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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

Chemical substances used in human activity can have detrimental effects on the environment and human health when released in a certain quantity or concentration in the environment. Scientific assessments of the impact of human and environmental exposure to a number of these substances have determined that these substances are toxic to human health and the environment as per section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

The objective of the proposed *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 CEPA 1999, is to add the following substances:

- Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]- (CAS No. 54079-53-7);
- Methyloxirane (CAS No. 75-56-9);
- Ethyloxirane (CAS No. 106-88-7);
- Naphthalene (CAS No. 91-20-3);

- Toluene diisocyanates (three substances: CAS No. 26471-62-5, 584-84-9 and 91-08-7);
- 1,2-Benzenediol (CAS No. 120-80-9); and
- 1,4-Benzenediol (CAS No. 123-31-9).

to the List of Toxic Substances in Schedule 1 of CEPA 1999. This addition would enable the departments to develop management measures with respect to taking preventive or control actions in relation to these substances.

Description and rationale

Background

In September 2006, the Minister of the Environment and the Minister of Health, pursuant to section 73 of CEPA 1999, completed the categorization of the approximately 2300A0;000 chemical substances listed on Canada2019;s *Domestic Substances List* (DSL). This categorization exercise identified 4 300 chemical substances needing further attention by the Government.

On December 8, 2006, the Government of Canada launched the Chemicals Management Plan with the objective to improve the degree of protection against hazardous chemicals. The Plan includes a number of new, proactive measures to manage chemical substances. The Plan targets 201C;legacy chemicals201D; that have not until now undergone scientific assessment.

A key element in the Chemicals Management Plan is the collection of information on the properties and uses of the approximately 200 chemical substances identified through the categorization process as high priorities for action. This information is being used to make decisions regarding the best approach to protect Canadians and their environment from risks that these substances might pose. This initiative is known as the 201C;Challenge.201D;

The draft screening assessments for the first batch of 15 substances under the Challenge were published on January 19, 2008. These substances were assessed as to whether they are toxic as defined under section 64 of the Act.

Assessments conducted under the Challenge are peer-reviewed and additional advice is sought, as appropriate, through the Challenge Advisory Panel. Members of the Challenge Advisory Panel are independent experts from various fields such as chemical policy, chemical production, economics, and environmental health.

Of the 15 substances assessed in Batch one of the Challenge, 9 substances have been determined to meet the criteria set out in section 64 of CEPA 1999, and the 6 others do not meet the criteria set out in section 64 of the Act. Assessment summaries for these substances are presented below.

Substances description and use

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

-2-methylphenyl]methylene]- (CHPD) is a manufactured yellow dye used as a colorant in the manufacture of various plastic consumer products. It is not manufactured in Canada, but is imported in small quantities as dye and, possibly, as part of finished articles (e.g. plastic, textile).

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 diiosocyanates (TDIs) are 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 is naturally occurring 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 is naturally occurring in plants, including some food items.

Assessment summary and conclusion for ecological priority

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

CHPD can be released to the environment during industrial use and processing. Being able to stay in the environment for a long period of time, CHPD has the potential to build up in animals and accumulate within the food chain. Small amounts can also harm organisms found in aquatic environments.

Based on the information available, it is concluded that CHPD is entering 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 as defined under section 64 of CEPA 1999. It is therefore proposed that this substance be added to Schedule 1 of CEPA 1999.

In addition, CHPD is not a naturally occurring substance, is predominantly anthropogenic, and the available data regarding persistence and bioaccumulation indicate that the substance meets the criteria set out in the *Persistence and Bioaccumulation Regulations*, made under CEPA 1999. The substance thus meets the criteria for implementation of virtual elimination of releases to the environment as defined under subsection 77(4).

Assessment summary and conclusion for human health priorities

The scientific assessments have determined that all human health priority substances (methyloxirane, ethyloxirane, naphthalene, toluene diisocyanates, 1,2-benzenediol and 1,4-benzenediol) can cause cancer in laboratory animals. In addition, methyloxirane, naphthalene and the three toluene diiosocyanates were also found to affect the respiratory system of laboratory animals.

On the basis of the carcinogenicity of the substances for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margins between levels of methyloxirane, TDIs and naphthalene that the general population may be exposed to and levels at which respiratory effects are observed in laboratory animals, it is concluded that all the human health priority 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 of section 64 of CEPA 1999. It is therefore proposed that these substances be added to Schedule 1 of CEPA 1999.

The screening assessment reports may be obtained from the Chemical Substances Web site at www.chemicalsubstances.gc.ca or from the Existing Substances Division, Environment Canada, Gatineau, Quebec K1A 0H3, 819-953-4936 (fax), Existing. Substances. Existantes@ec.gc.ca (email).

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 CEPA 1999. The Adding Order is made on the recommendation of the Minister of the Environment and the Minister of Health.

Alternative

The screening assessment reports conclude 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 section 64 of CEPA 1999.

The reports also concluded that propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl] methylene]- 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.

Given that these substances meet the criteria to be considered toxic under section 64 of CEPA 1999, adding them to Schedule 1 is the preferred option.

The presence of CHPD in the environment results primarily from human activity. The substance is not a naturally occurring radionuclide or inorganic substance and is persistent and bioaccumulative, as set out in the *Persistence and Bioaccumulation Regulations*. Consequently, the Ministers must propose to follow the process specified in CEPA 1999 for substances that meet the criteria for virtual elimination.

Benefits and costs

The addition of the substances 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 these toxic substances to Schedule 1 of CEPA 1999 is based on scientific assessments. It would be premature to proceed, at this point, with an assessment of costs to the public, industry or governments. The Government will undertake an appropriate assessment of the potential impacts of a range of possible instruments during the risk management phase.

Consultation

On January 19, 2008, the Ministers of the Environment and of Health 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 toxic under 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 the 60-day public comment period, a total of 42 submissions2014;from 4 Canadian citizens, 28 industry stakeholders and 4 non-governmental organizations2014;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.

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

Below is a summary of comments received and responses relevant to the overall process and approach to the assessment, as well as specifically for the nine substances proposed for addition to the List of Toxic Substances in Schedule 1 of CEPA 1999. Complete responses to the comments received are available on the Chemical Substances Web site at www.chemicalsubstances.gc.ca.

The following section summarizes comments received from non-governmental organizations and the departments2019; responses to them:

- Concern was expressed regarding the process that led to a change in the categorization results.

The departments clarified that the purpose of categorization was to identify priorities for assessment. The subsequent screening assessments of high priority substances provide an opportunity for a more in-depth evaluation of the substances (e.g. evaluation of risk) and this evaluation can therefore lead to conclusions that differ from categorization results.

- It was noted that consideration of isolated chemicals and the determination of appropriate risk management approaches under laboratory conditions are inadequate to address the real risks of exposure that are faced, including possible cumulative impacts of substances that have similar chemical structures or modes of action.

The departments clarified that assessments taking place under the Challenge focus on individual substances that were identified as high priorities due to either human health or ecological concerns. Substances that are structurally similar to those that have been identified as persistent, bioaccumulative and inherently toxic under the categorization criteria may be considered as higher priorities for future evaluation as part of a class assessment. This will facilitate, in some cases, consideration of cumulative impacts.

- While recognizing that screening assessments differ from full Priority Substances List assessments, it was noted that the full

life cycle of the substances should be provided and considered to identify all possible routes of exposure or impact to human health and the environment.

For screening assessments, available information is used to identify the sources of exposure to a substance, and the focus of the risk assessment is mainly on the significant pathways identified. Inventory update, research and monitoring may provide additional information to better inform risk management activities.

- It was recommended that surveys under section 71 of CEPA 1999 should be expanded in their scope to require experimental mammalian toxicity data for a number of toxicity endpoints. In addition, information regarding potential toxicity to children should be an integral requirement.

The comment needs to be taken in context given the government2019;s 201C;predisposition201D; to conclude that substances included in the Challenge are toxic under CEPA 1999, and to introduce control measures for the risk identified. Furthermore, the departments indicated that many studies relating to mammalian toxicity can require many years to complete. In the absence of experimental data, protective assumptions are used. In the Notice of Intent
(see footnote 1) published in the *Canada Gazette*, Part I, the Government of Canada invited industry and other stakeholders to provide specific information that may be used to inform risk assessment and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as the highest priorities.

- The weight and acceptability of experimental versus modelled, analogue and surrogate data was questioned.

The departments responded that when they are available and are of acceptable quality, experimental data are used. However, when there are no data on a specific substance, valid data for appropriately selected surrogate substances may be used. When suitable experimental data are not available, results of models are applied.

The following section summarizes comments received from industry stakeholders and the departments2019; responses to them:

- The benefits of the two-way dialogue between government and stakeholders were emphasized and it was requested that this be maintained during the Challenge period.

The departments indicated that opportunities for dialogue with all stakeholders are considered while recognizing both the available time and the level of need for more detailed discussions with respect to a specific substance.

- It was considered that the data submitted by the industry stakeholders during the call for information were not used in

the draft screening assessments.

The departments did, and will continue, to consider all information submitted in the development of the assessments, although the level to which any individual piece of information is used in an assessment is based on its scientific value. Additionally, the key studies considered have been more clearly identified in the screening assessments.

- An observation was made regarding the definition of weight-of-evidence which, in their view, seems to be a worst-case scenario in the draft screening assessments.

The departments responded that the application of weight-of-evidence accounts for and weighs multiple sources of information in the identification of critical values used in the assessment and in the evaluation of multiple lines of evidence in determining whether a substance may pose a risk. Exposure assessments conducted for characterization of risks to human health are upper bounded, not worst case.

- It was considered that the exposure scenarios used for the screening assessments were unrealistic.

00A0;The departments maintained that while efforts are made to identify available monitoring data for substances being assessed, it is not always feasible for the Government to conduct monitoring. Therefore, modeling of exposure, based on available information and using assumptions similar to those used by other international jurisdictions, is required in many cases. In addition, the comment period is thought to provide an opportunity for stakeholders to submit information that may be used to refine these scenarios. Refinements to exposure scenarios were made in response to public comments and the departments consider that the exposure scenarios presented in the screening assessments are realistic.

- The view was expressed that, in order to improve transparency in the decision-making process, documentation accompanying the screening assessment should discuss the evolution of the assessment conclusions that occurred throughout the process.

00A0;The departments indicated that the overall process followed in the evaluation of existing substances is outlined in documents available from the Chemical Substances Web site. Assessment reports present the scientific information that determines whether a substance is toxic as defined in section 64 of CEPA 1999.

- It was 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.

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 the substance as a carcinogen, based on international classifications. Advice of the Challenge Advisory Panel was taken into consideration in formulating this

approach.

- A lack of detail on the peer review process was noted (e.g. who conducted the peer review).

The departments have provided further details on the external peer review/consultation process in the final screening assessment reports.

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

- Industry stakeholders commented that the substance is a low volume chemical with a very low potential for exposure to the Canadian environment. Also, there is no potential exposure for the environment by the substance contained in finished products.

Environment Canada maintained that persistent substances remain in the environment for a long time, which increases the potential magnitude and duration of exposure. Products such as plastics will eventually degrade and release the substances, which will result in potential exposure.

- Industry stakeholders were of the view that modelled data used for bioaccumulation sometimes overestimate the bioaccumulation potential and the data used to draw conclusions on the potential for bioaccumulation are less than the cut-off (500A0;000) under the *Persistence and Bioaccumulation Regulations*.

Environment Canada stated that the use of the weight-of-evidence-based analysis explains the conservative choice of the value used in the assessment. If the bioaccumulation factor prediction is 2265;500A0;000, then the bioconcentration factor (BCF) predictions are examined. If one or more BCF predictions were found to be 2265;500A0;000, then the substance was considered to have met the categorization criteria for bioaccumulation.

Methyloxirane and Ethyloxirane

- Industry stakeholders commented that the consumer product scenarios were not based on current composition.

Health Canada considered these comments and the consumer product scenarios have been updated to reflect current uses, as appropriate.

- 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.

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.

Naphthalene

- Industry stakeholders commented that Health Canada should conduct a more in-depth weight-of-evidence analysis and that some of the exposure scenarios were unrealistic.

Health Canada considered these comments and determined that, in the absence of an analysis to clearly identify the mode of action, it was appropriate to consider the substance as a carcinogen, based on international classifications. The scenarios were updated by adding average and 90th percentile exposure values to the screening assessment as well as rationales for exposure values used in margin-of-exposure calculations.

1,2-benzenediol (Catechol) and 1,4-benzendiol (Hydroquinone)

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

The departments considered these comments and note that the screening assessments identify industrial uses of these substances and 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.

- Industry stakeholders commented that the exposure scenario for photographic developing solution was unrealistic.

Health Canada has refined its approach for characterizing exposure from use of photographic developing solution and this revised approach is reflected in the final screening assessments. However, the overall conclusion that these substances are toxic under CEPA 1999 remains the same as previously proposed in the draft screening assessment.

Toluene diiosocyanates (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.

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.

Implementation, enforcement and service standards

As the proposed Order would add the nine substances to Schedule 1 of CEPA 1999, developing an implementation plan, a compliance strategy or establishing a service standard are not considered necessary without any specific risk management proposals.

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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, 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 by mail to the Executive Director, Existing

Substances Division, Environment Canada, Gatineau, Quebec K1A 0H3, by fax to 819-953-4936 or 1-800-410-4314, or by electronic mail 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 2) is amended by adding the following:

Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino] 2-methylphenyl]methylene]-, which has the molecular formula $C_{27}H_{31}N_3O$

Methyloxirane, which has the molecular formula C_3H_6O

Ethyloxirane, which has the molecular formula C_4H_8O

Naphthalene, which has the molecular formula $C_{10}H_8$

Toluene diisocyanates, which have the molecular formula $C_9H_6N_2O_2$

1,2-Benzenediol, which has the molecular formula $C_6H_6O_2$

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.

[38-1-o]

Footnote 1
201C;*Notice of intent to develop and implement measures to assess and manage the risks posed by certain substances to the health of Canadians and their environment*,*201D;Canada Gazette*, Part I, Vol. 140, No. 49. http://canadagazette.gc.ca/partI/2006/20061209/html/notice-e.html#i5.

Footnote 2

S.C. 1999, c. 33

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

Footnote b
S.C. 1999, c. 33