

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

P.C. 2010-553 April 29, 2010

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 September 20, 2008, a copy of the proposed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*, substantially in the form set out in the annexed Order, and persons were given an opportunity to file comments with respect to the proposed Order or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

And whereas, pursuant to subsection 90(1) of that Act, the Governor in Council is satisfied that the substances set out in the annexed Order are toxic substances;

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 90(1) of the *Canadian Environmental Protection Act, 1999* ([see footnote c](#)), hereby makes the annexed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*.

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 1](#)) is amended by adding the following in numerical order:

- 86.** Methyloxirane, which has the molecular formula C_3H_6O
- 87.** Ethyloxirane, which has the molecular formula C_4H_8O
- 88.** Naphthalene, which has the molecular formula $C_{10}H_8$
- 89.** Toluene diisocyanates, which have the molecular formula $C_9H_6N_2O_2$
- 90.** 1,2-Benzenediol, which has the molecular formula $C_6H_6O_2$
- 91.** 1,4-Benzenediol, which has the molecular formula $C_6H_6O_2$

COMING INTO FORCE

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

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Order.)

Issue and objectives

Canadians depend on chemical substances that are used in the manufacturing of hundreds of goods, from medicines to computers, fabrics and fuels. Unfortunately, some chemical substances can negatively affect human health and the environment when released to the environment in a certain quantity or concentration or under certain conditions. Scientific assessments of the impact of human and environmental exposure have determined that a number of these substances constitute or may constitute a danger to human health and/or the environment as per the criteria set out under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999, also referred to as "the Act").

The *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999* (hereinafter referred to as "the Order"), made pursuant to subsection 90(1) of CEPA 1999, adds the following substances to the List of Toxic Substances in Schedule 1 of CEPA 1999:

- Methyloxirane (Chemical Abstracts Service Registry Number [CAS RN] 75-56-9)
- Ethyloxirane (CAS RN 106-88-7)
- Naphthalene (CAS RN 91-20-3)
- Toluene diisocyanates (three substances: CAS RN 26471-62-5, 584-84-9 and 91-08-7), hereafter referred to as "TDI"
- 1,2-Benzenediol (CAS RN 120-80-9), hereafter referred to as "catechol"
- 1,4-Benzenediol (CAS RN 123-31-9), hereafter referred to as "hydroquinone"

This addition enables the development of regulatory risk management proposals for these substances under CEPA 1999. The Ministers may, however, choose to develop non-regulatory instruments to manage human health and environmental risks posed by these substances.

Description and rationale

Background

Approximately 23 000 substances (often referred to as "existing" substances) were in use in Canada between January 1, 1984, and December 31, 1986. These substances are found on the *Domestic Substances List* (DSL), but many of them have never been assessed as to whether they meet any of the criteria set out in section 64 of CEPA 1999. Section 73 of the Act requires that substances on the DSL be categorized to determine which of them pose the greatest potential for exposure to the general population. Categorization also determines which of these substances are persistent or bioaccumulative in accordance with the *Persistence and Bioaccumulation Regulations* and inherently toxic to human beings or to non-human organisms. Pursuant to section 74 of the Act, substances that were flagged during the categorization process must undergo an assessment to determine whether they meet any of the criteria set out in section 64. Assessments may also be published under section 68 of the Act for substances identified as high priorities for action, but that do not meet the categorization criteria set out under section 73 of the Act.

The Minister of the Environment and the Minister of Health (the Ministers) completed the categorization exercise in September 2006. Of the approximately 23 000 substances on the DSL, about 4 300 were identified as needing further attention, and 200 of these were identified as high priorities for action.

As a result of categorization, the Chemicals Management Plan (the Plan) was launched on December 8, 2006, with the objective of enhancing protection against hazardous chemicals.

A key element of the Plan is the collection of information on the properties and uses of the approximately 200 substances identified as high priorities for action. This includes substances

- that were found to meet the categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms, and that are known to be in commerce, or of commercial interest, in Canada; these substances are considered to be high priorities for assessment of ecological risk; and/or
- that were found either to meet the categorization criteria for greatest potential for exposure of Canadians or to present an intermediate potential for exposure, and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity; these substances are considered to be high priorities for assessment of risk to human health.

This information is being used to make decisions regarding the best approaches to be taken in order to protect Canadians and their environment from the risks these substances might pose. This information-gathering initiative is known as the "Challenge."

To facilitate the process, Environment Canada and Health Canada have organized the approximately 200 substances into 12 "batches" of approximately 15 substances. A batch is released every three months, and stakeholders are required to report information such as quantities imported, manufactured or used in Canada via a mandatory survey issued under section 71 of CEPA 1999. Affected parties are required to submit this information to better inform decision making, including determining whether a substance meets one or more of the criteria set out in section 64 of CEPA 1999 — that is to say, whether the substance is entering or may enter the environment in a quantity or concentration or under conditions that

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitute or may constitute a danger to the environment on which life depends; or
- constitute or may constitute a danger in Canada to human life or health.

Based on the information received and other available information, screening assessments are conducted in order to assess whether substances meet one or more of the criteria of section 64. The screening assessments are peer-reviewed and additional advice is also sought, as appropriate, through the Challenge Advisory Panel. The Panel, made up of experts from various fields such as chemical policy, chemical production, economics and environmental health, was formed to provide advice to the Government on the application of precaution and weight of evidence to screening assessments in the Challenge. These screening assessments are then published on the Chemical Substances Web site at <http://www.chemicalsubstanceschimiques.gc.ca> along with notices that are published in the *Canada Gazette*, Part I, that signal the Ministers' intent with regard to further risk management.

The Minister of the Environment is required under section 91 of CEPA 1999 to publish in the *Canada Gazette* a proposed regulation or other instrument establishing preventive or control actions within two years of publishing a statement under paragraph 77(6)(b) of CEPA 1999 indicating that the measure the Ministers propose to take, as confirmed or amended, is a recommendation that the substance be added to the List of Toxic Substances in Schedule 1 of CEPA 1999. Section 92 then requires that the regulation or other instrument be finalized and published in the *Canada Gazette* within a further 18 months.

The addition of these substances to Schedule 1 of CEPA 1999 allows the Ministers to develop risk management instruments in order to meet these obligations. The Act enables the development of risk management instruments (such as regulations, guidelines or codes of practice) to protect the environment and human health. These instruments can be developed for any aspect of the

substance's life cycle, from the research and development stage through manufacture, use, storage, transport and ultimate disposal or recycling. Proposed Risk Management Approach documents, which provide an indication of where the Government will focus its risk management activities, have been prepared for Batch 1 substances and are available on the Chemical Substances Web site listed above.

The final screening assessments for the first batch of the Challenge, comprising 15 substances, were published on the Chemical Substances Web site, and the statements recommending addition to Schedule 1 were published in the *Canada Gazette* on July 5, 2008.

Of the 15 substances assessed in Batch 1, six substances and one group of three substances met one or more of the criteria set out in section 64 of CEPA 1999. Five substances and one group of three substances constitute or may constitute a danger in Canada to human life or health and are included in this Order. Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino] -2-methylphenyl]methylene]- (CHPD), a substance that was proposed for addition to Schedule I, is not included in this Order.

A summary of the assessments and conclusions and an overview of the public comments received during the public comment period on the draft assessment report and on the risk management scope documents for the substances are available from the Chemical Substances Web site, at www.chemicalsubstanceschimiques.gc.ca.

Descriptions and assessment summaries for Batch 1 substances listed on Schedule 1

Methyloxirane, also known as propylene oxide, is an industrial chemical used in the production of other chemicals that are used in the manufacture of a variety of industrial and consumer products.

Ethyloxirane, also known as 1,2-epoxybutane, is an industrial chemical primarily used as a stabilizer in industrial solvents for the removal of oils, lubricants, adhesives, inks and tars from a variety of metal, welded, machined, molded and die-cast surfaces, as well as reinforced fibreglass and plastics. The substance is also used in the manufacturing of automobile coatings and in the production of other chemicals.

Naphthalene is an industrial chemical that also occurs naturally. Extracted from crude oil, naphthalene has a wide variety of industrial uses such as solvents, fuel additives and corrosion inhibitors, among others. Naphthalene is also used in the manufacture of various products such as construction materials, pharmaceuticals, agricultural products and other chemicals. Naphthalene is also found in various consumer products such as paint solvents, mothballs and driveway sealants.

Toluene diisocyanates (TDIs) include three industrial chemicals, usually found as a commercial mixture of 2,4-TDI and 2,6-TDI, and are primarily used to manufacture polyurethane foam. Flexible polyurethane foam is used in applications such as household furniture and automotive upholstery. Semi-flexible and semi-rigid polyurethane foams are used in automotive panels, padding and bumpers. TDIs are also used in products such as paints and coatings and in paper production.

1,2-Benzenediol, also known as catechol, is an industrial chemical that also occurs naturally. Catechol is formed during the production of pulp (also found in pulp mill effluent) and is used as a component in photographic developing solutions and in specific applications, such as a laboratory reagent and an antioxidant in electroplating baths. Catechol occurs naturally in plants, including some food items.

1,4-Benzenediol, also known as hydroquinone, is an industrial chemical that also occurs naturally. Hydroquinone is used in the production of other chemicals and in a variety of products, such as adhesives, as a stabilizer or additive and as a reducing agent in photographic developing solutions. The substance is also used in certain cosmetic products such as hair dyes. Hydroquinone occurs naturally in plants, including some food items.

Final assessments conclusions

The scientific assessments have determined that these substances can cause cancer in laboratory animals. In addition, methyloxirane, naphthalene and the three toluene diisocyanates were also found to affect the respiratory system of laboratory animals.

On the basis of the carcinogenicity — for which there may be a probability of harm at any level of exposure — as well as the potential for other harmful effects, it is concluded that these substances may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health and hence meet the criteria set out in paragraph 64(c) of CEPA 1999. It is therefore proposed that these substances be added to Schedule 1 of CEPA 1999.

The final screening assessment reports, the proposed risk management approach documents and the complete responses to comments received on both ecological and health priorities were published on July 5, 2008, and may be obtained from the Chemical Substances Web site at www.chemicalsubstanceschimiques.gc.ca or from the Program Development and Engagement Division, Gatineau, Quebec K1A 0H3; 819-953-7155 (fax); or by email at Existing.Substances.Existantes@ec.gc.ca.

Alternatives

The following measures can be taken after a screening assessment is conducted under CEPA 1999:

- adding the substance to the Priority Substances List for further assessment (when additional information is required to determine whether or not a substance meets the criteria in section 64);
- taking no further action in respect of the substance; or
- recommending that the substance be added to the List of Toxic Substances in Schedule 1 and, where applicable, recommending the implementation of virtual elimination.

It has been concluded in the final screening assessment reports that methyloxirane, ethyloxirane, naphthalene, toluene diisocyanates, 1,2-benzenediol and 1,4-benzenediol are entering, or may enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health as defined under paragraph 64(c) of CEPA 1999. Adding these substances to Schedule 1 is therefore the best option.

Benefits and costs

Adding these substances to Schedule 1 enables the Ministers to develop regulatory risk management proposals for these substances under CEPA 1999. The Ministers may, however, choose to develop non-regulatory instruments to help protect human health and the environment. The Ministers will assess costs and benefits and consult with the public and other stakeholders during the development of these risk management proposals.

Consultation

On January 19, 2008, the Ministers published for a 60-day public comment period in the *Canada Gazette*, Part I, a summary of the scientific assessments for 15 substances of Batch 1 of the Challenge, and a statement indicating the risk management measures they propose to take for these substances. Risk management scope documents were also released on the same date for substances proposed for consideration as meeting the criteria set out in section 64 of the Act. Prior to these publications, the CEPA National Advisory Committee (CEPA NAC) was informed of the release of the screening assessment reports on the 15 substances, the risk management scope documents, and the public comment period mentioned above. No comments were received from

CEPA NAC. Additionally, the Challenge Advisory Panel provided advice on the appropriate application of weight of evidence and precaution in scientific decision making related to these substances. Advice from the Panel was taken into consideration during the development of the final screening assessment reports.

During this 60-day public comment period, a total of 42 submissions — from 4 Canadian citizens, 28 industry stakeholders and 4 non-governmental organizations — were received on the scientific assessment and risk management scope documents. Comments received on these documents have been considered when developing the final screening assessments.

Below is a summary of comments specific to the assessment conclusions for toxicity and the departments' responses to them. The complete responses to comments document is available via the Government of Canada's Chemical Substances Web site: www.chemicalsubstanceschimiques.gc.ca.

Industry stakeholders noted that more in-depth weight-of-evidence analyses should have been conducted to support the designations of toxic under CEPA 1999 based on carcinogenicity.

Response: The departments indicated that in the absence of an analysis to clearly identify the mode of action of the chemical, it was considered appropriate to view a substance as a carcinogen, based on international classifications. Advice of the Challenge Advisory Panel was taken into consideration in formulating this approach.

Methyloxirane and ethyloxirane

Industry stakeholders commented that methyloxirane should not be considered genotoxic and that the data do not support the conclusion of carcinogenicity for both methyloxirane and ethyloxirane.

Response: Health Canada considered these comments. After due consideration, and in the absence of an analysis to clearly identify the mode of action (that is, the identification of the way in which a chemical exerts its toxic effects at a cellular or molecular level), it was considered appropriate to consider the substances as carcinogens, based on international classifications. In addition, based on scientific data, it was concluded that a genotoxic mode of action for carcinogenicity of methyloxirane could not be precluded.

1,2-Benzenediol (catechol) and 1,4-Benzenediol (hydroquinone)

Industry stakeholders commented that it was not appropriate to conclude that the substances are toxic under CEPA 1999 when the predominant source of exposure is from naturally occurring sources.

Response: The departments considered these comments and note that the screening assessments identify industrial uses of these substances. The departments also acknowledge that current exposures from these uses are negligible relative to naturally occurring sources. A conclusion that these substances are toxic under CEPA 1999 means that the departments can take action to reduce anthropogenic sources now or in the future. This approach is consistent with the advice from the Challenge Advisory Panel on this matter.

Toluene diisocyanates (TDIs)

Some stakeholders commented that the conclusion of carcinogenicity was not warranted since the predominant route of exposure to Canadians is inhalation while the positive cancer bioassays are via the oral route.

Response: Health Canada has modified the screening assessment to include a fuller consideration of

route-specific effects. However, this modification did not change the conclusion of the assessment. Health Canada maintains that the evidence for carcinogenicity supports the conclusion of toxicity under CEPA 1999.

Comments received on the risk management scope documents regarding the substances were also considered when developing the proposed risk management approaches, which were also subject to a 60-day public comment period.

Comments received following publication of the proposed Order in the Canada Gazette , Part I

In accordance with the Act, on September 20, 2008, the Ministers published a proposed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999* in the *Canada Gazette*, Part I, for a 60-day public comment period. Below is a summary of comments or notices of objection received, along with the responses to them, relevant to the proposed addition of the eight substances to the List of Toxic Substances in Schedule 1 of CEPA 1999.

1,4-Benzenediol (hydroquinone)

During the 60-day public comment period, an industry association filed a notice of objection on hydroquinone and requested the establishment of a board of review under section 333 of CEPA 1999 on the assessment. A letter of support to the notice of objection was also received from a second industry association. The main concerns raised in the notice of objection are related to Health Canada's non-threshold toxicant policy and Health Canada's determination of hydroquinone as a carcinogen. The industry association questions Health Canada's interpretation of the European Union's and the International Agency for Research on Cancer's (IARC) classification of the substance as a category 3 carcinogen (not classifiable as to its carcinogenicity).

Response: *Health Canada indicates that neither of these classifications (IARC — Category 3 and EU — Category 3) can be interpreted as hydroquinone being non-carcinogenic for humans. Also, since no new scientific data or information were found beyond what the two departments had considered in preparing the final assessment published in August 2008, the Ministers concluded that it is unlikely that there is an acceptable justification for a board of review to reach a different conclusion regarding the danger posed by hydroquinone.*

The industry association commented that a study on the mode of action for hydroquinone submitted during the designated public comment period was not taken into account when finalizing the assessment.

Response: *Health Canada indicates that the study on the mode of action referred to in the notice has been considered along with other studies on the carcinogenicity to other species when finalizing the screening assessment, which is consistent with a weight-of-evidence approach. The analysis of the notice of objection conducted by Health Canada has found that the information brought forward would not lead to a different conclusion of toxicity of hydroquinone, even with the consideration of the new information made available by the industry association.*

Toluene diisocyanates (TDIs)

Comments were received on TDIs from one industry association and one industry stakeholder on the proposal to add TDIs to the List of Toxic Substances in Schedule 1 of CEPA 1999. In their comment, the industry association reiterated that the conclusion of carcinogenicity was not warranted since the predominant source of exposure to Canadians is inhalation while the positive cancer bioassays are via the oral route.

Response: *The Ministers have already provided responses to these comments in their "Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report on TDIs." Health Canada has modified the screening assessment to include a fuller consideration of*

route-specific effects. Health Canada continues to maintain that the evidence for carcinogenicity supports the conclusion of toxicity under CEPA 1999.

Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]- (CHPD)

An industry stakeholder filed a notice of objection with respect to the conclusion of the assessment of CHPD and requested the establishment of a board of review. In addition, the stakeholder submitted new data on bioaccumulation.

Response: The data submitted are currently being reviewed. A recommendation to the Governor in Council as to whether or not to add CHPD to Schedule 1 will be made at a later time.

Implementation, enforcement and service standards

The Order adds the five substances and one group of three substances mentioned above to Schedule 1 of CEPA 1999, thereby allowing the Ministers to publish proposed regulations or instruments no later than July 5, 2010, and finalize them no later than January 5, 2012. Developing an implementation plan or compliance strategy, or establishing service standards, is not considered necessary without any specific risk management proposals. An appropriate assessment of implementation, compliance and enforcement will be undertaken during the development of a proposed regulation or control instrument(s) respecting preventive or control actions for these substances.

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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](#)

S.C. 1999, c. 33

