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Revised Draft: Prohibition Of Certain Toxic Substances Regulations, 2005

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Please find below, **for information purposes only**, a revised draft of the proposed *Prohibition of Certain Toxic Substances Regulations, 2005*. The proposed Regulations were pre-published in the *Canada Gazette*, Part I, on April 3, 2004 (under the title *Total, Partial or Conditional Prohibition of Certain Toxic Substances Regulations*) for a 60-day comment period required under the *Canadian Environmental Protection Act, 1999*. The comment period ended on June 2, 2004. Comments received during that period were considered in the preparation of this revised draft. Please note that the information contained in this document is still subject to change pending approval. Once final approval of the Regulations is received, the Regulations will be published in Part II of the *Canada Gazette*.

APPLICATION

1. Subject to sections 2 and 3, these Regulations apply to substances that are both specified on the List of Toxic Substances in Schedule 1 to the *Canadian Environmental Protection Act, 1999* and set out in either Schedule 1 or 2 to these Regulations, referred to in these Regulations as "toxic substances".

EXCEPTIONS

2. These Regulations do not apply to any toxic substance set out in either Schedule 1 or 2 that is

- a. contained in a hazardous waste, hazardous recyclable material or non-hazardous waste to which Division 8 of Part 7 of the *Canadian Environmental Protection Act, 1999* applies;
- b. contained in a control product within the meaning of section 2 of the *Pest Control Products Act*; or
- c. present as a contaminant in a chemical feedstock used in a process from which there are no releases of the toxic substance and provided that the toxic substance is destroyed or completely converted in that process to a substance that is not a toxic substance set out in either Schedule 1 or 2.

3. (1) These Regulations, except subsections (2), (3) and (4), do not apply to any toxic substance set out in either Schedule 1 or 2 or to any mixture or product containing any such toxic substance that is for use

- a. in a laboratory for analysis;
- b. in scientific research; or
- c. as a laboratory analytical standard.

(2) Any person that intends to use a toxic substance, mixture or product referred to in subsection (1) for a use referred to in that subsection shall, if the quantity of the toxic substance will exceed 10 g in any calendar year, submit to the Minister, at least 30 days before the day on which the person begins using the substance, mixture or product, the information set out in Schedule 3.

(3) Any person that, at the time of coming into force of these Regulations, is using a toxic substance, mixture or product referred to in subsection (1) for a use referred to in that subsection shall, if the quantity of the toxic substance exceeded 10 g in the calendar year immediately preceding the coming into force of these Regulations, submit to the Minister, within 60 days after the date of coming into force of these Regulations, the information set out in Schedule 3.

(4) If, after the coming into force of these Regulations, a toxic substance is added to Schedule 1 or 2, any person that, at the time of the coming into force of the Regulations adding the toxic substance, is using the toxic substance or a mixture or product containing that toxic substance for a use referred to in subsection (1) shall, if the quantity of the toxic substance exceeded 10 g in the calendar year immediately preceding the coming into force of the Regulations adding the toxic substance, submit to the Minister, within 60 days after the date of coming into force of those Regulations, the information set out in Schedule 3.

PROHIBITIONS

4. Subject to section 6, no person shall manufacture, use, sell, offer for sale or import a toxic substance set out in Schedule 1 or a mixture or product containing any such toxic substance unless the substance is incidentally present.

5. Subject to section 6, no person shall manufacture, use, sell, offer for sale or import

- a. a toxic substance set out in column 1 of Part 1 of Schedule 2 if it is present, incidentally or not, in a mixture or product set out in column 2 and if the concentration of the toxic substance in the mixture or product exceeds the limit set out in column 3; or
- b. a toxic substance set out in column 1 of Part 2 of Schedule 2 or a mixture or product containing the toxic substance if the toxic substance, mixture or product is designed for uses other than the uses set out in column 2 unless the substance is incidentally present.

PERMITS

6. (1) Any person that, at the time of coming into force of these Regulations, is manufacturing, using, selling or offering for sale a toxic substance referred to in either section 4 or 5 or a mixture or product containing such a substance or imports such a toxic substance, mixture or product may continue that activity if that person has been issued a permit under subsection (4).

(2) In the case of a toxic substance added to Schedule 1 and referred to in section 4, any person that, at the time of coming into force of the Regulations adding the toxic substance, is carrying out an activity referred to in subsection (1) requires a permit issued under subsection (4) to continue that activity. This rule also applies to any such person in the case of a toxic substance added to Schedule 2 and referred to in section 5.

(3) An application for a permit shall be submitted to the Minister and contain the information set out in Schedule 4.

(4) Subject to subsection (5), the Minister shall issue the permit if the following conditions are met:

- a. there is no technically or economically feasible alternative or substitute available to the applicant, other than a substance regulated under these Regulations, for the toxic substance;
- b. the applicant has taken all necessary measures to minimize or eliminate any harmful effect of the toxic substance on the environment and human health; and
- c. a plan has been prepared respecting the toxic substance, identifying the measures to be taken by the applicant so that the applicant's continued activity will be in compliance with these Regulations, and the period within which the plan is to be fully implemented does not exceed three years from the date on which a permit is first issued to the applicant.

(5) The Minister shall refuse to issue a permit if the Minister has reasonable grounds to believe that the applicant has provided false or misleading information in support of their application.

(6) A permit issued under this section expires 12 months after the day on which it is issued and may, upon application, only be renewed twice for the same purpose or use of the substance.

(7) The Minister shall revoke a permit if the conditions set out in paragraphs (4)a. to c. are no longer met or if the Minister has reasonable grounds to believe that the permit holder has provided false or misleading information to the Minister.

(8) The Minister shall not revoke a permit unless the Minister has provided the permit holder with

- a. written reasons for the revocation; and
- b. an opportunity to be heard, by written representation, in respect of the revocation.

REPORTS

7. Every person that manufactures or imports a toxic substance set out in column 1 of Part 3 of Schedule 2 or a mixture or product containing, whether incidentally or not, any such toxic substance shall submit to the Minister the information set out in Schedule 5 within three months after the end of the calendar year during which the toxic substance, mixture or product was manufactured or imported if, in that calendar year,

- a. the quantity of the toxic substance was equal to or greater than that set out in column 2 of that Part, if any;
- b. the mixture or product contained the toxic substance in an average concentration equal to or greater than that set out in column 3 of that Part, if any; or
- c. the quantity of the toxic substance and its concentration in the mixture or product were equal to or greater than those set out in column 4 of that Part, if any.

TESTING REQUIREMENTS

8. Any concentration or quantity required to be determined under these Regulations shall be determined, in accordance with generally accepted standards of scientific practice, by a laboratory that is accredited under the International Organization for Standardization standard ISO/IEC 17025: 1999, entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time, or by a laboratory that meets an equivalent standard.

CERTIFICATION

9. Any information required to be submitted to the Minister under these Regulations shall be submitted in a form determined by the Minister and accompanied by a certification, dated and signed by the person referred to in those provisions, or the person authorized to act on their behalf, that the information is accurate and complete.

RECORD KEEPING

10. (1) Every person that submits information to the Minister under these Regulations shall keep a copy of that information, the certification and any documents supporting the information, including test data, if applicable, for a period of at least five years beginning on the date of the submission of the information.

(2) The information, certification and supporting documents shall be kept at the person's principal place of business in Canada or, on notification to the Minister, at any other place in Canada where the information, certification, documents and test data can be inspected.

REPEAL

11. The *Prohibition of Certain Toxic Substances Regulations, 2003* are repealed.

COMING INTO FORCE

12. These Regulations come into force three months after the day on which they are registered.

SCHEDULE 1 (Sections 1 to 4 and 6)

PROHIBITED TOXIC SUBSTANCES	
Item	Toxic Substances
1.	Dodecachloropentacyclo [5.3.0.0 ^{2,6} .0 ^{3,9} .0 ^{4,8}] decane (Mirex)
2.	Polybrominated Biphenyls that have the molecular formula C ₁₂ H _(10-n) Br _n in which "n" is greater than 2
3.	Polychlorinated Terphenyls that have the molecular formula C ₁₈ H _(14-n) Cl _n in which "n" is greater than 2
4.	Bis(chloromethyl) ether that has the molecular formula C ₂ H ₄ Cl ₂ O
5.	Chloromethyl methyl ether that has the molecular formula C ₂ H ₅ ClO
6.	(4-Chlorophenyl) cyclopropylmethanone, O-[(4-nitrophenyl)methyl] oxime that has the molecular formula C ₁₇ H ₁₅ ClN ₂ O ₃
7.	N-Nitrosodimethylamine, which has the molecular formula C ₂ H ₆ N ₂ O
8.	Hexachlorobutadiene, which has the molecular formula C ₄ Cl ₆
9.	Dichlorodiphenyltrichloroethane (DDT), which has the molecular formula C ₁₄ H ₉ Cl ₅

SCHEDULE 2
(Sections 1 to 3 and 5 to 7)

CONCENTRATION LIMITS, PERMITTED USES AND REPORTING THRESHOLDS

PART 1 CONCENTRATION LIMITS				
Item	Toxic Substance	Mixture or Product Containing the Toxic Substance	Concentration Limit of the Toxic Substance	
1.	Hexachlorobenzene	(a) Trichloroethylene	20 ppb	
		(b) Tetrachloroethylene	20 ppb	
		(c) Tetrachloromethane	20 ppb	
		(d) Magnesium salt (by-product from the magnesium industry)	20 ppb	
		(e) Magnesium sludge (by-product from the magnesium industry)	20 ppb	
		(f) Hydrochloric acid (by-product)	20 ppb	
		(g) Ferric chloride	20 ppb	
		(h) Ferrous chloride	20 ppb	
PART 2 PERMITTED USES				
Item	Toxic Substances	Permitted Uses		
1.	Benzidine and benzidine dihydrochloride, that have the molecular formula C ₁₂ H ₁₂ N ₂ and C ₁₂ H ₁₂ N ₂ •2HCl, respectively	(a) Staining for microscopic examination, such as immunoperoxidase staining, histochemical staining or cytochemical staining		
		(b) Reagent for detecting blood in biological fluids		
		(c) Niacin test to detect some micro-organisms		
		(d) Reagent for detecting chloralhydrate in biological fluids		
PART 3 REPORTING THRESHOLDS				
Item	Toxic Substance	Annual Quantity	Average Annual Concentration	Annual Quantity and Average Annual Concentration
1.	Hexachlorobenzene			10 g and 10 ppb
2.	Benzidine and benzidine dihydrochloride, that have the molecular formula C ₁₂ H ₁₂ N ₂ and C ₁₂ H ₁₂ N ₂ •2HCl, respectively	1 kg		

SCHEDULE 3 (Subsections 3(2) to (4))

INFORMATION RELATED TO THE USE OF CERTAIN TOXIC SUBSTANCES IN A LABORATORY FOR ANALYSIS, FOR SCIENTIFIC RESEARCH OR AS A LABORATORY ANALYTICAL STANDARD

1. Information respecting the laboratory where a toxic substance or a mixture or a product containing it will be or is being used:

- a. the name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the laboratory; and
- b. the name, title, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the person authorized to act on behalf of the laboratory, if any.

2. Information respecting each toxic substance set out in Schedule 1 or 2, and each mixture or product containing the toxic substance:

- a. the name of the toxic substance and the name of the mixture or product containing the toxic substance, if applicable;
- b. the anticipated period of its use;
- c. the estimated quantity to be used in a calendar year and the unit of measurement; and
- d. the identification of each proposed use and each actual use, as the case may be.

SCHEDULE 4 (Subsection 6(3))

INFORMATION TO BE CONTAINED IN AN APPLICATION FOR A PERMIT

1. Information respecting the applicant:

- a. their name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any; and
- b. the name, title, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the person authorized to act on behalf of the applicant, if any.

2. In the case of a toxic substance referred to in section 4 of these Regulations or a mixture or product containing any such toxic substance, the following information:

- a. the name of each toxic substance and the name of each mixture or product containing the toxic substance, if applicable;
- b. the estimated quantity to be manufactured, used, sold, offered for sale or imported in a calendar year and the unit of measurement;
- c. the identification of each proposed use, if known; and
- d. if the applicant is a manufacturer, seller or importer, the name, civic and postal address, e-mail address, if any, telephone number and fax number, if any, of each person in Canada to whom the applicant intends to sell a toxic substance or a mixture or product containing such a toxic substance and the identification of each toxic substance, mixture or product.

3. In the case of a toxic substance referred to in section 5 of these Regulations or any mixture or product containing any such toxic substance, the following information:

- a. the name of the toxic substance and the name of the mixture or product containing the toxic substance, if applicable;
- b. in the case of a toxic substance set out in column 1 of Part 1 of Schedule 2, the concentration of the toxic substance in the mixture or product;

- c. the estimated quantity to be manufactured, used, sold, offered for sale or imported in a calendar year and the unit of measurement;
- d. the identification of each proposed use, if known; and
- e. if the applicant is a manufacturer, seller or importer, the name, civic and postal address, e-mail address, if any, telephone number and fax number, if any, of each person in Canada to whom the applicant intends to sell a toxic substance or a mixture or product containing such a toxic substance and the identification of each toxic substance, mixture or product.

4. Evidence that there is no technically or economically feasible alternative or substitute available to the applicant, other than a substance regulated under these Regulations, for the toxic substance.

5. Evidence that explains what measures have been taken to minimize or eliminate any harmful effect of the toxic substance on the environment and human health.

6. A description of the plan prepared respecting the toxic substance identifying the measures to be taken so that the applicant's continued activity will be in compliance with these Regulations as well as the period within which the plan is to be implemented.

SCHEDULE 5 (Section 7)

INFORMATION RELATED TO THE MANUFACTURE OR IMPORT OF TOXIC SUBSTANCES

1. Information respecting the manufacturer or importer:

- a. their name, civic and postal addresses of principal place of business, e-mail address, if any, telephone number and fax number, if any; and
- b. the name, title, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the person authorized to act on behalf of the manufacturer or importer, if any.

2. Information respecting each toxic substance set out in column 1 of Part 3 of Schedule 2 and each mixture or product containing the toxic substance manufactured or imported during a calendar year:

- a. the name of the toxic substance and the name of the mixture or the product containing the toxic substance, if applicable;
- b. the calendar year;
- c. the total quantity manufactured, and the unit of measurement;
- d. the total quantity imported, and the unit of measurement;
- e. the quantity sold in Canada, and the unit of measurement;
- f. the identification of each proposed use of the toxic substance and the mixture or product containing the toxic substance, if applicable;
- g. the annual average concentration, if applicable;
- h. the analytical method used to determine the concentration of the toxic substance in the mixture or product, if applicable; and
- i. the analytical method detection limit used to determine the concentration of the toxic substance in the mixture or product, if applicable.

3. The name, civic and postal address, e-mail address, if any, telephone number and fax number, if any, of each person in Canada to whom the manufacturer or importer sold a toxic substance set out in column 1 of Part 3 of Schedule 2 or a mixture or product containing such a toxic substance and the identification of each toxic substance, mixture or product sold.

4. The name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the laboratory that determined the concentration of the toxic substance in the mixture or product, if applicable.