Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Discussion Document

DIS2003-02

Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products

The purpose of this document is to inform pesticide registrants and users, provinces, territories and stakeholders about, and solicit comments on, the Pest Management Regulatory Agency's (PMRA) proposal to implement elements of the Workplace Hazardous Material Information System (WHMIS) for pest control products. The new *Pest Control Products Act* (PCPA) requires that product safety information, including a Material Safety Data Sheet (MSDS), be provided to work places where a pesticide is used or manufactured (ss.8(3)). This document presents the proposed content of new regulations to specify the content and format of MSDSs and the means by which they would be provided to work places. It also presents proposed amendments to existing labelling regulations to include WHMIS-style hatched borders. There will be another, subsequent, opportunity to comment when the proposed regulations are pre-published in the Canada Gazette Part I.

Submit your comments within 30 days of publication of this proposal to the Publications Coordinator, PMRA. There will also be an opportunity to comment on the proposed regulations when they are pre-published in the Canada Gazette Part I.

(publié aussi en français)

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Requirement for MSDS

It is proposed to develop new regulations that would:

a) require that an MSDS be included with each container of a Commercial, Restricted or Manufacturing Class pest control product. An MSDS would also be required with the container of a technical grade active ingredient that is is used or manufactured in Canada.

b) require that the product name and registration number of the pest control product be provided on the MSDS and be expressed as on the container label.

c) specify the content and format of an MSDS.

d) require full disclosure on the MSDS of the identity and concentration of all active ingredients and of any formulants and contaminants of health or environmental concern that will be identified on the list established and maintained on the PMRA Web site, under the authority of s. 43(5)(b) of the new PCPA.

e) require disclosure on the MSDS of hazard information on both the pest control product and on individual active ingredients and formulants.

f) where Commercial, Restricted or Manufacturing Class pest control products are purchased in refillable containers, require the supplier to transmit to the purchaser a copy of a current MSDS, unless the purchaser has a current copy on hand.

g) require that the information on the MSDS be in English and in French.

Labelling changes

Schedule III of the Pest Control Products Regulations (PCPR) outlines the precautionary symbols and signal words necessary on the principal display panel of pest control products. To enhance the visibility of these symbols and signal words, it is proposed to revise existing labelling regulations to require that for all commercial, restricted and manufacturing class products:

a) the necessary precautionary symbols and signal words on the principal display panel be contained within a hatched border that is in a colour that contrasts with the background against which it appears and is as depicted in Schedule III of the Controlled Products Regulations under the *Hazardous Products Act*.

b) the precautions and first aid instructions on the secondary display panel be contained within a hatched border that is in a colour that contrasts with the background against which it appears and is as depicted in Schedule III of the Controlled Products Regulations.

c) a sentence be added to the "READ THE LABEL BEFORE USING" statement on the principal display panel of all Commercial, Restricted and Manufacturing Class products, "For additional information, refer to the MSDS".

The proposed requirements for MSDSs and package labels would be phased in over a five-year period, beginning six months after publication of the regulations in the Canada Gazette part II, as registrations are granted, amended or renewed. Beginning the implementation of WHMIS elements six months after the regulations are made would allow industry time to prepare for implementation.

1.0 Introduction

Consideration of workplace safety is a significant component of the regulation of pesticides under the *Pest Control Products Act* in Canada. Numerous mechanisms are in place to protect the health of individuals who may be exposed to pesticides through normal work activities. A major distinguishing feature between the regulation of pesticides and of other substances that are subject to the WHMIS program, is that all pest control products undergo pre-market assessment. Extensive health, environmental and value studies must be submitted to the PMRA before a pest control product can be considered for registration. Required studies typically include acute, short-term and long-term repeated exposure studies performed in animals to identify any potential health hazard. Reproductive and developmental toxicity studies, genotoxicity studies and lifetime cancer bioassays in two species are also typically required. In addition, worker exposure is assessed during all phases of application, as well as during post-application activities. All of these studies must be carried out to the detailed international specifications accepted by the PMRA including Good Laboratory Practice.

The PMRA carefully evaluates these studies and conducts rigorous scientific assessments. The result of these assessments is a determination regarding the acceptability of the health and environmental risks and the value of pesticides that are proposed for use in Canada. Exposure and potential risk to workers are important elements of this assessment. Detailed product safety information is provided to workers who handle and use pest control products through the product label and through provincial/territorial training programs.

The *Hazardous Products Act* (HPA) and the related *Controlled Products Regulations* (CPR) outline requirements for the transmission of hazard information for materials, unless excluded in the HPA, that are sold or imported for use in Canadian workplaces. The *Hazardous Products Act* is the federal statute which enables the implementation of the supplier/importer requirements of the Workplace Hazardous Materials Information System (WHMIS)—a system which balances workers' "right to know" with industry's right to protect trade secrets. The Minister of Health is responsible for the *Hazardous Products Act* and Controlled Products Regulations.

WHMIS is Canada's national workplace hazardous material information system. The prime objective of WHMIS is to provide relevant safety and health information to workers so that they can take the necessary precautions to avoid injury, illness and premature death while minimizing the economic impact on industry and the disruption of trade. The *Hazardous Products Act* ensures the systematic provision of appropriately labelled containers and the transmission of material safety data sheets from suppliers/importers to users in Canada. Co-ordinated federal, provincial and territorial WHMIS legislation requires employers to ensure that workplace products are properly labelled, that MSDSs are provided to workers and that workers are educated and trained in this information.

Exclusion of pesticides from WHMIS

When WHMIS was originally implemented, certain product categories subject to existing federal legislation (e.g. the PCPA) were excluded from all or some of the supplier and(or) employer requirements of the program. It was anticipated that extending WHMIS to these products at the outset would have required further study and possible amendments to other legislation leading to a lengthy delay in implementing the entire program. These exclusions were subject to review by a Parliamentary Committee to determine whether they should be retained or removed. For each of the product areas, a sectoral committee was established. The Sectoral Committee on Pesticides, chaired by the former federal Department of Agriculture and comprising representatives from industry, labour and the federal, provincial and territorial governments, was established to make recommendations to the Parliamentary Committee. In 1990, the sectoral committee recommended that the federal exclusion for pesticides be retained with the condition that a system of WHMIS equivalency be established under the *Pest Control Products Act* and that the hazard classification systems for WHMIS and pest control products be harmonized.

Pesticide Registration Review recommendations

The Pesticide Registration Review (PRR) Final Report (December 1990) endorsed the recommendations of the sectoral committee. Specifically, the PRR recommended that pesticide legislation include the following provisions:

- Material Safety Data Sheets (MSDS) meeting WHMIS standards be provided to workplaces where pesticides are used;
- pesticide labels be designed to provide WHMIS-style panels dealing with health and safety information; and
- employers be required to train workers who use pesticides.

Parliamentary Standing Committee on Consumer and Corporate Affairs and Government Operations

In 1992, the recommendations of the sectoral committee were also endorsed by the Parliamentary Standing Committee on Consumer and Corporate Affairs and Government Operations with the caveat that the benefits must outweigh the costs of implementation. In 1995, a cost/benefit analysis, initiated before the formation of the PMRA and completed according to Treasury Board policy, concluded that the costs of implementing the WHMIS requirements for pesticides outweighed the benefits at that time. The cost/benefit has now changed since the current proposal is to phase-in required labelling changes, in coordination with other labelling initiatives, versus the all-at-once changes which the study proposed. In addition, since the time of the study, various PMRA and industry initiatives have occurred that will lessen the impact of implementing the proposed changes. Material Safety Data Sheets have become commonplace for most Commercial, Restricted and Manufacturing Class products through the industry-driven Warehousing Standards initiative. WHMIS labelling changes will be implemented together with other labelling changes to minimize the overall costs involved with changing labels.

Parliamentary Standing Committee on Environment and Sustainable Development
In May 2000, the Standing Committee on Environment and Sustainable Development released a report entitled *Pesticides, Making the Right Choice for the Protection of Health and the Environment*. The report recommended that the current exemption of pesticides in the HPA be removed and that pesticides be required to meet WHMIS requirements. The government response indicated that a system of WHMIS equivalency under the PCPA, including WHMIS label standards and requirements for MSDS, would be considered to fulfil the objectives of the Standing Committee recommendation. This Discussion Document describes the proposed system.

The new *Pest Control Products Act*
The new PCPA was given Royal Assent on December 12, 2002. As indicated above, the new PCPA requires that product safety information, including an MSDS, be provided to workplaces where a pesticide is used or manufactured (ss.8(3)). It is proposed that new regulations be made to specify the content and format of MSDSs and the means by which they would be provided to work places and that existing labelling regulations be amended to include WHMIS-style hatched borders.

The proposed WHMIS-like system for pesticides will provide more regulatory oversight than required for those substances regulated under the *Hazardous Products Act*. The PMRA would require that an MSDS be submitted for registered pest control products and with the application to register a new pest control product. Based on pre-market assessments of health and environmental risk, the PMRA would be able to require changes if hazards were not reported accurately. Proposed labels are also submitted for review by the PMRA with registration applications. The *Hazardous Products Act*, does not require that the MSDS or label be reviewed by Health Canada scientists, with the exception of those products whose ingredients are submitted for non-disclosure under the *Hazardous Materials Information Review Act* (HMIRA). This constitutes approximately 2% of the MSDS utilized in workplaces in Canada.

The recommendations of the Sectoral Committee on Pesticides regarding the harmonization of hazard classes and hazard symbols for pest control products and workplace chemicals are under consideration and will not be implemented at this time. Given the commitment of the federal government, including both the WHMIS program and the Pest Control Products program, to adoption of the Globally Harmonized System (GHS) for the Classification and Labelling of Chemicals, the regulatory requirements of both programs are likely to converge when GHS is implemented. It is therefore possible that additional regulatory changes will be required in a few years, following a consultative process for determining how GHS should be implemented in these programs.

In the meantime, the PMRA recognizes the importance of providing information in a format that is similar to that used under WHMIS and is recognizable to workers. The existing infrastructure of worker safety information including the label and provincial certification programs, will be supplemented with additional information on an MSDS. The approach described herein is designed to meet the intent of the WHMIS program with requirements under the PCPA that are similar to those of the HPA, while minimizing costs to both government and industry.

2.0 Proposed changes

Requirement for MSDS
It is proposed to make new regulations that would:

a) require that an MSDS be included with each container of a Commercial, Restricted or Manufacturing Class pest control product. An MSDS would also be required with the container of a technical grade active ingredient that is is used or manufactured in Canada.

b) require that the product name and registration number of the pest control product be provided on the MSDS and be expressed as on the container label.

c) require that the MSDS be formatted under either the 16-heading format of the Globally Harmonized System or the very similar 16-heading format of the International Labour Organization (ILO), International Standards Organization, the European Commission and the American National Standards Institute. The 16 headings of the ILO/ISO/EC/ANSI and GHS formats are as follows:

ILO/ISO/EC/ANSI	Globally Harmonized System
1. Chemical product and company identification	1. Identification of substance/mixture and supplier
2. Composition/information on ingredients	2. Hazards identification
3. Hazards identification	3. Composition/information on ingredients
4. First-aid measures	4. First-aid measures
5. Fire-fighting measures	5. Fire-fighting measures
6. Accidental release measures	6. Accidental release measures
7. Handling and storage	7. Handling and storage
8. Exposure controls/personal protection	8. Exposure controls/personal protection
9. Physical and chemical properties	9. Physical and chemical properties
10. Stability and reactivity	10. Stability and reactivity
11. Toxicological information	11. Toxicological information
12. Ecological information	12. Ecological information
13. Disposal considerations	13. Disposal considerations
14. Transport information	14. Transport information
15. Regulatory information	15. Regulatory information
16. Other information	16. Other information

The required content for each of the 16 headings would include most of the sub-items of Schedule I, Column III of the Controlled Products Regulations. Where the registrant has no information that is applicable and available under one of the headings or sub-headings, the registrant would be required to state why no information is supplied, i.e., the MSDS must disclose “not available” or “not applicable”.

HEADING	SUB-HEADING
1. Chemical product and company identification	product trade name and Registration Number product use name, street address, postal code, and emergency telephone number of registrant and, if non-resident, of designated representative in Canada
2. Composition/information on ingredients	For each active ingredient and any formulants and contaminants that are on the list established and maintained under s. 43(5)(b) of the new PCPA: chemical name, common name if available, concentration and CAS No.
3. Hazards identification	list types of hazard for which product meets criteria
4. First-aid measures	necessary measures for: skin contact, eye contact, inhalation, ingestion
5. Fire-fighting measures	means of extinction nature of any hazardous combustion products flammability and under which conditions
6. Accidental release measures	leak and spill procedures
7. Handling and storage	precautions for safe handling conditions for safe storage
8. Exposure controls/personal protection	appropriate engineering controls personal protective equipment
9. Physical and chemical properties	physical state colour odour and odour threshold specific gravity vapour density (air=1) vapour pressure (mmHg) evaporation rate boiling point (°C) melting point/freezing point (°C) pH partition coefficient: n-octanol/water solubility in water sensitivity to static discharge, shock, vibration flash point (°C) upper and lower flammability (explosive) limits auto-ignition temperature (°C)

HEADING	SUB-HEADING
10. Stability and reactivity	chemical stability incompatible substances reactivity and under what conditions hazardous decomposition products
11. Toxicological information	probable routes of exposure exposure limits or biological limit values effects of short and long-term exposure including: - irritancy - skin and respiratory sensitization - carcinogenicity - reproductive toxicity - teratogenicity and embryotoxicity - mutagenicity numerical measures of toxicity (e.g. LD_{50}, LC_{50}, including species and route)
12. Ecological information	consistent with text on container label
13. Disposal considerations	consistent with text on container label
14. Transport information	any shipping information specific to product
15. Regulatory information	any safety, health or environmental regulations specific for the product
16. Other information	version control date(s) signature and attestation of registrant

An MSDS using the 16-heading ILO format is acceptable for WHMIS controlled products, provided that the required content specified under Schedule I, Column III of the Controlled Products Regulations is addressed.

(d) require full disclosure on the MSDS of the identity and concentration of all active ingredients and of any formulants and contaminants of health or environmental concern that will be identified on the list established and maintained on the PMRA Web site, under the authority of s.43(5)(b) of the new PCPA.

(e) require disclosure on the MSDS of hazard information on both the pest control product and on individual active ingredients and formulants. In the following table, a hazard in Column 1 must be identified under the heading “Hazards identification” if the product meets the criteria for the hazard in Column 2

Column 1: Type of hazard	Column 2: Criteria for requirement to list a hazard on MSDS under the heading "Hazards identification":
flammability corrosion acute toxicity irritation/damage to skin/eyes	if the symbol and(or) signal words for the hazard are required on the package label
compressed gas oxidizing material dangerously reactive material	if the pest control product (as a whole) meets respective criteria for the hazard in Controlled Products Regulations s.34 (compressed gas), s.42 (oxidizing material) or s.66 (dangerously reactive material)
chronic toxic effects teratogenicity embryotoxicity carcinogenicity reproductive toxicity respiratory tract sensitization skin sensitization mutagenicity	if either the pest control product (as a whole) or any contaminant or ingredient of the product meets respective criteria for the hazard in the Controlled Products Regulations s.52–59 and s.61–63

(f) where Commercial, Restricted and Manufacturing Class pest control products are purchased in refillable containers, require the supplier to transmit to the purchaser a copy of a current MSDS, unless the purchaser has a current copy on hand.

(g) require that the information on the MSDS be in English and in French. The MSDS will be part of the "label" of a pest control product, as defined in the PCPA.

For all MSDSs, registrants will be required to provide a detailed reference list of all literature consulted, existing in-house toxicology studies and documentation of any hazards found. The registrant will also be required to provide an attestation to the accuracy and completeness of all the information on the MSDS and to ensure that the MSDS is generally consistent and does not contradict any information on the container label. The PMRA will review elements of the MSDS for all new active ingredients and their associated end-use products at the time of petitioned registration. The PMRA will review the MSDSs of other products on a spot check basis, in order to verify the accuracy attested to by the registrant. In these instances, the registrant will be required to submit the articles and studies cited as references to verify the MSDS.

Labelling changes
Schedule III of the existing Pest Control Product Regulations outlines the precautionary symbols and signal words necessary on the principal display panel of pest control products. To enhance the visibility of these symbols and signal words, it is proposed that existing labelling regulations be amended to:

- Require that for all Commercial, Restricted and Manufacturing Class products, the necessary precautionary symbols and signal words on the principal display panel be contained within a hatched border that is in a colour that contrasts with the background against which it appears and is as depicted in Schedule III of the Controlled Products Regulations of the HPA.

- Require that the precautions and first aid instructions be contained within a hatched border that is in a colour that contrasts with the background against which it appears and is as depicted in Schedule III of the Controlled Products Regulations of the HPA.

- Require a sentence be added to the "READ THE LABEL BEFORE USING" statement on the principal display panel of all Commercial, Restricted and Manufacturing Class products, "For additional information, refer to the MSDS".

Trade secrets
Within the WHMIS program, the MSDS contents are prescribed by the *Controlled Products Regulations* under the *Hazardous Products Act* but suppliers of controlled products have the right to request exemption from disclosure of confidential information (trade secrets) and to appeal a negative decision on this request. The requests for exemption, which most often involve information about the ingredients of the product, are considered on a case-by-case basis.

Within the pesticide regulatory system, by contrast, the ingredient information that must be disclosed has been defined in legislation. According to the proposal described in this document, the Minister would be required to ensure that an MSDS discloses all active ingredients and all formulants and contaminants of health or environmental concern identified on the list established and maintained under the authority of s. 43(5)(b) of the new PCPA. A draft MSDS would be screened by the PMRA during the registration or amendment/renewal process and provision of the approved MSDS with the product packaging would become a condition of registration. An applicant would have the opportunity to make representations regarding the MSDS throughout the review process, as with any other aspect of their application.

Training of applicators and vendors

In 1995, to improve the consistency of pesticide educational programs across the country, the PMRA in conjunction with provincial/territorial regulatory authorities released the *Standard for Pesticide Education, Training and Certification in Canada*, for implementation across the country. The sectoral committee had endorsed the concept of a Standard. Since the time of the sectoral committee recommendations, the Standard was adopted by the provinces/territories and is approaching full implementation across the country. The National Standard applies strict certification/recertification criteria to the pesticide applicator and vendor training programs as well as defining the basic knowledge requirements for certified pesticide applicators and vendors. The PMRA continues to work co-operatively with the provinces/territories on developing and promoting high quality effective pesticide education programs for workers handling pesticides and to apply these programs to the broadest audience possible.

3.0 Enforcement

The PMRA would be responsible for enforcing compliance with the requirement that the approved MSDS and label are provided with each container of Commercial, Restricted or Manufacturing Class pest control product that is sold or imported into Canada. Provincial/territorial governments would be responsible for the WHMIS requirement that employers provide workers with access to the label and MSDS, as well as adequate training on health and safety information.

4.0 Implementation

The new PCPA received Royal Assent on December 12, 2002. To bring the new Act into force, existing regulations are being revised and certain new regulations will be made, including these proposed regulations for provision of product safety information to workplaces.

The proposed requirements for MSDSs and modifications to package labels would be phased in over a five-year period, beginning on a date six months after publication of the regulations in the Canada Gazette Part II. This means that all new product registration, amendment or product renewal which takes effect on or after that date would be subject to the proposed MSDS and labelling regulations. The requirements would apply to an amendment for emergency registration and to products which are subject to regulation under the PCPA, but which are exempt from registration requirements, e.g., products regulated under Schedule II of the PCP Regulations and the Own Use Import (OUI) Program, on January 1, 2010. Products which are not manufactured, imported, sold or used in Canada would be exempt from the proposed MSDS and labelling requirements.

Beginning implementation of WHMIS elements six months after the regulations are made would allow industry time to prepare for implementation. If some lead time was not provided, no registrations or amendments could be completed until MSDS and amended labels had been submitted and reviewed.

5.0 Invitation to comment

Please review the document and provide your written comments. The purpose of this document, in addition to outlining the proposed regulations, is to seek your comments regarding the implementation of such a system for the provision of product safety information to workplaces. As you review it and prepare your feedback, please consider the following:

- Explain your views as clearly and as concisely as possible.
- Be sure to distinguish between what you support and what you object to in the proposal.
- Provide the rationale for your views.
- Offer alternative ways to improve the proposal.
- Whenever possible, support your views and, in particular, concerns with facts, data or specific examples.
- Describe any assumptions that you used.
- If you have concerns regarding the potential burden or costs of implementing the proposal or certain aspects of it, please provide specific information about the nature of those burdens and costs, as well as an estimate of the costs, an explanation of how you arrived at the estimate, and any suggestions for how costs could be reduced or minimized.
- Provide copies of any technical information or data you used in your comments.
- Please include an electronic copy of your response to help us collate the comments received.

Submit your comments within 30 days of publication of this proposal to the Publications Coordinator, PMRA. There will also be an opportunity to comment on the proposed regulations when they are pre-published in the Canada Gazette Part I.

Appendix I

Referenced sections of the Controlled Products Regulations, Hazardous Products Act.

Schedule I	information to be disclosed on an MSDS
Schedule III	hatched borders
s.34	criteria for compressed gas
s.42	criteria for oxidizaing material
s.66	criteria for dangerously reactive material
s.52-59,61-63	criteria for health hazards other than acute toxicity and irritation/corrosion

SCHEDULE I

(s. 12)

INFORMATION TO BE DISCLOSED ON A MATERIAL SAFETY DATA SHEET

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Information in respect of Suggested controlled Item Category Headings products

	Column I	Column II	Column III
1.	Hazardous Ingredients	Hazardous Ingredients	(1) Information required by subparagraphs 13(*a*)(i) to (iv) of the Act (2) CAS registry number and product identification number (3) LD50 (species and route) (4) LC50 (species and route)
2.	Preparation Information	Preparation Information	(1) Name and phone number of the group, department or party responsible for the preparation of the material safety data sheet (2) Date of preparation of the material safety data sheet
3.	Product Information	Product Information	(1) Manufacturer's name, street address, city, province, postal code and emergency telephone number (2) Supplier identifier, the supplier's street address, city, province, postal code and emergency telephone number (3) Product identifier (4) Product use
4.	Physical Data	Physical Data	(1) Physical state (i.e. gas, liquid or solid) (2) Odour and appearance (3) Odour threshold (4) Specific gravity (5) Vapour pressure (6) Vapour density (7) Evaporation rate (8) Boiling point (9) Freezing point (10) pH (11) Coefficient of water/oil distribution

	Column I	Column II	Column III
5.	Fire or Explosion Hazard	Fire or Explosion Hazard	(1) Conditions of flammability (2) Means of extinction (3) Flash point and method of determination (4) Upper flammable limit (5) Lower flammable limit (6) Auto-ignition temperature (7) Hazardous combustion products (8) Explosion data--sensitivity to mechanical impact (9) Explosion data--sensitivity to static discharge
6.	Reactivity Data	Reactivity Data	(1) Conditions under which the product is chemically unstable (2) Name of any substance or class of substance with which the product is incompatible (3) Conditions of reactivity (4) Hazardous decomposition products
7.	Toxicological Properties	Toxicological Properties	(1) Route of entry, including skin contact, skin absorption, eye contact, inhalation and ingestion (2) Effects of acute exposure to product (3) Effects of chronic exposure to product (4) Exposure limits (5) Irritancy of product (6) Sensitization to product (7) Carcinogenicity (8) Reproductive toxicity (9) Teratogenicity (10) Mutagenicity (11) Name of toxicologically synergistic products
8.	Preventive Measures	Preventive Measures	(1) Personal protective equipment to be used (2) Specific engineering controls to be used (3) Procedures to be followed in case of leak or spill (4) Waste disposal (5) Handling procedures and equipment (6) Storage requirements (7) Special shipping information
9.	First Aid Measures	First Aid Measures	(1) Specific first aid measures

SCHEDULE III
(s. 20)
LABEL BORDER

GRAPHIC IS NOT DISPLAYABLE, SEE SOR/88-66, P. 584

CLASS A--COMPRESSED GAS

34. Any product, material or substance contained under pressure, including compressed gas, dissolved gas or gas liquefied by compression or refrigeration, that has any of the following characteristics shall be included in Class A--Compressed Gas listed in Schedule II to the Act:

(*a*) a critical temperature of less than 50°C (122°F);

(*b*) an absolute vapour pressure greater than 294 kilopascals (2.90 atmospheres) at 50°C (122°F);

(*c*) an absolute pressure in the cylinder or other pressure vessel in which it is packaged greater than 275±1 kilopascals (2.71±0.01 atmospheres) at 21.1°C (70°F) or 717±2 kilopascals (7.07±0.02 atmospheres) at 54.4°C (130°F); or

(*d*) in a liquid state, an absolute vapour pressure exceeding 275 kilopascals (2.71 atmospheres) at 37.8°C (100°F) as determined by the *Standard Test Method for Vapor Pressure of Petroleum Products (Reid Method)*, ASTM D323-82, dated August 27, 1982. SOR/97-543, s. 21.

CLASS C--OXIDIZING MATERIAL

42. Any product, material or substance shall be included in Class C--Oxidizing Material listed in Schedule II to the Act if

(*a*) it causes or contributes to the combustion of another material by yielding oxygen or any other oxidizing substance, whether or not the product, material or substance is itself combustible; or

(*b*) it is an organic peroxide that contains the bivalent 0-0 structure.

CLASS F--DANGEROUSLY REACTIVE MATERIAL

66. A product, material or substance shall be included in Class F--Dangerously Reactive Material listed in Schedule II to the Act if it

(*a*) undergoes vigorous polymerization, decomposition or condensation;

(*b*) becomes self-reactive under conditions of shock or increase in pressure or temperature; or

(*c*) reacts vigorously with water to release a gas that has an LC50 not exceeding 2,500 parts per million by volume of gas, when tested for four hours in accordance with OECD Test Guideline No. 403, "Acute Inhalation Toxicity", dated May 12, 1981.

Division 2: Materials Causing Other Toxic Effects

Subdivision A: Very Toxic Material

Pure Substances and Tested Mixtures

Chronic Toxic Effects

52. A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D -- Poisonous and Infectious Material if, in an animal assay for chronic toxic effects, it elicits a response of sufficient severity to threaten life or cause serious permanent impairment in a statistically significant proportion of the test population at

(*a*) a dose not exceeding 10 milligrams per kilogram of body weight of the animal per day when tested in accordance with

(i) OECD Test Guideline No. 408, "Subchronic Oral Toxicity--Rodent: 90-day", dated May 12, 1981,

(ii) OECD Test Guideline No. 409, "Subchronic Oral Toxicity--Non-Rodent: 90-day", dated May 12, 1981, or

(iii) the oral route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981;

(*b*) a dose not exceeding 20 milligrams per kilogram of body weight of the animal per day when tested in accordance with

(i) OECD Test Guideline No. 411, "Subchronic Dermal Toxicity: 90-day", dated May 12, 1981, or

(ii) the dermal route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981; or

(*c*) a concentration not exceeding 25 parts per million by volume of gas or vapour, or not exceeding 10 micrograms per litre or 10 milligrams per cubic metre of dust, mist or fume when tested in accordance with

(i) OECD Test Guideline No. 413, "Subchronic Inhalation Toxicity: 90-day", dated May 12, 1981, or

(ii) the inhalation route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981.

Teratogenicity and Embryotoxicity

53. (1) A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D--Poisonous and Infectious Material if, in an animal assay for teratogenicity and embryotoxicity, it is shown to cause injury to the embryo or fetus in a statistically significant proportion of the test population at a concentration that has no adverse effect on the pregnant female when tested in accordance with

(*a*) OECD Test Guideline No. 414, "Teratogenicity", dated May 12, 1981;

(*b*) OECD Test Guideline No. 415, "One-Generation Reproduction Toxicity", dated May 26, 1983; or

(*c*) OECD Test Guideline No. 416, "Two-Generation Reproduction Toxicity", dated May 26, 1983.

(2) In this section, "injury" includes death, malformation, permanent metabolic or physiological disfunction, growth retardation or psychological or behavioural alteration that occurs during pregnancy, at birth or in the postnatal period.

Carcinogenicity

54. A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D--Poisonous and Infectious Material if it is listed in

(*a*) section Ala, Alb or A2 of Appendix A of the *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment*, published by the ACGIH, as amended from time to time; or

(*b*) Group 1 or Group 2 in the *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*, published by the World Health Organization, as amended from time to time.

Reproductive Toxicity

55. A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D -- Poisonous and Infectious Material if

(*a*) there is evidence that shows that it causes sterility or an adverse effect on reproductive capability in persons following exposure to it in the work place; or

(*b*) sterility or an adverse effect on reproductive capability is shown in an animal assay for reproductive toxicity carried out in accordance with

(i) OECD Test Guideline No. 415, "One-Generation Reproduction Toxicity", dated May 26, 1983, or

(ii) OECD Test Guideline No. 416, "Two-Generation Reproduction Toxicity", dated May 26, 1983.

Respiratory Tract Sensitization

56. A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D -- Poisonous and Infectious Material if there is evidence that shows that it causes respiratory tract sensitization in persons following exposure to it in the work place.

Mutagenicity

57. (1) A pure substance or tested mixture falls into Subdivision A of Division 2 of Class D -- Poisonous and Infectious Material if

(*a*) there is epidemiological evidence that shows a causal connection between exposure of persons to the substance or mixture and heritable genetic effects; or

(*b*) there is evidence of mutagenicity in mammalian germ cells *in vivo* as shown by

(i) positive results in a study that measures mutations transmitted to offspring, or

(ii) positive results in an *in vivo* study showing chemical interaction with the genetic materials of mammalian germ cells and positive results in an *in vivo* study assessing either gene mutation or chromosomal aberration in somatic cells.

(2) The evidence referred to in paragraph (1)(*b*) shall be obtained

(*a*) in accordance with test methods described in the "Introduction to the OECD Guidelines on Genetic Toxicology Testing and Guidance on the Selection and Application of Assays", dated March 1, 1987, published in the Third Addendum to the *OECD Guidelines for Testing of Chemicals*; and

(*b*) using testing strategies described in the *Guidelines on the Use of Mutagenicity Tests in the Toxicological Evaluation of Chemicals*, dated 1986, published under the authority of the Minister of National Health and Welfare and the Minister of the Environment. SOR/97-543, s. 23(F).

Untested Mixtures

58. An untested mixture falls into Subdivision A of Division 2 of Class D -- Poisonous and Infectious Material if it contains a product, material or substance that meets the criteria applicable to a pure substance or tested mixture referred to in

(*a*) any of sections 53 to 57, if the product, material or substance is present at a concentration of 0.1 per cent or more; or

(*b*) section 52, if the product, material or substance is present at a concentration of one per cent or more.

Subdivision B: Toxic Material

Pure Substances and Tested Mixtures

Chronic Toxic Effects

59. A pure substance or tested mixture falls into Subdivision B of Division 2 of Class D -- Poisonous and Infectious Material if, in an animal assay for chronic toxic effects, it elicits a response of sufficient severity to threaten life or cause serious permanent impairment in a statistically significant proportion of the test population at

(*a*) a dose of more than 10 but not exceeding 100 milligrams per kilogram of body weight of the animal per day, when tested in accordance with

(i) OECD Test Guideline No. 408, "Subchronic Oral Toxicity -- Rodent: 90-day", dated May 12, 1981,

(ii) OECD Test Guideline No. 409, "Subchronic Oral Toxicity -- Non-Rodent: 90-day", dated May 12, 1981, or

(iii) the oral route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981;

(*b*) a dose of more than 20 but not exceeding 200 milligrams per kilogram of body weight of the animal per day, when tested in accordance with

(i) OECD Test Guideline No. 411, "Subchronic Dermal Toxicity: 90-day", dated May 12, 1981, or

(ii) the dermal route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981; or

(*c*) a concentration of more than 25 but not exceeding 250 parts per million by volume of gas or vapour, or more than 10 but not exceeding 100 micrograms per litre or more than 10 but not exceeding 100 milligrams per cubic metre, of dust, mist or fume, when tested in accordance with

(i) OECD Test Guideline No. 413, "Subchronic Inhalation Toxicity: 90-day", dated May 12, 1981, or

(ii) the inhalation route test in OECD Test Guideline No. 452, "Chronic Toxicity Studies", dated May 12, 1981.

Skin Sensitization

61. A pure substance or tested mixture falls into Subdivision B of Division 2 of Class D -- Poisonous and Infectious Material if

(*a*) in an animal assay carried out in accordance with OECD Test Guideline No. 406, "Skin Sensitization", dated May 12, 1981,

(i) it produces a response in 30 per cent or more of the test animals, when using one of the techniques incorporating the use of an adjuvant, or

(ii) it produces a response in 15 per cent or more of the test animals, when using one of the techniques not incorporating the use of an adjuvant; or

(*b*) evidence shows that it causes skin sensitization in persons following exposure in a work place.

Mutagenicity

62. A pure substance or tested mixture falls into Subdivision B of Division 2 of Class D -- Poisonous and Infectious Material if evidence of mutagenicity in mammalian somatic cells *in vivo* is obtained in a test to assess either gene mutation or chromosomal aberration carried out

(*a*) in accordance with test methods described in the "Introduction to the OECD Guidelines on Genetic Toxicology Testing and Guidance on the Selection and Application of Assays" published in the Third Addendum to the *OECD Guidelines for Testing of Chemicals,* dated March 1, 1987; and

(*b*) using testing strategies described in the *Guidelines on the Use of Mutagenicity Tests in the Toxicological Evaluation of Chemicals,* dated 1986, published by authority of the Minister of Health and the Minister of the Environment. SOR/97-543, s. 25.

Untested Mixtures

63. An untested mixture falls into Subdivision B of Division 2 of Class D--Poisonous and Infectious Material if it contains a product, material or substance that meets any of the criteria applicable to a pure substance or tested mixture referred to in any of sections 59 to 62 and is present at a concentration of one per cent or more.