



142, No. 38 — September 20, 2008

# **Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999**

*Statutory authority*

*Canadian Environmental Protection Act, 1999*

*Sponsoring departments*

Department of the Environment and Department of Health

## **REGULATORY IMPACT ANALYSIS STATEMENT**

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

### ***Issue and objectives***

The purpose of the *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999* (hereinafter referred to as the proposed Order) made pursuant to subsection 90(1) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) is to propose the addition of chlorinated paraffins to the List of Toxic Substances in Schedule 1 of the Act. These substances were found to be toxic as set out in section 64 of CEPA 1999.

### ***Description and rationale***

#### **Background**

Chlorinated paraffins refer to three classes of substances: short chain chlorinated paraffins (i.e. chlorinated paraffins with 10-13 carbon atoms), medium chain chlorinated paraffins (i.e. chlorinated paraffins with 14-17 carbon atoms) and long chain chlorinated paraffins (i.e. chlorinated paraffins with 18 or more carbon atoms). In Canada, these substances are mainly used in metalworking, in plastics/rubber and as lubricating additives.

Chlorinated paraffins were initially assessed under the first Priority

Substances List program. The assessment report concluded that short chain chlorinated paraffins constitute or may constitute a danger to human health or life as set out in CEPA 1999 ([see footnote 1](#)); however, data identified at that time were considered insufficient to conclude whether short, medium or long chain chlorinated paraffins were harmful to the environment or whether medium or long chain chlorinated paraffins were considered a danger to human health. Discussions aimed at managing the risks posed by short chain chlorinated paraffins were engaged with stakeholders under the framework of the Toxic Substances Management Policy. However, risk management discussions were suspended, pending the generation and review of new information concerning the risk of chlorinated paraffins to human health and the environment.

#### Final follow-up assessment report on chlorinated paraffins

Environment Canada and Health Canada conducted the follow-up assessment report on chlorinated paraffins pursuant to section 68 of CEPA 1999.

The final assessment concludes that

- all chlorinated paraffins meet the criteria under paragraph 64(c) of CEPA 1999; and
- chlorinated paraffins containing up to 20 carbon atoms (short- and medium-chain chlorinated paraffins, as well as liquid long chain paraffins) meet the criteria under paragraph 64(a) of CEPA 1999.

Based on conclusions of the assessment, it is therefore recommended that all chlorinated paraffins be added to the Schedule 1 of CEPA 1999.

Furthermore, chlorinated paraffins containing up to 20 carbon atoms are predominantly anthropogenic and the available data regarding their persistence and bioaccumulation potential indicates that they satisfy the criteria outlined in the *Persistence and Bioaccumulation Regulations*, made under CEPA 1999. Chlorinated paraffins containing up to 20 carbon atoms thus meet the criteria for virtual elimination ([see footnote 2](#)) of releases to the environment as set out in the Toxic Substances Management Policy.

The full assessment report may be obtained from the Chemical Substances Web site at [www.chemicalsubstances.gc.ca](http://www.chemicalsubstances.gc.ca), from the Existing Substances Division, Environment Canada, Gatineau, Quebec K1A 0H3, 819-953-4936 (fax), or by email at [Existing.Substances.Existantes@ec.gc.ca](mailto:Existing.Substances.Existantes@ec.gc.ca).

#### Authority

Under subsection 90(1) of CEPA 1999, the Governor in Council may, if satisfied that a substance is toxic, make an order adding the substance to the List of Toxic Substances in Schedule 1 of the Act. The Adding Order is made on the recommendation of the Minister of the Environment and the Minister of Health.

## Alternative

One of the following measures can be applied after an assessment is conducted under CEPA 1999: taking no further action in respect of the substance; unless the substance is already on the Priority Substances List, adding the substance to the Priority Substances List; or recommending that the substance be added to the List of Toxic Substances in Schedule 1, and when applicable, the implementation of virtual elimination.

The follow-up assessment report on chlorinated paraffins concludes that these substances are entering, or likely to enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the human health or life and that chlorinated paraffins containing up to 20 carbon atoms have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Additionally, chlorinated paraffins containing up to 20 carbon atoms are persistent, bioaccumulative, inherently toxic and present in the environment primarily as a result of human activity.

Given that these substances meet the criteria for 201C;toxic201D; under section 64 of CEPA 1999, adding them to Schedule 1 is the only option considered.

In addition and as previously mentioned, chlorinated paraffins containing up to 20 carbon atoms are predominantly anthropogenic and the available data regarding their persistence and bioaccumulation potential indicates that they satisfy the criteria outlined in the *Persistence and Bioaccumulation Regulations*, made under CEPA 1999. Chlorinated paraffins containing up to 20 carbon atoms thus meet the criteria for virtual elimination of releases to the environment as set out in the Toxic Substances Management Policy.

## Benefits and costs

The addition of chlorinated paraffins to Schedule 1 of CEPA 1999 would enable preventive or control actions on these substances to be taken to ensure the protection of human health and the environment.

The decision to add toxic substances to Schedule 1 of CEPA 1999 is based primarily on a scientific assessment. Adding a substance to Schedule 1 of CEPA 1999 allows the Government of Canada to access the regulatory tools provided for under the Act. The Government will undertake appropriate socioeconomic assessment of the potential impacts of a range of possible instruments during the risk management phase.

## ***Consultation***

On June 11, 2005, the Ministers of the Environment and of Health published in the *Canada Gazette*, Part I, for a 60-day public comment period, the summary of the scientific results of the follow-up assessment on chlorinated paraffins and a statement indicating the measures they propose to take on the basis of scientific considerations. Prior to this publication, the CEPA National Advisory

Committee was informed about the release of the follow-up assessment on chlorinated paraffins and the public comment period mentioned above.

During the 60-day public comment period, submissions were received from industry and industry associations on the scientific assessment. No comments were received from non-governmental organizations, members of the public or academia. Technical comments on the assessment report submitted by stakeholders were carefully reviewed by Environment Canada and Health Canada. The assessment report was revised based on these comments. Responses to the comments are summarized below. The full responses to the comments are available on the Chemical Substances Web site at [www.chemicalsubstances.gc.ca](http://www.chemicalsubstances.gc.ca).

Industry stakeholders acknowledged that the toxicity of short chain chlorinated paraffins is well documented, but they were concerned about the paucity of information and the uncertainty in the assessment with regards to medium- and long-chain chlorinated paraffins. Considering the state of science and current international work on these substances, they believe that the conclusion on whether medium- and long-chain chlorinated paraffins meet the criteria set out in paragraph 64(a) of CEPA 1999 is premature. They also sought clarification or provided suggestions on what the appropriate risk management of chlorinated paraffins should be.

In addition, industry stakeholders provided various technical comments on the assessment. They criticized the use of non-Canadian, outdated or conservative data and assumptions for estimating effects and exposure. They also questioned the validity of some calculation methods and modeling used to determine the persistence and bioaccumulation. Finally, they proposed that the modes of action by which some tumours are induced in animals exposed to short-chain chlorinated paraffins are not relevant to human health.

Environment Canada indicated that data used in the assessment are selected on the basis of their relevance to Canadian conditions. The data used and assumptions made about the exposure, persistence and bioaccumulation potential were updated to reflect current international practices used in risk assessment. In addition, the department modified the approach for the assessment of long-chain chlorinated paraffins by subdividing them further into three groups and recognizing their different physical and chemical properties. New information in support of the bioaccumulation conclusion on all chlorinated paraffins was also added.

With respect to the comment pertaining to human health, Health Canada indicated that there is insufficient information to rule out concerns of tumour induction for humans similar to those stated for animals and that, in addition, short-chain chlorinated paraffins already meet the criterion under paragraph 64(a). Therefore, the department considered that further research is not a priority.

As a result of a thorough scientific review of experimental and modeled data, Environment Canada and Health Canada believe there

is now sufficient information to conclude that short- and medium-chain chlorinated paraffins, as well as liquid long-chain paraffins containing up to 20 carbon atoms, meet the criteria set out in paragraphs 64(a) and (c) of CEPA 1999. However, based on the limited information available, the assessment conclusions for long-chain paraffins containing over 20 carbon atoms have been revised so that these substances meet the criterion set out in paragraph 64(c) of CEPA 1999, but do not meet the criterion set out in paragraph 64(a) of the Act. A risk management approach for chlorinated paraffins is being prepared and consultations will be held with affected stakeholders following publication of the final assessment report in 2008.

### ***Implementation, enforcement and service standards***

As the proposed Order would add the substances to Schedule 1 of CEPA 1999, developing an implementation plan, compliance strategy or establishing a service standard are not necessary. In addition, there is no compliance or enforcement requirement associated with Schedule 1 of CEPA 1999, itself.

### ***Contacts***

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### **PROPOSED REGULATORY TEXT**

Notice is hereby given, pursuant to subsection 332(1) ([see footnote a](#)) of the *Canadian Environmental Protection Act, 1999* ([see footnote b](#)), that the Governor in Council proposes, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to

subsection 90(1) of that Act, to make the annexed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*.

Any person may, within 60 days after the date of publication of this notice, file with the Minister of the Environment comments with respect to the proposed Order or a notice of objection requesting that a board of review be established under section 333 of that Act and stating the reasons for the objection. All comments and notices must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be sent to the Executive Director, Existing Substances Division, Environment Canada, Gatineau, Quebec K1A 0H3 by mail, by fax at 1-800-410-4314 or 819-953-4936, or by email to Existing.Substances.Existantes@ec.gc.ca.

A person who provides information to the Minister of the Environment may submit with the information a request for confidentiality under section 313 of that Act.

Ottawa, September 4, 2008

MARY PICHETTE  
*Assistant Clerk of the Privy Council*

## **ORDER ADDING TOXIC SUBSTANCES TO SCHEDULE 1 TO THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999**

### **AMENDMENT**

**1. Schedule 1 to the *Canadian Environmental Protection Act, 1999* (see [footnote 3](#)) is amended by adding the following:**

Chlorinated paraffins that have the molecular formula  $C_nH_xCl_{(2n+22013;x)}$  in which 10 2264; n 2264; 38

### **COMING INTO FORCE**

**2. This Order comes into force on the day on which it is registered.**

[38-1-o]

#### [Footnote 1](#)

The Canadian Environmental Protection Act is now repealed and replaced by the Canadian Environmental Protection Act, 1999.

#### [Footnote 2](#)

The federal government's Toxic Substances Management Policy further require virtual elimination from the environment of toxic substances that are persistent and bioaccumulative and are present in the environment primarily due to human activity (Track 1), and of their precursors.

#### [Footnote a](#)

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

[Footnote b](#)

S.C. 1999, c. 33

[Footnote 3](#)

S.C. 1999, c. 33 