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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

Canadians depend on chemical substances that are used in hundreds of goods, from medicines to computers, fabrics and fuels. Unfortunately, some chemical substances can negatively affect our health and environment when released in a certain quantity or concentration in the environment. Scientific assessments of the impact of human and environmental exposure have determined that a number of these substances are toxic 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).

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 under subsection 90(1) of CEPA 1999, is to add the following substances to the List of Toxic Substances in Schedule 1 of CEPA 1999:

- Sulfuric acid, diethyl ester (CAS No. 64-67-5), hereafter referred to as "diethyl sulfate,"
- Sulfuric acid, dimethyl ester (CAS No. 77-78-1), hereafter referred to as "dimethyl sulfate," and
- Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (CAS No. 68921-45-9), hereafter referred to as "BNST."

This addition would enable the development of measures (which could include regulatory and non-regulatory instruments) under CEPA 1999 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), many of which have never been assessed as to whether they meet any of the toxicity 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 as well as those that are persistent or bioaccumulative and inherently toxic to human beings or non-human organisms. Pursuant to section 74 of the Act, substances that are "categorized in" must undergo an assessment to determine whether they meet any of the toxicity criteria set out in section 64.

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, around 200 of which 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 improving the degree of protection from 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 mentioned above. 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 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 priorities for assessment of risk to human health.

This information is being used to make decisions regarding the best approaches 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 12 to 20 substances, and every three months a batch is released, 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 if the substance is entering or may enter the environment in a quantity or concentration or under conditions that

- has or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitutes or may constitute a danger to the environment on which life depends; or
- constitutes 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 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, comprised of experts from various fields such as chemical policy, chemical production, economics and environmental health, was formed to provide advice to Government pertaining to the application of precaution and weight of evidence in screening assessments in the Challenge. These screening assessments are then published on the Chemical Substances Web site at www.chemicalsubstances.gc.ca, along with notices that are published in the *Canada Gazette*, Part I, which signal the Ministers' intent with regards to further risk management.

The Minister of 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 that the Ministers recommend adding the substance to Schedule 1. 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 on 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. "Risk management approach" documents, which provide an indication of where the Government will focus its risk management activities, have been prepared for Batch 4 substances and are available on the Chemical Substances Web site listed above.

The draft screening assessments for the fourth batch of the Challenge comprising 18 substances were published on the Chemical Substances Web site, and the statements recommending addition to Schedule 1 were published in the *Canada Gazette* on January 24, 2009.

Of the 18 substances assessed in Batch 4, 3 substances have been concluded to meet one or more of the criteria set out in section 64 of CEPA 1999. Of these, 2 substances are considered to be toxic to human health and 1 is considered to be toxic to the environment. The assessment summaries and conclusions and an overview of the public comments received during the public comment period for the 3 substances are presented below.

Substance descriptions, assessment summaries and conclusions

1. Human health priority substances

Diethyl sulfate

Diethyl sulfate, also known as "sulfuric acid, diethyl ester," is a man-made organic chemical. It has traditionally been used in the manufacture of a wide variety of other chemicals used in dyes, agricultural chemicals and pharmaceuticals. It is also used in the production of certain kinds of salts which are in textile applications, detergents, dyes and pigments, hair products, sanitization and disinfection products as well as in the manufacture of organically modified clays. In Canada, according to the information received as a result of a notice issued under section 71 of CEPA 1999, diethyl sulfate is used as a processing aid in the manufacture of abrasive grinding tools and as a chemical intermediate, especially in the paper industry. The substance can be found in residual amounts in chemical additives that are used as fabric softeners and as release technology aids to increase the absorbency of paper media. No companies in Canada reported manufacturing of diethyl sulfate in a quantity greater than 100 kg for the 2006 calendar year, and only one import of approximately 1 000 kg was reported.

Diethyl sulfate was considered a high priority for assessment of risk to human health as it was determined to present intermediate potential for exposure to individuals in Canada and had been classified by other agencies on the basis of carcinogenicity and genotoxicity, including

- the International Agency for Research on Cancer (IARC) — as a substance that is "probably carcinogenic to humans";
- the European Commission — as a substance "which should be regarded as carcinogenic to humans" and as a substance "which should be regarded as if mutagenic to humans"; and
- the United States National Toxicology Program (NTP) — as a substance that is "reasonably anticipated to be a human carcinogen".

Dimethyl sulfate

Dimethyl sulfate, also known as "sulfuric acid, dimethyl ester," is mainly used in the chemical and pharmaceutical industry, particularly in the preparation of dyes, agricultural chemicals, drugs and other specialty products. According to the information received as a result of a notice issued under section 71, dimethyl sulfate is used in Canada as a pharmaceutical intermediate. No companies in Canada reported manufacture in a quantity greater than 100 kg for the 2006 calendar year, though importation of approximately 1 000 kg was reported.

Dimethyl sulfate was considered a high priority for assessment of risk to human health as it was determined to present intermediate potential for exposure to individuals in Canada and had been classified by other agencies on the basis of carcinogenicity and genotoxicity, including:

- IARC — as a substance that is "probably carcinogenic to humans";
- European Commission — as a substance "which should be regarded as carcinogenic to humans" and as a substance which "causes concern for humans owing to possible mutagenic effects";
- United States Environmental Protection Agency — as a "probable human carcinogen"; and
- NTP — as a substance that is "reasonably anticipated to be a human carcinogen".

Assessment conclusions

On the basis of the carcinogenicity for which there is a probability of harm at any level of exposure, it is concluded that diethyl sulfate and dimethyl sulfate 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 as set out in section 64 of CEPA 1999. These substances are thus proposed for addition to Schedule 1 of CEPA 1999.

2. Ecological priority substances

BNST

The substance BNST, also known as "Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene," is used in Canada in a number of products such as engine oil and industrial lubricants. In 2006, between 100 000 and 1 000 000 kg of the substance were imported into Canada and between 1 000 000 and 10 000 000 kg were manufactured. The quantity of BNST manufactured and imported into Canada, along with the potentially wide-ranging uses of this substance, indicate that it could potentially be released in conditions that can have a detrimental effect on the Canadian environment.

The physical and chemical properties of BNST indicate that the substance does not degrade quickly in the environment. It is therefore expected to be persistent in water, soil and sediments. The substance also has the potential to accumulate in the tissues of living organisms and may further accumulate in the tissues of other organisms along the food chain. The substance has been determined to meet the persistence and bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* (see footnote 1) and therefore presents the potential to cause harm to the environment.

Assessment conclusion

Based on the information available, it is concluded that BNST 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 as defined under section 64 of CEPA 1999. This substance is thus proposed for addition to Schedule 1 of CEPA 1999.

In addition, the presence of BNST in the environment results primarily from human activity 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).

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 August 1, 2009, and may be obtained from the Chemical Substances Web site at www.chemicalsubstances.gc.ca or from the Program Development and Engagement Division, Gatineau, Quebec K1A 0H3, 819-953-4936 (fax), or by email at Existing.Substances.Existantes@ec.gc.ca.

Alternatives

The following measures can be taken after an assessment is conducted under section 74 of CEPA 1999:

- adding the substance to the Priority Substances List for further assessment (when additional information is required to determine if a substance meets the criteria in section 64 or not);
- 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, the implementation of virtual elimination.

It has been concluded in the final screening assessment reports that diethyl sulfate and dimethyl sulfate 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 set out in section 64 of CEPA 1999.

It has also been concluded that BNST 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.

These substances pose a risk to human health or the environment, and they meet one or more of the criteria under section 64 of CEPA 1999. Adding these substances to Schedule 1, which will enable the development of regulations or other risk management instruments, is therefore the best option.

In addition, the presence of BNST 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 of releases to the environment.

Benefits and costs

Listing these substances on Schedule 1 enables the Ministers to develop risk management proposals for these substances under CEPA 1999, which may be both regulatory and non-regulatory (such as pollution prevention plans, environmental emergency plans, guidelines, codes of practice or regulations), to help protect human health and the environment. The Government will assess costs and benefits and consult with the public and other stakeholders during the development of these risk management proposals.

Consultation

In accordance with the Act, on January 24, 2009, the Ministers published a summary of the scientific assessments for 18 substances of Batch 4 in the *Canada Gazette*, Part I, for a 60-day public comment period. Risk management scope documents were also released on the same date, outlining the preliminary options being examined for the management of the 3 substances proposed to be toxic under section 64 of CEPA 1999. Prior to this publication, Environment Canada and Health Canada have informed the governments of the provinces and territories through the CEPA National Advisory Committee (NAC) of the release of the Screening Assessment reports on the 18 substances, the risk management scope documents, and the public comment period mentioned above. No comments were received from CEPA NAC.

During the 60-day public comment period, a total of 14 submissions were received from 5 industry stakeholders, 2 industry associations and 3 non-governmental organizations, on the scientific assessment and risk management scope documents. All comments were considered in developing the final screening assessments.

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

Below is a summary of comments received for the Batch 4 assessments and new comments relevant to the overall process, as well as responses to these comments. In cases where comments have been made concerning whether or not a substance meets the criteria of section 64 of the Act due to uncertainty or lack of information, the Government will proceed to take action to protect the health of Canadians and their environment. The complete responses to comments received may be obtained at the Web site, address or fax number or email address listed above.

Summary of general comments

- Some non-government environmental health organizations commented that the screening assessments completed under the Chemicals Management Plan have not been consistent in their consideration of vulnerable populations, such as aboriginal communities or people who live in areas of high population.

  The screening assessments take into consideration the available data and the various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada. However, if information suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the screening assessment.

- Some non-government environmental health organizations recommended that the Government improve its assessment process to account for the exposure and release of substances (including breakdown products) throughout their life cycle.

  Extensive data are required to conduct complete life-cycle analysis, including assessment of the breakdown products, and its collection is normally only a possibility for very detailed risk assessments, such as those that may be conducted under the Priority Substance List program. In screening assessments, information obtained in response to the Challenge, as well as from a range of other sources, is used to identify sources of exposure to a substance. Assessment of risk then focuses on those sources that are most likely to be of concern. Breakdown products are addressed in screening assessments conducted under the Challenge if sufficient information is available and there is indication these products are hazardous.

- Some non-government environmental health organizations commented that to improve transparency in the screening assessments, the Government should clearly identify the toxicity data that are new since categorization and that were considered in the assessment.

  The Ministers are committed to transparency in conducting screening assessments, which are based on the collective information currently available for determination of the critical health and ecological effects, which could include data collected under the section 71 surveys, publicly available scientific data from a range of sources including published literature in scientific journals, as well as other international reviews. References are provided for data cited in the screening assessment reports.

Summary of comments on human health priority substances

Diethyl sulfate

- Some non-government environmental health organizations suggested that the assessment should consider exposure of workers, because exposure in the workplace may be prolonged and concentrated.

  Exposure of the general population to chemicals through environmental media (e.g. food, ambient air, soil, consumer products) is taken into account in developing both the screening assessment and risk management scope documents. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is also considered in the risk assessment.

- A non-government environmental health organization suggested that exposure data should reflect combined exposure from all potential sources, including consumer products.

  In the screening assessment, combined exposures from multiple sources are considered in the estimation of exposure from environmental media (air, soil, water, etc.). While risk from exposure to consumer products is calculated for individual products, the effect of combined exposures may be considered in determining the adequacy of the margin of exposure. However, since diethyl sulfate is used mainly as an intermediate in a closed system, emission to the environment is likely to be very low; furthermore, the substance has no direct use in consumer products. The combined exposure to diethyl sulfate from all sources is therefore likely to be also low.

- A chemical manufacturer suggested that diethyl sulfate does not meet the criteria of section 64 of CEPA 1999, as there does not appear to be any exposure to Canadians.

  Based on the conservative estimates of exposure presented in the screening assessment, Canadians' exposure is expected to be very low. However, in light of the carcinogenicity of the substance, for which there is a probability of harm to human health at any level of exposure, the screening assessment concluded that diethyl sulfate 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, thereby meeting one of the criteria set out in section 64 of CEPA 1999.

Dimethyl sulfate

- Some non-government environmental organizations suggested that the assessment consider exposure of workers in industrial facilities, wholesale operations, and trades, because exposure in the workplace may be prolonged and concentrated.

  Exposure of the general population to chemicals through environmental media (e.g. food, ambient air, soil, consumer products) is taken into account in developing both the screening assessment and risk management scope documents. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is also considered in the risk assessment.

- Some non-government environmental organizations suggested that exposure data should reflect cumulative exposure and include emissions from oil-fired power plants.

  There are currently no data available (in Canada or otherwise) that would permit quantification of emissions from oil-fired power plants. However, exposure of Canadians to dimethyl sulfate from these sources is likely much lower than levels reported several years ago in the United States, as measures have been introduced since to significantly reduce sulphur-based emissions. In addition, any dimethyl sulfate present in the atmosphere would undergo rapid hydrolysis.

Summary of comments on ecological priority substances

BNST

- A chemical manufacturer commented that given the low levels of BNST in the lubricating fluids, it is expected that the toxicity characteristics would be dominated by the base oil.

  The base oil is the major component of lubricants; however, even low percentages of lubricant additives may have an effect on organisms in the environment.

- A chemical manufacturer commented that the main use of BNST is as an additive to a product that, at the end of its life cycle, no longer contains BNST and that release of BNST to the environment may not occur.

  Potential for releases to the environment and potential to cause detrimental effects to organisms, along with evidence that a substance is persistent and bioaccumulative, provides sufficient evidence of the substance's potential to be entering the environment under conditions that may have harmful long-term ecological effects. Because of the use of BNST as an additive in lubricating oils, there is a potential for release of BNST to the environment due to spills, leaks and disposal of lubricants that have not been depleted of BNST.

- Some chemical manufacturers requested clarification on the chemical structure of BNST used in the draft screening assessment

report. They also submitted an alternate structure and recommended that the report be revised accordingly.

The range of structures that may represent BNST has been examined. This examination resulted in a new representative structure being used to model parameters considered in the final screening assessment for BNST.

Implementation, enforcement and service standards

The proposed Order would add the three above-mentioned substances to Schedule 1 of CEPA 1999, thereby allowing the Ministers to meet their obligation to publish proposed regulations or other instruments no later than August 1, 2011, and finalize them no later than February 1, 2013. Developing an implementation plan, a compliance strategy or establishing service standards are 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 respecting preventive or control actions for these substances. In addition, the Ministers intend to examine a variety of tools to ensure virtual elimination of BNST through subsequent consultation and cost-benefit analysis.

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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 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 17, 2009

JURICA ČAPKUN
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:**

Sulfuric acid, diethyl ester, which has the molecular formula $C_4H_{10}O_4S$

Sulfuric acid, dimethyl ester, which has the molecular formula $C_2H_6O_4S$

Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene

COMING INTO FORCE

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

[40-1-o]

Footnote 1
The *Persistence and Bioaccumulation Regulations* set the criteria which are used to determine if a substance is persistent or bioaccumulative for the purposes of section 77.

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

Footnote b
S.C. 1999, c. 33

Footnote 2
S.C. 1999, c. 33

Date Modified: 2009-10-02