Fatty acids, tall-oil, conjugated *
	N/A	Oils, cannabis *
2.	***Dibasic and Tribasic Acids and Esters***	
	88-99-3	1,2-Benzenedicarboxylic acid
	100-21-0	1,4-Benzenedicarboxylic acid
	106-65-0	Butanedioic acid, dimethyl ester
	106-79-6	Decanedioic acid, dimethyl ester
	110-15-6	Butanedioic acid
	110-17-8	Fumaric acid
	110-40-7	Decanedioic acid, diethyl ester
	110-94-1	Pentanedioic acid
	111-16-0	Heptanedioic acid
	111-20-6	Decanedioic acid
	120-61-6	1,4-Benzenedicarboxylic acid, dimethyl ester
	121-91-5	1,3-Benzenedicarboxylic acid
	123-25-1	Butanedioic acid, diethyl ester
	123-99-9	Nonanedioic acid
	124-04-9	Hexanedioic acid
	141-28-6	Hexanedioic acid, diethyl ester
	505-48-6	Octanedioic acid
	528-44-9	1,2,4-Benzenetricarboxylic acid
	624-17-9	Nonanedioic acid, diethyl ester
	627-93-0	Hexanedioic acid, dimethyl ester
	636-09-9	1,4-Benzenedicarboxylic acid, diethyl ester
	693-23-2	Dodecanedioic acid
	818-38-2	Pentanedioic acid, diethyl ester
	1119-40-0	Pentanedioic acid, dimethyl ester
	1459-93-4	1,3-Benzenedicarboxylic acid, dimethyl ester
	1732-08-7	Heptanedioic acid, dimethyl ester
	1732-09-8	Octanedioic acid, dimethyl ester
	1732-10-1	Nonanedioic acid, dimethyl ester
	1852-04-6	Undecanedioic acid
	61788-89-4	Fatty acids, C_{18}-unsaturated, dimers *
3.	***Polyols***	
	56-81-5	1,2,3-Propanetriol
	57-55-6	1,2-Propanediol

	77-85-0	1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-
	77-99-6	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-
	105-08-8	1,4-Cyclohexanedimethanol
	107-21-1	1,2-Ethanediol
	107-88-0	1,3-Butanediol
	110-63-4	1,4-Butanediol
	111-46-6	Ethanol, 2,2'-oxybis-
	115-77-5	1,3-Propanediol, 2,2-bis(hydroxymethyl)-
	126-30-7	1,3-Propanediol, 2,2-dimethyl-
	144-19-4	1,3-Pentanediol, 2,2,4-trimethyl-
	629-11-8	1,6-Hexanediol
	2163-42-0	1,3-Propanediol, 2-methyl-
	25119-62-4	2-Propen-1-ol, polymer with ethenylbenzene
	25618-55-7	1,2,3-Propanetriol, homopolymer
4.	***Modifiers***	
	71-36-3	1-Butanol **
	80-04-6	Cyclohexanol, 4,4'-(1-methylethylidene)bis-
	108-93-0	Cyclohexanol
	110-99-6	Acetic acid, 2,2'-oxybis-
	111-27-3	1-Hexanol
	112-34-5	Ethanol, 2-(2-butoxyethoxy)-
	13393-93-6	1-Phenanthrenemethanol, tetradecahydro-1, 4-a-dimethyl-7-(1-methylethyl)-
	25036-25-3	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis (4,1-phenyleneoxymethylene)]bis[oxirane]
	68037-90-1	Silsesquioxanes, phenyl propyl *
	68440-65-3	Siloxanes and silicones, dimethyl, diphenyl, polymers with phenyl silsesquioxanes, methoxy-terminated *
	68957-04-0	Siloxanes and silicones, dimethyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy-terminated *
	68957-06-2	Siloxanes and silicones, methyl phenyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated *
	72318-84-4	Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane *

* Chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB)

** This substance may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of those reactants.

SCHEDULE 9
(Subsection 2(2), paragraphs 10(a) and 18(2)(b), subparagraph 18(2)(d)(i) and paragraph 18(2)(e))

INFORMATION RESPECTING REDUCED REGULATORY REQUIREMENT POLYMERS AND OTHER POLYMERS AND BIOPOLYMERS (1 000 KG)

1. The type of polymer:

(*a*) a reduced regulatory requirement polymer;

(*b*) a polymer on the NDSL;

(*c*) a polymer with all of its reactants on the DSL or the NDSL; or

(*d*) a polymer with one or more reactants not on either the DSL or NDSL.

2. The new substances pre-notification consultation number if it has been assigned and if known.

3. The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

4. The trade names of the polymer and the synonyms of its chemical name, if known.

5. The CAS registry number of the polymer, if such a number can be assigned.

6. The molecular formula of the polymer.

7. The structural formula of the polymer, if possible, or else a partial structural formula.

8. The reaction scheme if the polymer is a reduced regulatory requirement polymer, unless it is a polymer referred in paragraph 9(*c*) of these Regulations.

9. The following physical and chemical data in respect of the polymer:

(*a*) its number average molecular weight (Mn); and

(*b*) the maximum concentrations, expressed as a percentage, of all residual constituents having molecular weights of less than 500 daltons and of all residual constituents having molecular weights of less than 1 000 daltons.

10. The known impurities present and their concentration by weight.

11. The composition of the polymer including constituents — such as monomers and other reactants, additives, stabilizers and solvents — which constituents are present when the polymer is tested, and their concentration by weight.

12. A material safety data sheet in respect of the polymer, if available.

13. The following exposure information respecting the polymer:

(*a*) the anticipated annual quantity to be manufactured, if applicable;

(*b*) the anticipated annual quantity to be imported, if applicable;

(*c*) the anticipated uses within Canada; and

(*d*) if the polymer is not a reduced regulatory requirement polymer,

(i) the anticipated concentration of the polymer in products and, if known, in end-use products,

(ii) the anticipated degree of direct human exposure to the polymer, including concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure,

(iii) whether the polymer is anticipated to be used in products intended for use by or for children, and

(iv) if known, the three sites in Canada where the greatest quantity of the polymer, manufactured or imported by the person, is anticipated to be used or processed and the estimated quantity by site.

14. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

15. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the polymer and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

SCHEDULE 10
(Subsection 2(2), paragraph 11(1)(a), subsection 11(5) and subparagraph 18(2)(d)(i))

INFORMATION RESPECTING OTHER POLYMERS AND BIOPOLYMERS ON THE NDSL OR ALL OF WHOSE REACTANTS ARE ON THE DSL OR NDSL (10 000 KG)

1. The information specified in Schedule 9 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.

2. The following physical and chemical data in respect of the polymer:

(*a*) its physical state;

(*b*) whether it is formulated for dispersal in water;

(*c*) its water extractability measured at

(i) pH 7 for anionic and neutral polymers,

(ii) pH 2 and 7 for cationic polymers, or

(iii) pH 2, 7 and 9 for amphoteric polymers;

(*d*) its octanol-water partition coefficient; and

(*e*) if water extractability is determined to be greater than 2%, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

3. Unless the polymer has a water extractability at pH 7 of less than or equal to 2%, an acute toxicity test of the polymer for the most sensitive species: fish, daphnia or algae or, if the sensitivity of these three species is unknown, an acute algae toxicity test. *

4. Data from one acute mammalian oral toxicity test of the polymer and the following information:

(*a*) the age, sex, number, species, strain and source of the animals tested;

(*b*) the route by which the polymer is administered and the conditions under which the test is conducted; and

(*c*) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle. *

5. The following exposure information respecting the polymer:

(*a*) a description of the expected modes for its transportation and storage;

(*b*) a description of the size and type of container used for its transportation and storage;

(*c*) its anticipated releases into municipal wastewater systems;

(*d*) a description of the methods recommended for its destruction or disposal;

(*e*) its historical and other likely uses;

(*f*) any factors that may limit environmental exposure;

(*g*) whether it is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and, if the release is less than or equal to 3 kg per day, per site, the data substantiating the quantity released; and

(*h*) whether the public is anticipated to be significantly exposed to the polymer in a product taking into account factors including the concentration of the polymer, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed.

6. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

Note: The asterisks (*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the *New Substances Notification Regulations (Chemicals and Polymers)*.

SCHEDULE 11
(Subsection 2(2), paragraph 12(1)(a), subsection 12(3) and paragraph 18(2)(e))

INFORMATION RESPECTING OTHER POLYMERS AND BIOPOLYMERS NOT ON THE NDSL (10 000 KG)

1. The information specified in Schedule 9 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.

2. The following physical and chemical data in respect of the polymer:

(*a*) its physical state;

(*b*) whether it is formulated for dispersal in water;

(*c*) its water extractability measured at

(i) pH 7 for anionic and neutral polymers,

(ii) pH 2 and 7 for cationic polymers, or

(iii) pH 2, 7 and 9 for amphoteric polymers;

(*d*) its octanol-water partition coefficient; and

(*e*) if water extractability is determined to be greater than 2%, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

3. Data from a ready biodegradation test on the water-soluble portion of the polymer, unless the polymer has a water extractability at pH 7 of less than or equal to 2% or is a branched silicone or siloxane polymer. *

4. Unless the polymer has a water extractability at pH 7 of less than or equal to 2%, the following tests:

(*a*) if the sensitivity of the three species is known, an acute toxicity test of the polymer for each of the two most sensitive species: fish, daphnia or algae;

(*b*) if the sensitivity of only one species is known and that species is not algae, an acute algae toxicity test and either a fish or daphnia acute toxicity test selected on the basis of the most sensitive of these species; or

(*c*) if the sensitivity of only one species is known and that species is algae or if the sensitivity of the three species is unknown, an acute algae toxicity test and either a fish or daphnia acute toxicity test. *

5. Data from one acute mammalian oral toxicity test of the polymer. *

6. Information sufficient to assess skin irritation in respect of the polymer. *

7. Data from a skin sensitization test in respect of the polymer. *

8. Data from one repeated-dose mammalian toxicity test in respect of the polymer, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation. *

9. For the tests referred to in items 5 to 8, the following additional information:

(*a*) the age, sex, number, species, strain and source of the animals tested;

(*b*) the route by which the polymer is administered and the conditions under which the test is conducted; and

(*c*) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle. *

10. Mutagenicity data obtained from each of the following tests of the polymer:

(*a*) one *in vitro* test, with and without metabolic activation, for gene mutations;

(*b*) one *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and

(*c*) one *in vivo* mammalian test, for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* mutagenicity. *

11. The following exposure information respecting the polymer:

(*a*) a description of the expected modes for its transportation and storage;

(*b*) a description of the size and type of container used for its transportation and storage;

(*c*) an identification of the components of the environment into which it is anticipated to be released;

(*d*) its anticipated releases into municipal wastewater systems;

(*e*) a description of the methods recommended for its destruction or disposal;

(*f*) its historical and other likely uses; and

(*g*) any factors that may limit environmental exposure.

12. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

Note: The asterisks (*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the *New Substances Notification Regulations (Chemicals and Polymers)*.

SCHEDULE 12
(Subsection 2(2))

OVERVIEW OF INFORMATION REQUIREMENTS

1. The information required under the *New Substances Notification Regulations (Chemicals and Polymers)* is divided into three flowcharts according to the type of

substance:

(*a*) research and development, contained site-limited intermediate and contained export-only substances — Flowchart 1;

(*b*) chemicals and biochemicals other than research and development, contained site-limited intermediate and contained export-only substances — Flowchart 2; and

(*c*) polymers and biopolymers other than research and development, contained site-limited intermediate and contained export-only substances — Flowchart 3.

2. Choose the appropriate flowchart according to the type of substance. Each flowchart identifies the information to be provided and the quantity that triggers the regulatory obligation to provide it.

3. References in the flowcharts are to provisions of the Regulations, in italics, and to schedules to the Regulations. Note that certain words and expressions used in the flowcharts are defined in section 1 of the Regulations.

4. The shapes used in the flowcharts distinguish their contents as follows:

(*a*) the ovals identify the type of substance referred to in the flowchart, as more particularly described in the flowchart's title;

(*b*) the diamonds identify the timeline and quantity trigger; and

(*c*) the rectangles identify the required information.

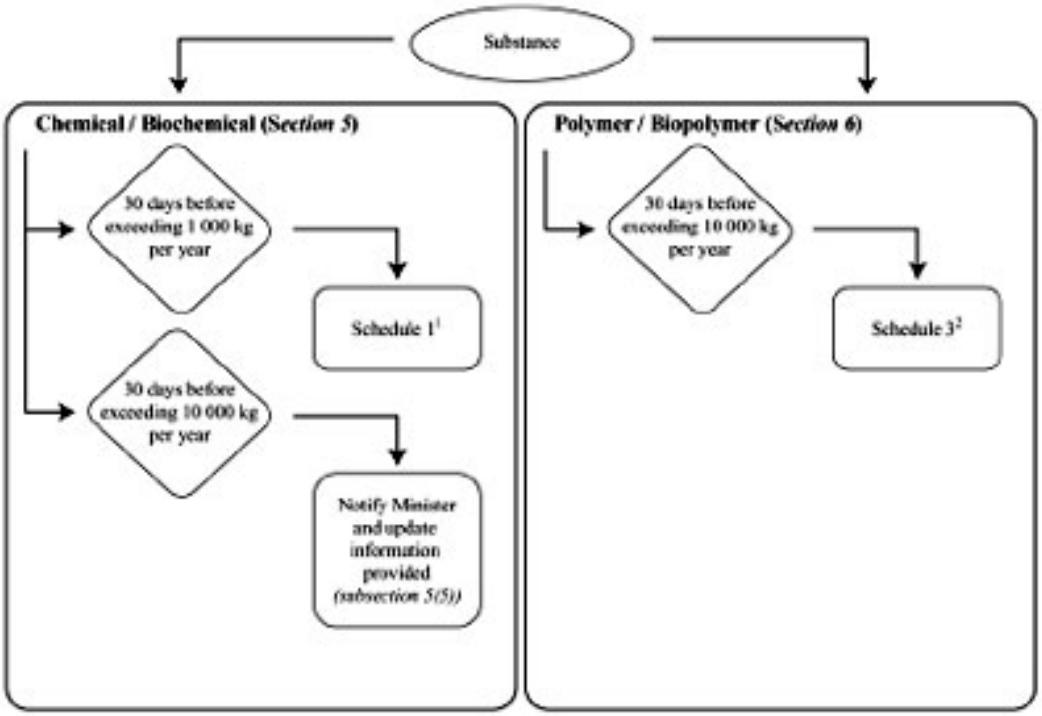
5. Shapes outlined with a broken line signal that information is required only in certain circumstances.

6. Additional information is set out in footnotes to each flowchart.

7. The Minister of the Environment and the Minister of Health must assess the information within the same number of days as are afforded to the manufacturer or importer for provision of that information — see section 16 of the Regulations. For example, if a manufacturer or importer is required to provide information at least 30 days before the day on which a certain quantity is exceeded, then the Ministers must assess that information within 30 days after receiving it.

Flowchart 1

RESEARCH AND DEVELOPMENT, CONTAINED SITE-LIMITED INTERMEDIATE OR CONTAINED EXPORT-ONLY SUBSTANCES

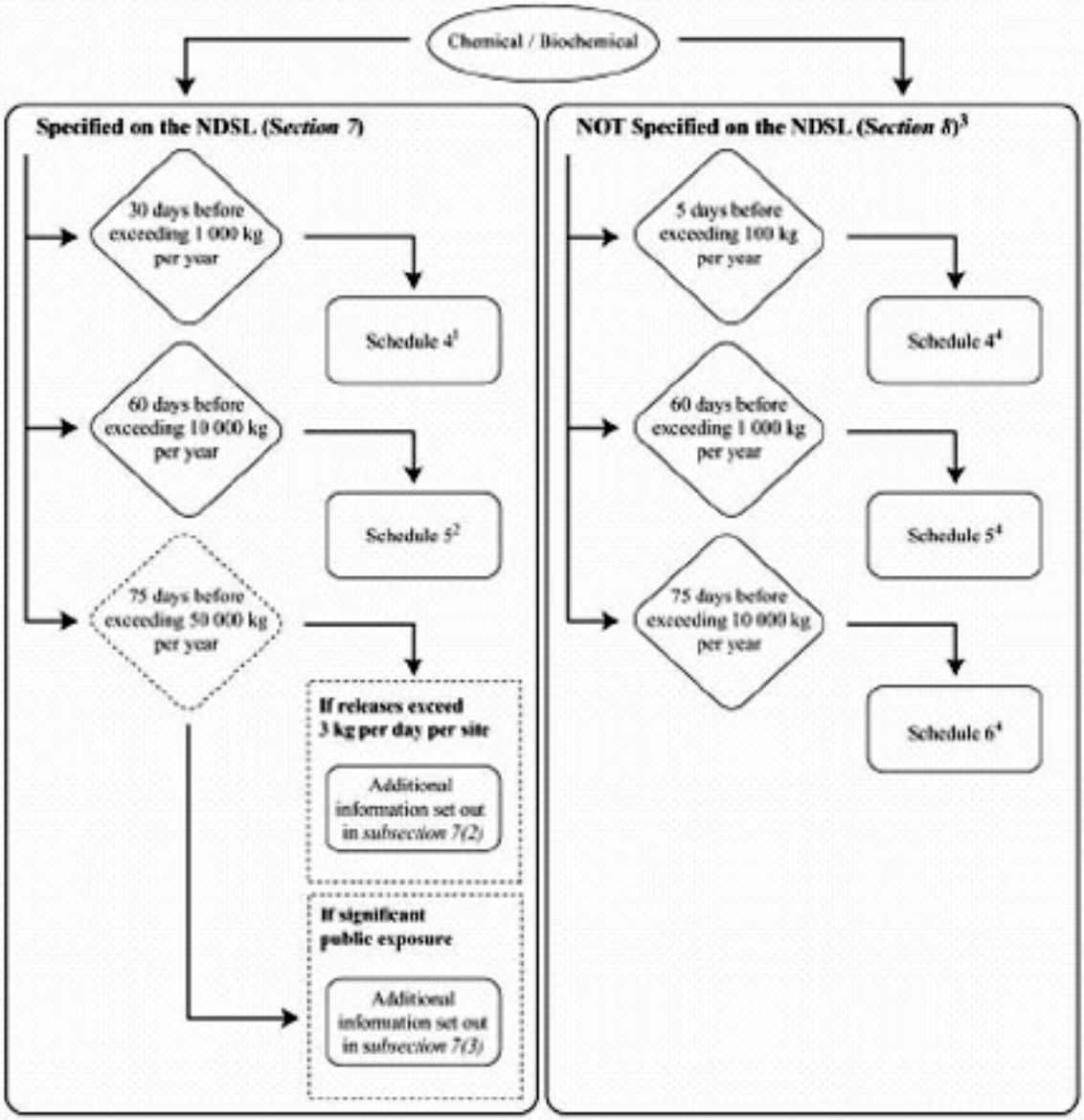


[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subsections 5(2), (3)* and *(4)*.

[2] Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *subsections 6(2), (3)* and *(4)*.

Flowchart 2

CHEMICALS / BIOCHEMICALS
OTHER THAN THOSE IN FLOWCHART 1



[1] Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraph 7(1)(a)(ii)*.

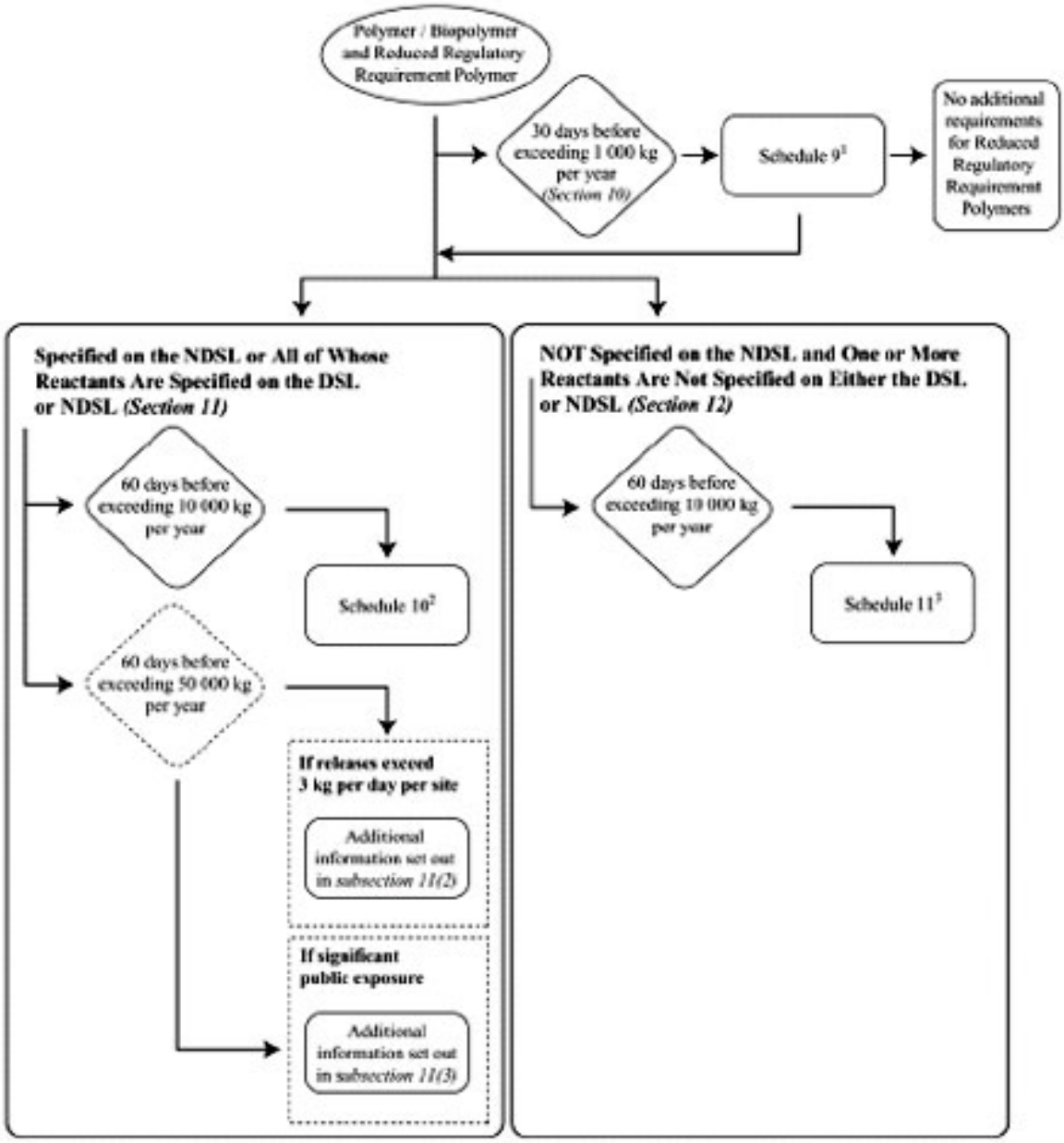
[2] Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraph 7(1)(b)(ii)*. No further information will be required unless: (a) the chemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment – see *subsection 7(2)* – or (b) the public may be significantly exposed to the chemical in a product – see *subsection 7(3)*.

[3] Notification must be sent to the Minister if: the chemical or biochemical is specified on the NDSL following submission of the information referred to in subparagraph *8(1)(b)(i)* and item 10 of Schedule 5 – see *subsection 8(2)*.

[4] Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraphs 8(1)(a)(ii), (b)(ii)* and *(c)(ii)*.

Flowchart 3

POLYMERS / BIOPOLYMERS
OTHER THAN THOSE IN FLOWCHART 1



[1] Required for polymers/biopolymers including reduced regulatory requirement polymers. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *paragraph 10(b)*.

[2] Not required for reduced regulatory requirement polymers. Also subject to certain exceptions – see *subsection 11(5)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see paragraph *11(1)(b)*. No further information will be required unless: (a) the polymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment – see subsection *11(2)* – or (b) the public may be significantly exposed to the polymer in a product – see subsection *11(3)*.

[3] Not required for reduced regulatory requirement polymers. Also subject to certain exceptions – see *subsection 12(3)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *paragraph 12(1)(b)*.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

The *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) are the culmination of an extensive stakeholder consultation on the chemicals and polymers portion of the existing *New Substances Notification Regulations*

(NSNR) and the New Substances Program (NS Program). The purpose of the New Substances Notification multistakeholder consultative process was to use the experience of stakeholders to improve the effectiveness and efficiency of the new substances notification and assessment process for chemicals and polymers, while maintaining high standards in the protection of the environment and human health. The Regulations implement consensus-based recommendations from these consultations. The existing NSNR will be repealed and replaced with these Regulations and the *New Substances Notification Regulations (Organisms)* pursuant to subsections 89(1) and 114(1) of the *Canadian Environmental Protection Act, 1999* (the Act).

The NS Program ensures that no new substance (chemical, biochemical, polymer, biopolymer, or living organism) is imported into, or manufactured in Canada before a formal assessment of its potential risks to the environment and human health has been completed, and any appropriate risk management measures have been implemented (see footnote 1). The NSN Program (as of October 2004) has assessed 10,558 notifications. The notifications were split evenly between chemicals and polymers. Almost one quarter of the substances (23%) have been added to the Domestic Substances List (DSL). Over three quarters of the substances (77%) can be used by the notifier but are not yet eligible for inclusion on the DSL. Canada uses a tiered notification system that depends on quantity. However, 95 percent of the chemicals and polymers were only notified once. Assessments typically can take anywhere from five to 90 days to complete but 95 percent of the assessments were completed in 45 days or less. Parts I and II of the NSNR for chemicals and polymers came into force in 1994, and were amended in 1997 to include both provisions for biochemicals and biopolymers, and Part II.1 for New Substances that are Organisms.

These Regulations are part of a new regulatory structure that divides the current NSNR into two distinct regulations:

1. *New Substances Notification Regulations (Chemicals and Polymers)*, which will apply to chemicals (including biochemicals) and polymers (including biopolymers) that are for a use not covered under other federal legislation listed in Schedule 2 of the Act; and
2. *New Substances Notification Regulations (Organisms)*, which will apply to living organisms that are for a use not covered under other federal legislation listed in Schedule 4 of the Act.

The *New Substances Fees Regulations*, which apply to chemicals and polymers, have been amended to ensure consistency with these Regulations. Environment Canada and Health Canada will publish new Guidelines to facilitate notifier understanding of and compliance with the changes to the new substances notification and assessment process for chemicals and polymers. Until these new Guidelines are finalized, the existing Guidelines will be in effect to the extent they are consistent with the revised Regulations.

All three Regulations will come into force 60 days after the day on which they are registered.

Background

When the chemicals and polymers portion of the NSNR came into force in 1994, Environment Canada and Health Canada committed to conduct a formal review of the

first three years of their implementation. A multistakeholder consultative process was initiated in 1999 to benefit from government, industry and public experience with the NSNR and NS Program. The outcome of these consultations was 76 consensus recommendations, including revisions to the NSNR and Guidelines, changes to program procedures, increased program transparency, increased collaboration with other governments, and improved service delivery. The Regulations are one of several ways, in addition to changes in program administration and ongoing international collaboration efforts, in which Environment Canada and Health Canada are implementing these recommendations.

New Substances Notification Regulations (Chemicals and Polymers)

The primary function of the Regulations remains the same as the existing NSNR: both provide the regulatory framework for the notification and assessment of new chemicals and polymers (see footnote 2). Those proposing to import or manufacture new chemicals or polymers (hereafter referred to as "notifiers") are responsible for providing specific information to the NS Program, as set out primarily in the Schedules to the Regulations. These notifications may include a statement of the uses of the substance, information regarding its physical and chemical properties, and/or toxicity and ecotoxicity data. The amount and nature of the information required varies depending on the type of substance (i.e. chemical, biochemical, polymer, biopolymer), its intrinsic properties, its intended purpose (e.g. research and development, contained site-limited intermediate, contained export-only, etc.), whether it is already in commerce in United States, and the quantity to be imported or manufactured.

Using the information provided by notifiers and other available information, Environment Canada and Health Canada conduct a joint assessment to determine the risk that the substance may pose to the environment and human health. Appropriate risk management measures are implemented when required.

A chemical or polymer is considered new for the purposes of the Act and the Regulations if it does not appear on the DSL. The DSL is a comprehensive compilation of all known substances falling within the scope of the NSNR and the Regulations that were in commercial use in Canada between January 1, 1984 and December 31, 1986, or that have subsequently been fully notified and assessed under the Act, the NSNR and the Regulations. Chemicals and polymers that are listed on the DSL are exempt from any reporting requirements under the NSNR and the Regulations.

Chemicals and polymers on the Non-domestic Substances List (NDSL), while benefiting from reduced reporting requirements, must follow the notification and assessment process. The NDSL, which is based on the United States *Toxic Substances Control Act* Chemical Substance Inventory, specifies substances that are not listed on the DSL but are believed to be in United States commerce. The NDSL has historically been updated annually based on the version of the U.S. Inventory published five years earlier. When the Regulations come into force, the NS Program will implement a change in program administration and begin updating the NDSL annually based on the U.S. inventory of the previous year, as recommended by stakeholders. This will result in notifiers being able to notify substances in Canada under the reduced information requirements for NDSL substances sooner than they would have been able to in the past.

While these Regulations serve the same function as the chemicals and polymers portion of the current NSNR, they contain certain improvements in structure and content.

Stakeholders found the NSNR to be complex and confusing. To address these concerns, the Regulations:

- are one part of a new, simplified regulatory structure for new substances notification and assessment;
- are written in plain language with readers' aids (e.g. table of contents, descriptive titles, marginal notes) to increase ease of use for notifiers;
- contain Schedules that have been reorganized to reduce repetition and optimize information requirements; and
- use flowcharts to assist notifiers in identifying relevant provisions and Schedules.

Stakeholders also identified opportunities for re-focusing notifier and government resources where they are most effective in the notification and assessment process, without compromising the protection of the environment and human health. Therefore the Regulations are a movement toward smarter regulation. The following is a summary of the key changes that are reflected in the Regulations:

- Notifiers are no longer required to track their cumulative and in-possession quantities of new chemicals and polymers. It was determined that the elimination of these notification triggers will not affect the ability of the Government to assess persistence, bioaccumulation and toxicity of substances.
- The previously separate categories of "research and development" and "product development" substances are simplified into a single definition.
- Notifiers of special category (e.g. research and development, product development, site-limited intermediate and export-only) chemicals and polymers are only required to submit test data that are already available, rather than generating new test data specifically for the purpose of notification.
- Information requirements and the import/manufacturing quantities that trigger their submission have been optimized for each category of chemical and polymer. Depending on the category of substance, test requirements may be added, removed or requested at a different quantity trigger.
- There are new notification requirements for high-volume chemicals and polymers that are specified on the NDSL and meet specific criteria that are indicative of significant release into the environment and/or human exposure.
- The Regulations clearly identify the test data that must comply with the practices set out in the Organization for Economic Co-operation and Development "Principles of Good Laboratory Practice (GLP)" that are current at the time the test data are developed.
- The assessment periods prescribed for the evaluation of notifications have been optimized to better reflect the complexity of the assessment required.
- Regulatees are also required to keep a copy of the 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. This information and the supporting data must be retained for a period of five years after the year in which the information is provided.

Alternatives

The NSNR, as amended in 1997 and 2003, are an integral part of the federal government's national pollution prevention strategy. When the NSNR came into force in

1994, a unique Canadian regulatory alternative was chosen over voluntary measures and regulatory systems used in other countries (see footnote 3). This was viewed as the most effective way of ensuring a proactive and preventative approach to the control of substances new to Canada, in line with the "cradle to grave" management approach to toxic substances laid out in the Act.

The New Substances Notification Multistakeholder Consultations held between 1999 and 2001 were intended to improve the existing regulatory approach to new substances notification and assessment, and not to re-evaluate its existence. While it was recognized by all stakeholders that the outcomes of the consultations could not bind the Parliamentary process, government representatives assured the stakeholders involved in the consultations that consensus recommendations would be reflected in regulatory change where appropriate and legally feasible. The changes to the new substances notification and assessment process included in the Regulations enable Environment Canada and Health Canada to maintain the same level of protection of the environment and human health.

In implementing the consensus recommendations, Environment Canada and Health Canada had the option of amending or replacing the existing regulatory structure. Repealing and replacing the NSNR with two new Regulations allowed for:

- better alignment of the regulatory structure for new substances notification with the structure of the Act (see footnote 4); and
- the use of innovative drafting techniques to reduce the complexity and increase the user-friendliness of the Regulations.

Benefits and Costs

Profile of Affected Sectors

As the principal notifiers of chemicals and polymers under the NSNR, chemicals manufacturers and importers will be most affected by the Regulations. However, given the role of the chemicals industry in transforming the resource base into products used by other industries in their production processes, associated upstream and downstream industries may also experience impacts.

The Canadian chemicals industry is a key industrial sector for the Canadian economy. According to 2001 Statistics Canada data, Canada produced $38.6 billion in shipments of chemicals and chemical products (approximately 1.5 percent of the world chemical output of $2.7 trillion) with value-added of $14.9 billion. The industry directly employed 87,500 people in 2,067 principal establishments, which are regionally concentrated in Ontario, Quebec and Alberta. Overall, Canada was a net importer of chemicals and chemical products, with a trade deficit of $11.24 billion. Of the $19.84 billion in Canadian chemicals exports, approximately 86 percent were destined for the United States.

Most NSNs are submitted by multinational or large enterprises. In 2003, notifiers with sales of >$13 million were responsible for 85 percent of NSNs, and notifiers with annual sales of <$13 million were responsible for 15 percent of NSNs. Two sectors accounted for approximately 77 percent of the new substance notifications - Chemical Industry nearly 51 percent, and Wholesalers & Distributors nearly 25 percent. The majority of new substances are specialty and fine chemicals. Ninety percent of the notified new

substances are imported into Canada.

Benefit-Cost Analysis Framework

Benefit-cost analysis is used to identify, and quantify the incremental costs and benefits of the Regulations in monetary terms. However, due to data limitations and uncertainties all costs and benefits could not be quantified.

It is important to note that actual test costs are highly variable depending on the substance, purpose, allowable exemptions, waivers, etc. which has not been factored into the test cost estimations. In many cases, firms may be able to use surrogate data or waivers which would result in lower costs. These costs, therefore, represent a conservative estimate. Also, the estimates of forecasted notifications do not account for changes in the volume or distribution of notifications that may result from changes to information requirements and notification triggers in the Regulations.

The costs that have been quantified include:

- Private sector notification test costs; and
- Costs to the federal government.

Other costs and benefits have been described qualitatively, due to data limitations and uncertainties.

Benefits to Canadians

Pollution Prevention

The new substances notification and assessment process prevents adverse environmental and human health effects associated with the exposure of Canadians and the Canadian environment to toxic substances, to the extent that:

- information provided by notifiers in notifications results in the conclusion that new substances may pose an environmental or human health risk that requires risk management measures or further regulatory control; and
- the private sector redirects its investment away from classes of substances that are likely to be suspected of being toxic after an Environment Canada and Health Canada assessment.

Optimization of Requirements

The Regulations optimize both the type of information required for notification and when this information is provided to Environment Canada and Health Canada (see Table 1). These changes improve the efficiency of the assessment process from an evaluation perspective, without compromising the level of protection of the environment and human health provided by the NSNR.

The number of notification schedules will be reduced, and in some cases, the quantity that triggers the need for a notification has been increased. New substances are typically

notified in very small quantities, and may only be notified once. By raising the threshold quantity that triggers a notification, notifiers may realize savings where they may no longer have to notify a substance used in small quantities or may be able to postpone notification to a production or import level where they may more easily recover their costs.

The Regulations eliminate the cumulative and in-possession triggers. Removal of the cumulative and in-possession tracking requirements in the Regulations will result in savings to notifiers, in terms of employee time and administrative costs. The magnitude of these cost savings will vary with the size and complexity of each notifier's business operations.

The notification requirements for research and development, site limited intermediates and export-only substances have been simplified in the Regulations. Companies do not have to generate new data in order to notify "special category substances". The notifiers only need to provide the available data that they have in their possession. The definition of product development has also been included in the definition of research and development.

High release and exposure chemicals will face increased testing requirements.

Table 1: Changes to the notification triggers between the NSNR and the Regulations

Category of substance	Notification level	Notification triggers under the NSNR	Notification triggers under the Regulations
Special category chemicals	R&D / product development (entry)	Non-NDSL: > 1,000 kg/yr OR > 5,000 kg acc. and < 50,000 kg acc. NDSL: > 1,000 kg/yr OR > 5,000 kg acc. and < 25,000 kg acc.	> 1,000 kg/yr, with an update at > 10,000 kg/yr
	R&D / product development (final)	Non-NDSL: ≥ 50,000 kg acc. NDSL: ≥ 25,000 kg acc.	

	Site-limited / export-only (entry)	Non-NDSL: > 20 kg/yr and ≤ 1,000 kg/yr AND ≤ 5,000 kg acc. NDSL: > 1,000 kg/yr and ≤ 5,000 kg/yr OR > 5,000 kg acc. and ≤ 25,000 kg acc.	
	Site-limited / export-only (final) [a]	Non-NDSL: > 1,000 kg/yr OR > 5,000 kg acc. NDSL: > 5,000 kg/yr OR > 25,000 kg acc.	
Non-NDSL chemicals	Entry	> 20 kg/yr and ≤ 1,000 kg/yr AND ≤ 5,000 kg acc.	> 100 kg/yr
	Interme-diate	> 1,000 kg/yr and ≤ 10,000 kg/yr OR > 5,000 kg acc. and ≤ 50,000 kg acc.	> 1,000 kg/yr
	Final	> 10,000 kg/yr OR > 50,000 kg acc.	> 10,000 kg/yr
NDSL chemicals	Entry	> 1,000 kg/yr and ≤ 5,000 kg/yr OR > 5,000 kg acc. and ≤ 25,000 kg acc.	> 1,000 kg/yr
	Interme-diate / final	> 5,000 kg/yr OR > 25,000 kg acc.	> 10,000 kg/yr
	Final	not applicable	> 50,000 kg/yr
Reduced regulatory requirement polymers	Entry	> 1,000 kg/yr and ≤ 10,000 kg/yr OR > 5,000 kg acc. and ≤ 50,000 kg acc.	> 1,000 kg/yr

	Interme- diate (non-NDSL and all monomers are not specified on the DSL/NDSL)	> 10,000 kg/yr OR > 50,000 kg acc.	not applicable
Special category polymers	R&D (entry)	> 1,000 kg/yr and ≤ 10,000 kg/yr OR > 5,000 kg acc. and ≤ 50,000 kg acc.	> 10,000 kg/yr
	Product develop- ment (entry)	> 10,000 kg/yr OR > 50,000 kg acc.	
	Site-limited / export-only (entry)	> 1,000 kg/yr and ≤ 10,000 kg/yr	
	Site-limited / export-only (final) [b]	> 10,000 kg/yr	
Polymers (non-NDSL and NDSL)	Entry	> 1,000 kg/yr and ≤ 10,000 kg/yr OR > 5,000 kg acc. and ≤ 50,000 kg acc.	> 1,000 kg/yr
	Interme- diate / final	> 10,000 kg/yr OR > 50,000 kg acc.	> 10,000 kg/yr
	Final (NDSL)	not applicable	> 50,000 kg/yr

[a] Under the NSNR, there is an additional trigger for possession > 10,000 kg for site-limited intermediate and export-only chemicals (non-NDSL and NDSL), as well as a trigger at > 50,000 kg accumulated for site-limited intermediate chemicals (non-NDSL and NDSL).

[b] Under the NSNR, there is an additional trigger for possession ≤ 20,000 kg for site-limited intermediate and export-only polymers, as well as a trigger at ≤ 50,000 kg accumulated for site-limited intermediate polymers.

Quicker Time to Market

The maximum total assessment period prescribed for reduced regulatory requirement polymers and polymers not specified on the NDSL is reduced under the Regulations (see Table 2). This will enable notifiers to bring these substances to market more quickly. Depending on the specific market context, the ability to bring products to market more quickly may result in monetary benefits for notifiers.

Table 2: Changes to prescribed assessment periods between the NSNR and the Regulations

	NSNR	The Regulations

Category of substance	Assessment periods for successive notification levels (in days)	Maximum total assessment period (in days)	Assessment periods for successive notification levels (in days)	Maximum total assessment period (in days)
Special category chemicals [a]	Ranges from 5 to 90 days	Ranges from 21 to 116 days	30 + 30	60
Non-NDSL chemicals	5 + 45 + 90	140	5 + 60 + 75	140
NDSL chemicals [b]	5 + 45	50	30 + 60 + [75]	90 or [165]
Reduced regulatory requirement polymers	45 or 45 + 45 (if non-NDSL and reactants not on DSL/NDSL)	45 or 90 (if non-NDSL and reactants not on DSL/NDSL)	30	30
Special category polymers [c]	Ranges from 5 to 90 days	Ranges from 5 to 156 days	30	30
Non-NDSL polymers	45 + 90	135	30 + 60	90
NDSL polymers or polymers with all monomers specified on the DSL/NDSL [b]	45 + 45	90	30 + 60 + [60]	90 or [150]

[a] Under the NSNR, the length of the assessment period is determined by: (*a*) the specific category to which the chemical belongs; (*b*) whether the chemical is specified on the NDSL; and (*c*) the notification trigger reached (e.g. quantity, cumulative or in-possession).

[b] Under the Regulations, only NDSL-specified chemicals and polymers that meet specific criteria indicative of significant release into the environment or human exposure are subject to the additional assessment period (indicated in brackets) before DSL listing.

[c] Under the NSNR, the length of the assessment period is determined by: (*a*) the specific category to which the polymer belongs; (*b*) whether the polymer is specified on the NDSL; (*c*) whether the polymer is a reduced regulatory requirement polymer; (*d*) whether the reactants are specified on the DSL/NDSL; and (*e*) the notification trigger reached.

An additional benefit from a change in program administration is the reduction in the time delay (from five years to one year) for addition of substances to NDSL from the United States *Toxic Substance Control Act* (TSCA) inventory. This is an important benefit as substances on the NDSL have less onerous testing requirements for addition to the DSL which may result in test cost savings (see Table 3 and Cost to Notifiers section below).

Improved Accessibility and User-Friendliness

The structure of the NSNR has been simplified to increase accessibility and clarity for notifiers. The revised framework reduces complexity and improves clarity by separating the provisions applicable to chemicals and polymers from those applicable to living organisms. Furthermore, the text of the Regulations has been drafted in plain language with readers' aids to allow notifiers to more easily identify the provisions that apply to them. These include: a clear table of contents; a concise title for each section; self-explanatory notes introducing each subsection; and flow charts.

It is anticipated that changes to the regulatory structure for new substances notification and the use of innovative drafting techniques in the Regulations (e.g. plain language text) will reduce confusion surrounding the new substances notification and assessment process. As a result, notifiers may save administrative costs and/or time associated with fulfilling their obligations under the Regulations. In turn, Environment Canada may also experience administrative savings due to a reduction in the number of notifications containing errors.

In addition, the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* are presently being revised. The new guidelines will also be written in plain language and will be adapted to the revised Regulations and will be streamlined to follow the notification process.

Costs to Notifiers

Optimization of Information Requirements, Notification Triggers and Assessment Periods

One of the key changes in the Regulations was the optimization of information requirements, notification triggers, and assessment periods for each category of chemical and polymer.

Table 3 summarizes estimated changes in direct notification costs for chemicals and polymers, based on changes in test requirements between the current NSNR and these Regulations. The estimated changes were based on the test requirements for a hypothetical chemical or polymer that: (*a*) does not meet regulatory exemption or waiver requirements; and (*b*) is not subject to additional test requirements (e.g. specific to anionic or cationic polymers) under either the NSNR or the Regulations. Positive figures indicate incremental costs, while negative figures indicate incremental cost savings. All dollar values have been converted from US dollars to 2004 Canadian dollars and adjusted for inflation.

The key assumptions upon which the analysis is based include the following:

- Most testing required by the Regulations is based on standard internationally accepted test protocols (i.e. OECD testing guidelines).
- Notification testing costs were taken from the most recent and readily available data from the United States Environmental Protection Agency (EPA);
- Test costs are based on the "best estimates" obtained as an average of high and low estimates from the United States EPA;
- All test cost calculations are based on notifiers being subject to all stated tests specified in the Schedules;
- The forecasted distribution of annual notifications is based on average actual

notifications to the NS Program between 1994 and 2003 (excluding notifications for transitional substances);
- The forecasted total volume of notifications is based upon a three- to five-year projection;
- Benefits and costs have been calculated using a discount rate of five percent; and
- Sensitivity testing was carried out for discount rates of three and seven percent.

The assumptions used in the analysis require qualification. Ninety percent of the substances have already been notified in other jurisdictions. In many cases notifiers may already have done much of the testing required for regulatory submissions elsewhere. Notifiers can also obtain a waiver or exemption or provide surrogate data for many of the tests. For example, in the past the NSN program has granted over 1,100 waivers. The distribution of notifications will also change. In the future more chemicals will be notified from the NDSL, because of the decrease waiting time to add a substance on the NDSL. By raising the quantities that triggers the need for a notification in some cases, companies can defer testing until they market greater quantities of the substance and are more capable of recovering the costs.

The per-notification cost estimates in Table 3 are highly dependent on the estimated cost of each test and the assumed change in test requirements between the NSNR and the Regulations. The cost of individual tests can vary substantially depending on a series of factors, including: the nature of the substance being tested, the complexity of the test, and the availability of laboratory facilities. Similarly, the tests required at a particular notification trigger under the NSNR and/or the Regulations will vary depending on the specific characteristics of the substance being notified. Deviations from the test cost best estimates and/or the assumptions used in this analysis will affect the magnitude of the incremental costs or cost savings actually experienced by notifiers. In some instances, such deviations may turn what was estimated to be an incremental cost into a cost saving (or vice versa)).

Table 3: Change in Notification Costs between the NSNR and the Regulations (in 2004 Canadian dollars)

Category of substance [a]	**Revised schedule numbers**	**Notification level** [b]	**Change in per notification test costs** [c]	**Forecasted annual notifications**	**Total annual incremental impact on notifiers**
No Change in Notification Testing Costs					
Special category chemicals	1	R&D	no change	2	no change
Non-NDSL chemicals	4	Entry	no change	197	no change
NDSL chemicals	4	Entry	no change	79	no change

Reduced regulatory requirement polymers	9	Entry / final	no change	159	no change
Special category polymers	3	R&D	no change	4	no change
		Product development [d]	no change	2	no change
Non-NDSL and NDSL polymers	9	Entry	no change	197	no change
Increased Notification Testing Costs					
Non-NDSL chemicals	5	Intermediate	$2,547	48	$122,239
NDSL chemicals		Final – releases [e]	$140,076	4	$560,302
	5	Final – exposure [e]	$118,698	4	$474,790
		Final – releases and exposure [e]	$163,411	4	$653,643
NDSL polymers		Final – releases [e]	$121,687	2	$243,373
	10	Final – exposure [e]	$148,011	2	$296,021
		Final – releases and exposure [e]	$148,011	2	$296,021
Reduced Notification Testing Costs - Incremental Cost Savings					
Special category chemicals	1	Site-limited / export-only	-$38,779	6	-$232,675
Non-NDSL chemicals	6	Final	-$11,102	20	-$222,038
NDSL chemicals	5	Intermediate / final	-$38,287	36	-$1,378,336
Special category polymers	3	Site-limited / export-only	-$31,725	2	-$63,450
Non-NDSL and NDSL polymers	11	Final (non-NDSL)	-$10,039	8	-$80,309
	10	Intermediate / final (NDSL)	-$698	40	-$27,922
Net Impact on Notification Testing Costs					
TOTAL				**818**	**$641,660**

Note: All dollar figures have been rounded off to the nearest thousand. This convention has been used across the board and as a result the numbers may not add up.

[a] Special category and reduced regulatory requirements substances are excluded from the following categories of substances: "Non-NDSL chemicals", "NDSL chemicals" and "Non-NDSL and NDSL polymers".

[b] The following assumptions were made regarding notifications under the NSNR: all research and development chemicals are notified under Schedule IV; all site-limited intermediate and export-only chemicals are notified under Schedule V; all research and development polymers are notified under Schedule XI; all product development polymers are notified under Schedule XII; all site-limited intermediate and export-only polymers are notified under Schedule XIII; and all reduced regulatory requirement polymers are notified under Schedule VI only.

[c] Inhalation test routes were excluded from the best estimates for all tests of health effects to better reflect the average expected cost to notifiers of these tests.

[d] The product development category is amalgamated with the research and development category in the Regulations.

[e] NDSL-specified chemicals and polymers that meet specific criteria indicative of significant release into the environment and/or human exposure are subject to an additional level of notification (at 50,000 kg) before DSL listing.

Table 3 shows that, subject to assumptions discussed previously, changes in test requirements between the NSNR and the Regulations will result in a net incremental cost to notifiers of approximately $642,000 per year.

This net incremental cost is driven primarily by the introduction of new test requirements for high-volume chemicals and polymers that are specified on the NDSL and meet specific criteria that are indicative of significant release into the environment and/or human exposure. While such notifications are expected to be only two percent of total annual notifications, the incremental cost ranges from approximately $119,000 to $148,000 per notification. Independently derived test cost data arrives at similar cost range estimates for chemicals and polymers with significant release into the environment and/or human exposure. The highest test costs are associated with NDSL-listed high release and high exposure chemicals polymers when these are compared to the current Regulations. The time to market for chemicals and polymers that meet the high release and/or high exposure criteria will also increase under the Regulations.

For the majority of notifications (approximately 78 percent) there will be no change in test requirements and therefore no change is anticipated in notification costs between the NSNR and the Regulations.

There will be incremental cost savings for notifiers of special category chemicals and polymers, resulting from:

- the reduction in information requirements for site-limited intermediate and export-only substances; and

- the fact that notifiers will only be required to submit test data that are already available, rather than generating new test data specifically for the purpose of notification under the Regulations.

Incremental cost savings are also anticipated for notifiers of other categories of chemicals and polymers (see Table 3 above).

It should also be noted that, financial incentives exist in terms of cost savings for firms to shift chemical notifications from non-NDSL to NDSL schedules as a result of reduced notification requirements and provisions for notifiers to use existing data. The following table illustrates the potential cost savings that notifiers can obtain, despite the higher notification costs associated with high-exposure and high-release chemicals.

Table 4: Cost Savings from Shifting Non-NDSL Chemicals to NDSL Schedule

Category of Substance	Unit Cost	Annual Incremental Impact on Notifiers	
		0% Shift	**20% Shift**
Non-NDSL Chemicals Intermediate			
Notification Costs	$2,547	$122,239	$97,805
Forecasted Annual Notifications (Sch. 5)		48	38
Final			
Notification Costs	-$11,102	-$222,038	-$177,632
Forecasted Annual Notifications (Sch. 6)		20	16
NDSL Chemicals Intermediate/Final			
Notification Costs	-$38,287	-$1,378,336	-$1,899,035
Forecasted Annual Notifications (Sch. 5)		36	50
Sub-Total		***-$1,478,135***	***-$1,978,862***
All Other Notifications Costs[a]		$2,119,802	$2,119,802
Impact on Notification Costs			
Total [b]		**$641,660**	**$140,933**

Category of Substance	Unit Cost	Annual Incremental Impact on Notifiers		
		30% Shift	**40% Shift**	**80% Shift**
Non-NDSL Chemicals Intermediate				
Notification Costs	$2,547	$85,579	$73,354	$24,451
Forecasted Annual Notifications (Sch. 5)		34	29	10

Final				
Notification Costs	-$11,102	-$155,428	-$133,224	-$44,408
Forecasted Annual Notifications (Sch. 6)		14	12	4
NDSL Chemicals Intermediate/Final				
Notification Costs	-$38,287	-$2,159,387	-$2,419,738	-$3,461,145
Forecasted Annual Notifications (Sch. 5)		56	63	90
Sub-Total		***-$2,229,236***	***-$2,479,609***	***-$3,481,102***
All Other Notifications Costs[a]		$2,119,802	$2,119,802	$2,119,802
Impact on Notification Costs				
Total [b]		**-$109,441**	**-$359,814**	**-$1,361,307**

Note: All dollar figures have been rounded off to the nearest thousand. This convention has been used across the board and as a result the numbers may not add up.

[a] "All Other notification Costs" remain the same (as given in Table 3) and are not impacted by the shift in notifications of chemicals from non-NDSL to NDSL.

[b] The "total" row reflects the impact on total annual incremental notification costs as a result of shifts in notifications. Only changes in notification costs from shifting non-NDSL chemicals to NDSL are considered.

Table 4 is simply an example of the gains that notifiers may be able to obtain from shifting notifications. It represents a range of possible cost savings to the notifiers. For example, 25 to 30 percent shift of non-NDSL chemicals to NDSL chemicals, the chemical industry can break even. While for an 80 percent shift, the overall annual cost savings to the chemical industry could be close to $1.4 million.

Costs to the Government of Canada

Although there are important changes in the structure of the regulatory text, the Regulations do not significantly alter the activities conducted by Environment Canada and Health Canada. Nonetheless, the one-time incremental costs of $447,000 described below are necessary for their implementation. With the exception of the cost estimate for enforcement training, all figures include only operations and maintenance expenditures. Existing staff resources will be reallocated to accommodate the remaining personnel requirements of the Regulations.

Environment Canada and Health Canada will jointly incur costs of approximately $70,000 to develop new Guidelines for the Regulations.

In addition, Environment Canada will incur costs of $27,000 to conduct a series of notifier information sessions and $350,000 to train enforcement officers on the new structure and changes in the Regulations.

Because the assessment periods in the Regulations have been reorganized to more accurately reflect the length of time actually required to assess each type of chemical and polymer, the assessment costs to Environment Canada and Health Canada associated with each notification are not expected to increase.

Insofar as the Regulations alter the total volume or distribution of notifications submitted, Environment Canada and Health Canada will experience changes to their assessment costs. There are no forecasts of how the Regulations may affect the distribution of notifications received, so the cost implication (if any) is unknown.

Impacts on Competitiveness

Provisions within the Regulations provide an incremental improvement from the NSNR for notifiers in terms of competitiveness.

The Regulations simplify the notification requirements for non-commercial and other special categories of chemicals and polymers. Specifically, the definitions for research and development and product development are amalgamated, and the notification requirements for site-limited intermediate and export-only substances are reduced to bring them in line with those for the newly-created category of research and development. Further, notifiers of these special category chemicals and polymers are only required to submit test data that are already available to them.

The tiered approach to notification introduced in the NSNR is maintained, allowing the level of testing to increase in step with increases in usage and commercial viability. In addition, information requirements and assessment periods are optimized to enable notifiers to bring some of their products to market more cheaply and/or more quickly than is possible under the NSNR. When it is possible to do so without jeopardizing environmental and human health objectives, information requirements are delayed to higher quantity triggers to render the cost of testing more affordable to notifiers.

Net Benefits

Because monetized estimates are not available for all of the incremental benefits and costs, it is not possible to accurately estimate the overall net benefit of the Regulations.

The monetized estimates that are available indicate an annual net cost to notifiers of $642,000 and one-time costs to the Government of Canada of $447,000. Assuming the estimated volume of notifications remains stable for the first five years after implementation of the Regulations, the overall result would be a net present value of -$3,054,000 (2004 Canadian dollars) using a discount rate of five percent over a five-year period. Sensitivity analysis at three and seven percent yields net present values of -$3,276,000 and -$2,853,000, respectively. These figures underestimate primarily the incremental benefits of the Regulations, as they do not account for the impacts discussed qualitatively in this Regulatory Impact Analysis Statement (RIAS).

As stated earlier, the net benefits represent a conservative estimate of the incremental costs and benefits. The annual net costs calculated above could turn into annual net benefits with a net present value of approximately $5,137,000 using a discount rate of

five percent, if 80 percent of the chemicals as presented in Table 4 shift from non-NDSL to NDSL. Sensitivity analysis at three and seven percent yields a net present value of $5,557,000 and $4,759,000, respectively.

Consultation

Consultation prior to pre-publication of the proposed Regulations in the *Canada Gazette*, Part I

In June 1999, Environment Canada and Health Canada contracted an independent facilitator and a Secretariat to design and implement a multistakeholder consultative process for the NS Program and the chemicals and polymers portion of the NSNR. A multistakeholder Table was convened to guide the consultative process, including representatives from Environment Canada, Health Canada, Industry Canada, the Industry Coordinating Group for the *Canadian Environmental Protection Act, 1999* (see footnote 5), and public advocacy groups for the environment, consumers, public health and labour.

At the outset, the Table identified the objectives and scope of the consultations and agreed to a set of procedural rules to guide its deliberations. Between November 1999 and August 2001, the Table conducted eight meetings and numerous subcommittee and other meetings to identify, discuss and develop consensus recommendations on ways to improve the NSNR and the NS Program.

The Table's deliberations and subsequent recommendations were structured according to five themes: (1) improving the environmental and health assessments for new substances; (2) the regulatory framework; (3) transparency of the NSN regulatory process; (4) improving responsiveness of the NSNR and NS Program in the global context; and (5) service delivery. The Final Report of the Multistakeholder Consultations, published in May 2002, outlines 76 consensus-based recommendations produced by the multistakeholder and articulates the differing views of stakeholders on issues where consensus was not reached, despite best efforts.

The Final Report (see footnote 6) was reviewed through an iterative process involving other government departments and agencies and a response team comprised of government officials not directly involved with the consultations. Participants included: Industry Canada, the Department of Fisheries and Oceans, the Pest Management Regulatory Agency, Natural Resources Canada, Agriculture and Agri-Food Canada, the Privy Council Office, the Canadian Food Inspection Agency, and the Department of National Defence. In September 2002, Environment Canada and Health Canada published a document (see footnote 7) responding to each of the recommendations, and outlined a workplan and timeline for their implementation.

Those consensus recommendations that are regulatory in nature are implemented in the Regulations. To ensure consistency with the recommendations, the Regulations are based on both the Final Report and Response Document. In addition, stakeholders were given the opportunity to review and comment on drafts of the proposed Regulations in June 2003 and again in March 2004. Industry and public advocacy groups were satisfied with the outcome of this consultation, and look forward to the timely implementation of recommended changes to the existing NSNR.

Since the Environment Canada/Health Canada response document was published, it has become apparent that certain regulatory-related recommendations will not be realized in the Regulations.

- Recommendation 5 – Endocrine disrupting substances (EDS): Test protocols for EDS are too preliminary to be included in the Regulations. Once suitable test protocols are available, Environment Canada and Health Canada will integrate them into the NS Program by the most appropriate mechanism.
- Recommendation 16 – Guidelines: Legal considerations prevent the Regulations from including references to the associated Guidelines.
- Recommendation 55 – Waivers: Environment Canada and Health Canada were unable to identify purposes of use and/or categories of substances for which certain exposure or effect information could be systematically waived under paragraph 81(8)(*b*) of the Act. Consequently, the Regulations do not include provisions to facilitate requests for waivers. Waivers will continue to be determined on a case-by-case basis, although some examples of the application of waivers may be provided in the Guidelines.

Comments received during the comment period following pre-publication in the *Canada Gazette*, Part I

The Regulations were pre-published in the *Canada Gazette*, Part I on October 30, 2004. The pre-publication was followed by the 75-day public review period during which five written comments were received, including four submissions from industry and industry associations and one from an environmental non-governmental orgganization. In general the Regulations received wide support and positive feedback. Several comments provided during the public review period were reiterating the consensus recommendations reached at the Multistakeholder Consultations. All the comments received during the public review period were considered and taken into account during the development of the final regulatory text.

Some revisions have been made to the Regulations and further explanations of the terminology used and regulatory requirements of the Regulations is provided in the revised *Guidelines for the Notification and Testing of New Substances: Chemical and Polymers.*

A detailed report on the comments received and Environment Canada's and Health Canada's responses has been posted on EC's Web site (see footnote 8) along with the revised draft of the Regulations. The main comments and EC's and HC's response have been categorized into the following broad areas:

- Policy Issues
- Administrative Issues
- Technical Issues

The majority of the comments received focused on issues and concerns raised during the 1999 to 2001 Multistakeholder Consultations. EC and HC maintain their proposals with regards to the issues as the changes presented in the Regulations were consistent with the 76 consensus-based recommendations as outlined in the *Final Report of the Multistakeholders Consultations*. However, some of the comments which required further explanations, clarification and revisions to the regulatory text as well as comments which

had not been addressed during the 1999 to 2001 Multishakeholder Consultations are given below.

It should also be noted that there was a typographical error in the Benefits and Costs section of the RIAS that was pre-published in the *Canada Gazette*, Part I. The correction reduces the total net cost figure (calculated using a seven percent discount rate) from -$22,853,000 to -$2,853,000. Also, some sections of the RIAS have been supplemented with additional information to clarify and explain the incremental benefits and costs of these Regulations.

Policy Issues

- Clarification of what is meant by "the chemical is present in products to which the public may be significantly exposed" in the guidelines or explanatory notes was requested. It was also recommended that EC and HC review the need for using "significant exposure" in the Regulation. Clarification of the meaning of "significantly exposed" will be provided in the revised *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*. EC and HC believe that the word "significant" is important in the Regulations to discriminate the different levels of exposure.
- A recommendation was made for a single window submission for all New Substance Notifications including notifications for substances in products that are regulated under the *Food and Drug Act* (F&DA). EC and HC have initiated an Option Analysis process with regard to the regulatory framework of the F&DA substances. The option chosen will determine the notifications procedures over the long term. In addition, EC and HC are willing to examine the current arrangement again in the future.
- One of the comments supported the use of a sunrise system for regulating chemicals and polymers as this approach requires key test data at the lowest volumes possible to prevent the release of harmful substances. The principle of this system is gauged on hazard assessment as opposed to risk assessment and considers only the substance's inherent toxicity and not the exposure. In responding to the comment, EC and HC point out that the revised Act did not adopt a hazard-based definition; rather an assessment of toxicity based on section 64 of the Act calls for a consideration of both intrinsic properties and exposure potential of the substance being assessed. The NSN Regulations are based on the intent of the Act, and therefore adopt the same approach. Furthermore, the departments believe that implementing the sunrise system would not lead in an optimization of the resources both on the industry and the government side. EC and HC view is that the quantity-triggered tiered approach does not compromise the protection of the environment and human health.
- One of the comments sought clarification on paragraph 84(1)(*c*) of the Act, citing it as lacking transparency as to what is sufficient to trigger a suspicion of toxicity. It was suggested that either the authority of the regulators to require additional information as a result of suspicion of toxicity be clarified or additional tests in the schedules be requested to ensure that sufficient data is available to demonstrate the risk. In response, the departments will continue to use this provision under similar circumstances to those under which it was used in the past, as per its intended use (i.e. when the departments have concerns about the hazards of a substance but are unable to quantify the risks). The departments also mentioned that suspicion of toxicity is based on expert judgment and is better treated on a case by case basis and that requiring further tests for all notifications would not be cost effective.

- A recommendation was made for reinserting certain testing requirements of the existing NSNR and subjecting export-only substances to the same level of scrutiny as substances destined for the domestic market. EC and HC in response stated that the departments will conduct risk assessment of the substance on the basis of the information that they receive. Analogue data can be used and modeling can be performed based on the structure information. The departments expect that the same level of environment and human health protection will be maintained with the new approach. Export-only substances and site-limited intermediate also need to satisfy the "contained" criteria in order to fall under sections 5 and 6 of the Regulations. As defined, a maximum of one kg per day per site can be released in the aquatic environment after wastewater treatment. Substances with releases higher than one kg per day per site will be subjected to the regular notification requirements, even though they are manufactured or imported for export-only. It was also pointed out by EC and HC that Canada is the only jurisdiction that requires notification of substances intended to be manufactured or imported for export-only purposes.
- A comment voiced the concern for addressing the exposure information relating to children more comprehensively and asked for expanding the data requirements to include neurotoxicological testing. EC and HC maintain that the Regulations reflect the 76 consensus recommendations that came out of the Multistakeholder Consultations. Moreover, the departments feel that exposure scenarios based on the collected information will be undertaken during the assessment process of the substance. If the substance is found to be potentially harmful for children appropriate risk management measures can then be taken.

Technical Issues

- An explanation of the purpose of the hatched box in the flowcharts 2 and 3 of the Regulations was requested. The hatched boxes were used in the Regulations to emphasize the potential additional information requirements set out in subsections 7(2) and 7(3) of the Regulations. The departments have added an explanation of the hatched box in Schedule 12 of the Regulations.
- A comment suggested that the net impact on testing costs associated with the elimination of two physical/chemical tests and the addition of tests for environmental fate and acute eco-toxicity would be greater than what has been calculated in the benefit-cost analysis. The testing costs for the Regulations were derived independently and were calculated based on standard US EPA data and methods to assess the affordability of changes in testing requirements. This approach provides a common basis for comparing the previous and proposed testing requirements. Actual testing costs may be higher or lower depending on the circumstances.
- An elaboration of the relationship between the Regulations and the existing international data-sharing arrangements was also requested. In response, EC and HC stated that the Four Corners Arrangement or any other international agreement, to which Canada is a party, would provide notifiers with the opportunity to submit relevant data used for other purposes to meet the regulatory requirements specified in the Schedules of these Regulations. This would avoid duplication of effort and lower the costs to the notifiers.
- Clarifications were requested about the pre-notification consultation (PNC) as being an optional step in the notification process. EC and HC have revised the text of the Regulations to clarify the purpose of PNC. The regulatory text now reads "the new substances pre-notification consultation number, if it has been assigned, and if known". Further clarifications are provided in the *Guidelines for*

the Notification and Testing of New Substances: Chemical and Polymers, as suggested.

- It was also pointed out in one comment that the regulatory text concerning the three kg per day per site cut-off fails to reference the added stipulation that the volume should be calculated "including envisioned future uses by multiple users and/or a variety of applications", and that this oversight should be corrected. EC has taken note of the issue. However, it was decided that the Regulations would not be changed, rather further explanation are provided in the *Guidelines for the Notification and Testing of New Substances: Chemical and Polymers,* as suggested.
- An inconsistency in section 18 of the Regulations with the conditions of adding a polymer to the DSL through the Notice of Excess Quantity (NoEQ) route was pointed out in one of the comments. The conditions of eligibility allow a DSL substance for DSL listing upon completing the prescribed information and either exceeding 10,000 kg/year or commencing import/manufacture. EC and HC recognize the inconsistency and have revised section 18 of the Regulations to align the conditions for DSL listing with it.
- Clarifications on the procedures were sought for NDSL substance once they are listed on the DSL and a user subsequently exceeds the 50,000 kg/year manufacture or import limit and either high environmental release or significant human exposure condition. The departments point out that substances on the DSL are not subject to NSNR unless they are subject to a Significant New Activity (SNAc). SNAc are used where the potential for a substance to be toxic in applications other than those proposed by the notifier, is unknown. The SNAc requires notification where the proposed activities are not within the scope of the permitted activities defined in the SNAc Notice.
- Concern was voiced with regard to inadequate monitoring and enforcement mechanism of substances after they have been added on the DSL, citing that in some cases the substances (e.g. the Reduced Regulatory Requirement polymers) become eligible for DSL while there are still limitations imposed upon its use. It was suggested that a combination of SNAcs and/or "tags" be used to track substances after they have been listed on the DSL. EC and HC stated that flags are now included on the DSL for the Reduced Regulatory Requirement polymer and will be monitored by the compliance monitoring and enforcement group as is the current practice for SNAc's. More detailed definitions of SNAc and flags are provided in the *Guidelines for the Notification and Testing of New Substances: Chemical and Polymers.*

Administrative Issues

- Clarifications were requested for the definition of substances that were exempted or excluded from notification under the Regulations as well as clarification on amphoteric polymer, export-only substances, impurities and water solubility versus water extractability. Although definitions for these substances were not included in the text of the Regulations, the departments provide further explanations in the *Guidelines for the Notification and Testing of New Substances: Chemical and Polymers.*

Compliance and Enforcement

Since the Regulations are made under subsection 89(1) of the Act, enforcement officers will, when verifying compliance with the Regulations, apply the Compliance and

Enforcement Policy implemented under the Act. The policy also sets out the range of possible responses to alleged violations: warnings, directions, environmental protection compliance orders, ticketing, ministerial orders, injunctions, prosecution, and environmental protection alternative measures (which are an alternative to a court trial after the laying of charges for a CEPA 1999 violation). In addition, the policy explains when Environment Canada will resort to civil suits by the Crown for costs recovery.

When, following an inspection or an investigation, an enforcement officer discovers an alleged violation, the officer will choose the appropriate enforcement action based on the following factors:

- Nature of the alleged violation: This includes consideration of the damage, the intent of the alleged violator, whether it is a repeat violation, and whether an attempt has been made to conceal information or otherwise subvert the objectives and requirements of the Act.
- Effectiveness in achieving the desired result with the alleged violator: The desired result is compliance within the shortest possible time and with no further repetition of the violation. Factors to be considered include the violator's history of compliance with the Act, willingness to cooperate with enforcement officers, and evidence of corrective action already taken.
- Consistency: Enforcement officers will consider how similar situations have been handled in determining the measures to be taken to enforce the Act.

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Footnote a

S.C. 2004, c. 15, s. 31

Footnote b

S.C. 1999, c. 33

Footnote c

S.C. 1999, c. 33

Footnote 1

Sections 84 and 85 of the *Canadian Environmental Protection Act, 1999* provide a comprehensive overview of the risk management options available.

Footnote 2

For a more detailed description of the new substances notification and assessment process, and the specific types of substances to which it applies, please refer to the Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers (available online at: www.ec.gc.ca/substances/nsb/download/cpg0901.pdf).

Footnote 3

Economic instruments were not a suitable alternative for achieving the goals of the program.

Footnote 4

When the NSNR were amended in 1997 to include organisms, the "Substances New to Canada" provisions in Part II of the *Canadian Environmental Protection Act* (CEPA) of 1988 provided the authority to regulate both new organisms and new chemicals and polymers. Following the first five-year review of CEPA, the authority to regulate new substances was divided between Part 5 and Part 6 of the Act, with Part 6 focusing solely on living organisms, which are defined in this part as animate products of biotechnology.

Footnote 5

The Industry Coordinating Group is a group of associations which represents over 800 Canadian companies that produce or use chemical substances in Canada, and are therefore subject to the new substances notification and assessment process.

Footnote 6

The Final Report is available online at: www.ec.gc.ca/ceparegistry/documents/ part/nsnr-nsp_con/nsnr_nsp_e.pdf

Footnote 7

The Response Document is available at: www.ec.gc.ca/ceparegistry/documents/

regs/nsnp_nsp/nsnp_resp_e.pdf

Footnote 8

http://www.ec.gc.ca/substances/nsb/eng/reg_e.htm

NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

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Important notices