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SOR/2017-247 November 24, 2017

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

P.C. 2017-1427 November 23, 2017

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 November 5, 2016, a copy of the proposed Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012 and persons were given an opportunity to file comments with respect to the proposed Regulations or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

Whereas, pursuant to subsection 93(3) of that Act, the National Advisory Committee has been given an opportunity to provide its advice under section 6 (see footnote c) of that Act;

And whereas, in the opinion of the Governor in Council, pursuant to subsection 93(4) of that Act, the proposed Regulations do not regulate an aspect of a substance that is regulated by or under any other Act of Parliament in a manner that provides, in the opinion of the Governor in Council, sufficient protection to the environment and human health;

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 93(1) of the *Canadian Environmental Protection Act, 1999* (see footnote d), makes the annexed *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012.*

Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012

Amendments

1 Subsection 9(3) of the Prohibition of Certain Toxic Substances Regulations, 2012 (see footnote 1) is replaced by the following:

Temporary permitted uses

(3) Any person that, under paragraph 6(2)(b), manufactures or imports a toxic substance that is set out in Part 2 of Schedule 2 or a product containing it on the date set out in column 3 in respect of that substance may continue that activity if they have been issued a permit under section 10.

2 Item 3 of Part 1 of Schedule 2 to the Regulations is repealed.

3 Item 1 of Part 2 of Schedule 2 to the Regulations is repealed.

Coming into Force

4 These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Issues

In 2009, the substance "benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene" (BNST) was assessed as toxic under the *Canadian Environmental Protection Act, 1999* (CEPA),was determined to be persistent and bio-accumulative, and therefore met the criteria for virtual elimination (VE). As a result, BNST was added to Schedule 1 of CEPA in 2011, and the manufacture, use, sale, offer for sale and import of BNST was prohibited under the *Prohibition of Certain Toxic Substances Regulations, 2012* (the Prohibition Regulations, 2012) with exemptions for limited additional uses as well as a permit scheme to allow certain uses, which expires on March 14, 2018.

Based on new empirical data that was unavailable in 2009, the Department of the Environment and the Department of Health have since concluded that BNST does not pose a risk to the environment or to human health, does not meet any of the criteria outlined under CEPA for listing as a toxic substance, and does not meet the criteria for virtual elimination set out in CEPA. (see footnote 2) As a result, existing prohibitions and regulatory controls on BNST under the Prohibition Regulations, 2012 are no longer necessary. In addition, information from industry shows that if permits can no longer be renewed after March 14, 2018, this could lead to a shortage and the premature end-of-life of replacement parts and legacy equipment for the automotive sector as well as the electrical and electronic equipment sectors.

Background

The substance BNST was identified as one of approximately 200 substances that were high priorities for action under the Chemicals Management Plan (CMP). In 2009, the final screening assessment for BNST found that it may be moderately to highly hazardous to aquatic organisms. BNST met the criteria for persistence and bioaccumulation potential under the *Persistence and Bioaccumulation Regulations* since available evidence at that time indicated that it did not degrade quickly in the environment, and may also accumulate in the tissues of living organisms in food chains. (see footnote 3), (see footnote 4) As a result, the assessment concluded that BNST was potentially harmful to the environment as it met the criteria set out in paragraph 64(a) under CEPA for listing as a toxic substance. (see footnote 5) As a result, BNST was subsequently added to the List of Toxic Substances in Schedule 1 of CEPA on March 2, 2011.

BNST also met the virtual elimination (VE) criteria set out in subsection 77(4) of CEPA as it was found to be persistent and bioaccumulative, and its presence in the environment was primarily a result of human activity. (see footnote 6) Under CEPA, VE is the reduction of the quantity or concentration of a toxic substance in releases to the environment to below a level of quantification specified by the Ministers of Health and of the Environment. (see footnote 7) To meet the environmental objective of achieving the lowest possible concentration in the environment, BNST was also prohibited under the Prohibition Regulations, 2012.

The manufacture, use, sale, offer for sale and import of BNST and products containing BNST was prohibited under the Prohibition Regulations, 2012 on January 2, 2013, with exemptions that allow

- the on-going use, sale, offer for sale of BNST and products containing BNST that were manufactured or imported before the regulations came into force on March 13, 2013;
- the manufacture, use, sale, offer for sale and import of BNST, or a product that contains BNST, as an additive in rubber (except in tires); and
- the manufacture, use, sale, offer for sale and import of BNST, or a product that contains BNST, as an additive in lubricants until March 13, 2015. After this deadline, permits were available for the continued use of BNST, and products containing BNST, as an additive in lubricants. Permits are valid for one year and can be renewed twice for a total of three years ending March 14, 2018.

Leading up to, and following the expiry of the temporary exemption for BNST, industry stakeholders in the automotive, as well as the electrical and electronic equipment sectors, submitted information to the Department of the Environment (the Department) through permit applications. These permit applications indicated that it was not technically or economically feasible to completely phase-out the use of BNST as an additive in lubricants in replacement parts and legacy equipment by the March 14, 2018, regulatory deadline.

In 2015, the Department received over 50 permit applications for the use of BNST in replacement parts and legacy equipment. Stakeholders indicated again that it was not technically or economically feasible to phase out the use of BNST in replacement parts and legacy equipment by 2018. As a result, the Department conducted further consultations between November 2015 and February 2016. These consultations confirmed that the Prohibition Regulations, 2012 could lead to a shortage and the premature end-of-life of replacement parts and legacy equipment containing BNST in cases where it was not technically or economically feasible to replace such parts and equipment with BNST-free alternatives.

To address this issue, the proposed *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012* (the proposed Amendments) were published in the *Canada Gazette*, Part I, on November 5, 2016. (see footnote 8) The proposed Amendments would have enabled the continued use of BNST in replacement parts and legacy equipment, and would have extended the time limited exemption for BNST in lubricants until 2025.

New information and recent developments

The substance BNST is part of a larger class of substituted diphenylamine (SDPAs) chemicals which are alternatives to BNST based on their common chemical structures and similar physical-chemical properties. To support industry's transition to BNST alternatives and as part of the CMP, a screening assessment of the ecological and human health risks of 14 SDPA substances, including BNST, was conducted by the Department of the Environment and the Department of Health, beginning in 2013. The final screening assessment for SDPA substances was published on December 9, 2017, in the *Canada Gazette*, Part I.

Based on new empirical data, this peer-reviewed assessment indicated that there was a low risk of harm to organisms and the broader integrity of the environment, and a low potential to cause harm to human health from these substances. As a result, the 2017 assessment concluded that the 14 SDPA substances, including BNST, do not meet any of the criteria outlined under CEPA for listing as a toxic substance. (see footnote 9) Based on this conclusion, BNST no longer meets the VE provisions set out under CEPA.

Changes between the 2009 and 2017 assessments

The 2009 assessment conducted on BNST was based on information available at the time, which suggested that BNST may be harmful to aquatic organisms at low concentrations and that it may accumulate in the tissues of living organisms in food chains. (see footnote 10) Therefore, based on analysis of available evidence, the Department implemented the precautionary principle which resulted in the addition of BNST to Schedule 1 of CEPA and subsequent prohibition. (see footnote 11) Furthermore, the 2009 assessment of BNST focused primarily on information relevant to the evaluation of ecological risks, as BNST was not considered to be a high priority for assessment of potential risks to human health. (see footnote 12)

The 2017 assessment included new data that was not available in 2009. The 2017 assessment used new empirical evidence (including field sampling data) and models generated by the Department, to determine the potential ecological risks associated with releases of the 14 SDPA substances, including BNST, to the environment from activities in which they are used (such as manufacturing). (see footnote 13), (see footnote 14) The 2017 conclusion differs from the 2009 conclusion because new data indicated that concentrations of these substances found in fish tissue were low, with many below detection limits. Concentrations found in other organisms (such as shrew and earthworm) also showed a low potential for harm when compared to thresholds at which SDPA substances could have an effect. As such, the Department concluded that aquatic organisms are not being

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exposed to sufficient quantities of these substances to cause harm. Furthermore, the 2017 assessment also included a human health assessment for the 14 SDPA substances, including BNST, which concluded that based on current exposure levels, these substances do not pose a risk to human health.

A separate regulatory proposal, based on the 2017 assessment, to remove BNST from Schedule 1 of CEPA is being published in the *Canada Gazette*, Part I, concurrently with the publication of the Amendments to the Prohibition Regulations, 2012, in the *Canada Gazette*, Part II, to end the prohibition on BNST. (see footnote 15)

BNST use in Canada

The substance BNST is an industrial chemical and is part of the diarylamine class of antioxidants. In many types of lubricant formulations, diarylamine antioxidants are typically used at rates up to 1.0% by weight of lubricant. The substance BNST has been used mainly as an antioxidant additive in vehicle engine oil, but has also been used in commercial and industrial lubricants. About 500 tonnes of BNST were consumed in Canada in 2006, of which over 90% was used in vehicle engine oil formulations. In 2006, sales of BNST were estimated to represent 15% to 18% of the overall market for diarylamine antioxidants.

In 2015, the quantities of BNST used in Canada ranged between 0.66 and 2.45 tonnes for use as an additive in lubricants. It is estimated that since 2006, the use of BNST in lubricants had decreased by more than 99% and were replaced with other SDPA substances. The information obtained, through the permit applications submitted under the Prohibition Regulations, 2012, shows that BNST continues to be used as an additive in lubricants found in replacement parts and in legacy equipment primarily in the automotive, as well as the electrical and electronic equipment sectors. No permits have been requested or granted for the use of BNST as an additive in engine oil in Canada. Available information suggests that there may also be a minor use of BNST as an additive in rubber applications for industrial equipment and machinery and in rubber parts used in vehicles. The use of BNST in rubber products, except in tires, is exempted under the Prohibition Regulations, 2012.

Legacy equipment is equipment that is still available or required for use. This equipment has been manufactured or designed before the coming into force of the Prohibition Regulations, 2012 and its usage is currently authorized through permit applications until 2018. This category includes, for example, vehicles, computers, printers, electronic storage systems, electric power supplies, or heating and cooling equipment, that are in consumer, commercial or industrial operation, or available for sale in Canada.

Replacement parts (commonly referred to as spare parts) are required to maintain and service legacy equipment sold in Canada. Examples of replacement parts include automotive or other assemblies that require lubrication, such as hydraulic brakes, drivetrain components, motor fans and other electronic components. Replacement parts may already be available for use or may be manufactured and imported into Canada to meet warranty and contractual obligations as well as performance standards. Lubricant quantities can range from a drop to a few litres in equipment and its parts, and typically contain less than 1% of BNST by weight of lubricant.

Technical and economic issues raised by industry

Stakeholders have indicated that the use of BNST as an additive in lubricants is expected to be phased-out of new replacement parts and new equipment by 2018. However, for existing legacy equipment and their replacement parts, it may not be technically or economically feasible to remove the BNST-containing lubricants found in the parts or equipment, and replace them with a BNST-free alternative. Furthermore, it may not be feasible to replace such parts or equipment with newer versions that may be BNST-free within warranty and contractual obligations, as well as performance standards to service and maintain them.

For legacy equipment, a three to ten year sale window is expected to be necessary to deplete remaining stock. Service contracts vary (typically ranging from 5 to 10 years) but the obligations to maintain and provide replacement parts can be longer depending on the operating life of the equipment used (e.g. approximately 15 to 30 years for vehicles).

Release profile for current uses of BNST

BNST continues to be used as an additive in lubricants found in replacement parts and in existing equipment, primarily in the automotive as well as the electrical and electronic equipment sectors. In these sectors, given that BNST is used in low quantities (milligrams of BNST) and at low concentrations (less than 1% by weight of lubricant) within sealed components or enclosed within equipment, releases to the environment during normal use are not expected. In addition, recycling programs are in place for end-of-life vehicles as well as electrical and electronic equipment which further prevent the potential releases of BNST associated with replacement parts and legacy equipment. Given the above, current releases of BNST to the environment from the use of replacement parts and legacy equipment is minimal.

Objectives

The objective of the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012* (the Amendments) is to update the Prohibition Regulations, 2012 to reflect new information on BNST from the final screening assessment for SDPAs, which concluded that it does not pose a risk to the environment or to human health.

Description

The Amendments remove BNST from the Prohibition Regulations, 2012 by modifying Part 1 and Part 2 of Schedule 2 accordingly. As a result, this will allow the manufacture, use, sale, offer for sale, or import of BNST, or a product containing it. The Amendments come into force on the day they are registered.

"One-for-One" Rule

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The "One-for-One" Rule does not apply to the Amendments as there will be no incremental administrative impacts on business. Since permits for the temporary use of BNST expire as of March 14, 2018, under the Prohibition Regulations, 2012, stakeholders will not be applying for permits after this date. The Amendments remove BNST from the Prohibition Regulations, 2012 and will not include any administrative requirements related to BNST use as a result. Therefore, compared to the Prohibition Regulations, 2012, there is no change in administrative costs. Laboratories that use more than 10 grams of any of the toxic substances listed under the Prohibition Regulations, 2012 for analysis, in scientific research, or as a laboratory analytical standard, are subject to a reporting requirement. The Department has not received any reports from laboratories using more than 10 grams of BNST, therefore, the Amendments are not expected to change laboratory reporting compared to the Prohibition Regulations, 2012.

Small business lens

The small business lens does not apply to the Amendments as no additional costs would be incurred by small businesses.

Consultation

Consultations prior to the Canada Gazette, Part I, publication of the proposal to allow BNST use after 2018

The Department conducted outreach between November 2015 and February 2016 in order to seek comments from a wide range of interested parties on the proposal to amend the Prohibition Regulations, 2012 to allow BNST use after 2018 in replacement parts and legacy equipment lubricant (prior to its *Canada Gazette*, Part I, publication on November 5, 2016). The Department solicited feedback from stakeholders on changes to BNST controls under the Prohibition Regulations, 2012 to address the issues raised by current permit holders. All industry stakeholders who were granted permits for the continued use of BNST, as well as stakeholders who submitted comments in 2011 to the Department during the public consultation period on the proposed addition of BNST to the Prohibition Regulations, 2012 were consulted. These stakeholders included two environmental non-governmental organizations (ENGOs).

ENGOs had expressed concern regarding the proposed addition of an exemption for replacement parts containing BNST without an expiry date. They also suggested that a five-year extension to the temporary exemption for BNST used as an additive in lubricants would be adequate to allow for the phase out of the substance in all uses, including replacement parts. Furthermore, ENGOs suggested that broader consultation be undertaken to solicit feedback from stakeholders on the changes under consideration.

Overall, industry stakeholders were very supportive of the proposal to provide flexibility for the use of BNST beyond March 2018, in replacement parts and legacy equipment. Ten industry stakeholders and associations commented that it was not technically and economically feasible to phase out all uses of BNST as an additive in lubricants by March 14, 2018, in replacement parts used to service and maintain equipment manufactured or imported prior to the coming into force of the BNST provisions. Seven industry stakeholders and associations also commented that there were technical and economic difficulties in phasing out all uses of BNST as an additive in lubricants by March 14, 2018, in replacement parts the provide that there were technical and economic difficulties in phasing out all uses of BNST as an additive in lubricants by March 14, 2018, in legacy equipment used to service and maintain equipment in the electrical and electronic sectors. (see footnote 16)

Comments received following the Canada Gazette, Part I, and Consultation Document publications

The proposal to amend the Prohibition Regulations, 2012 to allow BNST use after 2018 was published in the *Canada Gazette*, Part I, on November 5, 2016, for a 75-day public comment period. Subsequent to this publication, on December 10, 2016, a draft screening assessment for SDPAs was published for a 60-day public comment period. (see footnote 17) The draft screening assessment indicated that none of the SDPAs, including BNST, were harmful to the environment or human health. Given this new information, the Department published a separate consultation document, seeking comment from stakeholders regarding possible approaches to modifying the proposed amendments to the Prohibition Regulations 2012, based on possible outcomes of the final screening assessment of SDPAs.

In the first scenario, if the assessment concluded that BNST was not toxic under CEPA, the Department of the Environment and the Department of Health would recommend changing the regulatory proposal to remove all existing prohibitions and regulatory controls on BNST from the Prohibition Regulations, 2012. In the second scenario, if the assessment concluded that BNST was still a risk to the environment, the Department would recommend finalizing the Amendments to provide flexibility for the use of BNST beyond March 2018 in replacement parts and legacy equipment.

During the two comment periods, stakeholders were given the opportunity to provide comments on the proposal to allow BNST use after 2018, as published in the *Canada Gazette*, Part I, and the proposed approaches presented in the consultation document. Two ENGOs and four industry stakeholders provided comments which are summarized below.

<u>Comment 1</u>: Two ENGOs stated that the two scenarios presented in the consultation document were premature given data gaps and uncertainty of information presented in the draft screening assessment of SDPAs.

<u>Response 1</u>: The Department reassessed BNST based on new empirical data that became available after its assessment in 2009. The 2017 assessment concluded that the 14 SDPAs considered, including BNST, do not meet any of the criteria set out under CEPA for listing as a toxic substance. Furthermore, as a result of the new information presented in the 2017 assessment, BNST no longer meets the VE provisions of CEPA.

Under the CMP, the Department takes a scientific, evidence-based and peer-reviewed approach to assessing substances that may pose a risk to the environment or to human health as part of its risk management activities. Based on the conclusions of the 2017 assessment, the Department is taking the most appropriate course of action for BNST. As a result, the first scenario to remove BNST from the Prohibition Regulations, 2012 is now being published by the Department in the *Canada Gazette*, Part II. The Department acknowledges that there is always some uncertainty involved with any type of scientific assessment. However, given that there is more data and information available to support the analysis than there was in 2009, the Department is confident in the final results.

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Furthermore, the Department met with the two ENGOs to provide them with more details about the assessment and the approach/process taken under the CMP. Following this meeting ENGOs did not express opposition, or support for the approach taken by the Department.

<u>Comment 2</u>: Four industry stakeholders were supportive of the two proposals described in the consultation document. These stakeholders were especially supportive of the proposed removal of existing prohibitions and regulatory controls on BNST given that the 2016 draft screening assessment proposed that BNST was not toxic.

<u>Response 2</u>: As a result of the final screening assessment for SDPAs, the first scenario to remove BNST from the Prohibition Regulations, 2012 is now being published by the Department in the *Canada Gazette*, Part II. The Department will not be moving forward with the second scenario, which would have involved publishing final Amendments in the *Canada Gazette*, Part II, to allow limited BNST use after 2018.

<u>Comment 3</u>: One industry association commented that the series of announcements on BNST was confusing and urged the Department to avoid similar complexities in the future. In particular, when the initial publication of proposed Amendments came out in the *Canada Gazette* on November 5, 2016, there was no technical justification for allowing the extension of BNST's use in commerce which made it difficult to determine an appropriate response.

<u>Response 3</u>: The Department acknowledges that there has been a period of uncertainty with respect to BNST. The consultation document, published on the same day as the draft screening assessment for SDPAs, on December 10, 2016, sought to clearly communicate the Department's regulatory approach for BNST as a result of the assessment's conclusion proposing that it was no longer toxic, and intended to provide the full range of regulatory options pending the outcome of the final screening assessment for SDPAs.

The Department also acknowledges that the phase-out of BNST has been completed in the majority of applications in Canada. However, previous outreach consultations confirmed there were remaining uses in replacement parts and legacy equipment which represented a challenge for some industry stakeholders and a risk of the premature end-of-life of equipment without an extension to the permitting regime. To address this issue and ensure regulatory certainty before the expiry of the BNST permits in March 2018, the Department proceeded with the publication of the proposed Amendments in *Canada Gazette*, Part I, on November 5, 2016, shortly before the draft screening assessment for SDPAs was published.

<u>Comment 4</u>: Two ENGOs stated that the scenarios presented in the consultation document lacked details. Regarding the first scenario, ENGOs commented that it did not articulate whether restrictions would remain for BNST following its removal from the Prohibition Regulations, 2012. Regarding the second scenario, ENGOs commented that it did not provide details on how the extension of the time-limited exemption for BNST used as an additive in lubricants would allow the continued use of new parts.

<u>Response 4</u>: The Department originally published a detailed explanation of the second scenario when it was proposed in the *Canada Gazette*, Part I, on November 5, 2016, which provided stakeholders with a 75-day comment period. As such, it was not provided in as much detail within the consultation document but rather gave a summary of this explanation as well as a link to the publication instead.

The Department acknowledges that there has been a period of uncertainty with respect to BNST. The consultation document, published on the same day as the draft screening assessment for SDPAs, on December 10, 2016, sought to clearly communicate the Department's regulatory approach for BNST as a result of the assessment's conclusion proposing that it was no longer toxic, and intended to provide the full range of regulatory options pending the outcome of the final screening assessment for SDPAs.

Furthermore, the Department met with ENGOs to provide more details about the two scenarios presented in the consultation document. Following this meeting, ENGOs did not present further questions to the Department.

As a result of the final screening assessment for SDPAs, the Department is implementing the first scenario. Stakeholders were provided an opportunity to submit comments during the public consultation period for the assessment, and no evidence was provided that contradicted its conclusions. Therefore, all regulatory controls for BNST under the Prohibition Regulations, 2012 are removed.

<u>Comment 5</u>: In response to the second scenario, one industry stakeholder proposed that a concentration limit be added for BNST as part of the final Amendments as the substance is found in very small quantities.

Response 5: As a result of the final screening assessment for SDPAs, all regulatory controls for BNST under the Prohibition Regulations, 2012 are removed.

Rationale

Based on new information, the 2017 final screening assessment for SPDAs concluded that BNST does not pose a risk to the environment or to human health and no longer meets any of the criteria outlined under CEPA for listing as a toxic substance or for VE. As a result, existing prohibitions and regulatory controls on BNST under the Prohibition Regulations, 2012 are no longer necessary.

The Amendments remove existing prohibitions and regulatory controls on BNST from the Prohibition Regulations, 2012 and allow the manufacture, use, sale, offer for sale and import of BNST, for all uses, including as an additive in lubricants. As a result, the Amendments will prevent a shortage and the premature end-of-life of replacement parts and legacy equipment in cases where it is not technically or economically feasible to replace such parts and equipment with BNST-free alternatives.

It is expected that existing businesses will not revert back to using BNST as costs have already been incurred by the majority of this industry to switch to alternatives, and replacement alternatives are similar to BNST in regards to performance and cost. It is possible that new businesses that enter the market may use BNST, thus increasing its use over time. However, this is not expected to result in increased harm to the environment because manufacturing quantities would need to increase over 100 times for there to be a significant change in expected exposure. Further, the SDPA market is mature, and it is expected that there would not be any substantial changes in demand for SDPAs, including BNST.

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The "One-for-One" Rule and the small business lens would not apply to the proposed Amendments, as there would be no change in administrative burden and no negative impacts to business.

During the comment periods for the *Canada Gazette*, Part I, and the Consultation Document publications, stakeholders were given the opportunity to provide comments on the proposed Amendments and the regulatory approach. Industry stakeholders responded and were supportive of the removal of BNST from the Prohibition Regulations, 2012. ENGOs initially raised concerns on the approach taken in the consultation document. However, in follow-up meetings with ENGOs, the Department provided additional information and no further concerns were raised.

Strategic environmental assessment

As required by the Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals, a preliminary scan was conducted which concluded that a strategic environmental assessment is not required as there would be no expected important environmental effects, either positive or negative. (see footnote 18)

Contacts

Gwen Goodier Executive Director Chemicals Management Division Department of the Environment Gatineau, Quebec K1A 0H3 Telephone: 819-938-4506 Email: <u>ec.interdiction-interdiction.ec@canada.ca (mailto:ec.interdiction-interdiction.ec%40canada.ca)</u>

Matthew Watkinson Director Regulatory Analysis and Valuation Division Department of the Environment Gatineau, Quebec K1A 0H3 Telephone: 873-469-1452 Email: <u>ec.darv-ravd.ec@canada.ca (mailto:ec.darv-ravd.ec%40canada.ca)</u>

Footnote a

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

Footnote b S.C. 1999, c. 33

Footnote c S.C. 2015, c. 3, par. 172(d)

<u>Footnote d</u> S.C. 1999, c. 33

Footnote 1 SOR/2012-285

Footnote 2

The 2017 final screening assessment for substituted diphenylamines (SDPAs) is available on the <u>Environment Canada website</u> (<u>https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-substituted-diphenylamines.html</u>).

Footnote 3

The persistence and bioaccumulation criteria are set out in the Persistence and Bioaccumulation Regulations pursuant to CEPA, and are available on the <u>CEPA Environmental Registry website (http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=35)</u>.

Footnote 4

The notice summarizing the scientific considerations of the 2009 final screening assessment report for BNST (*Canada Gazette*, Part I, Vol. 143, No. 31, Supplement pp. 10-12) is available on the <u>Canada Gazette website (http://www.gazette.gc.ca/archives/p2/2009/index-eng.html)</u>.

Footnote 5

Paragraph 64(a) stipulates that a substance is toxic if it 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.

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Footnote 6

Criteria outlined under CEPA are available on the <u>CEPA Environmental Registry website (https://www.ec.gc.ca/lcpe-cepa/default.asp?</u> lang=En&n=CC0DE5E2-1&offset=&toc=show).

Footnote 7

The level of quantification is the lowest concentration of a toxic substance that can be accurately measured using sensitive but routine sampling and analytical methods. This level is determined in a laboratory. The risk posed by the substance and socio-economic factors have no bearing in its determination.

Footnote 8

The proposed Amendments published in the *Canada Gazette*, Part I, are available on the *Canada Gazette* website (http://www.gazette.gc.ca/rppr/p1/2016/2016-11-05/html/reg3-eng.php).

Footnote 9

The 2017 final screening assessment for substituted diphenylamines (SDPAs) is available on the <u>Environment Canada website</u> (<u>https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-substituted-diphenylamines.html</u>).

Footnote 10

The data used to develop the assumptions and to estimate input parameters of the models came from regulatory surveys, Statistics Canada, manufacturers' websites, technical databases and other relevant documents.

Footnote 11

Under CEPA, the precautionary principal indicates that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Footnote 12

The criteria to determine if a substance is a high priority for human health assessment are available on the <u>CEPA Environmental Registry website</u> (<u>http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=6FCF94B3-CD63-CE3A-4A08-7764E4B847C6</u>).

Footnote 13

Field sampling data on concentration levels associated with the SDPA substances was collected between 2012 and 2015 from six waterbodies near a manufacturing site and four waterbodies across Ontario.

Footnote 14

This new empirical evidence became available through government-led and industry submitted studies.

Footnote 15

The proposal to remove BNST from Schedule 1 published in the *Canada Gazette*, Part I, is available on the <u>Canada Gazette website</u> (http://www.gazette.gc.ca/rp-pr/p1/index-eng.html).

Footnote 16

Detailed comments and responses to stakeholder consultations from the proposed Amendments published in the *Canada Gazette*, Part I, are available on the *Canada Gazette* website (http://www.gazette.gc.ca/rp-pr/p1/2016/2016-11-05/html/reg3-eng.php).

Footnote 17

The Consultation Document on the Proposed Approach to Regulatory Amendments to the Prohibition of Certain Toxic Substances Regulations, 2012 in consideration of the draft Screening Assessment for Substituted Diphenylamine (SDPA) Substances is available on the <u>CEPA Environmental Registry</u> <u>website (https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/consultation-document-amending-prohibition-diphenylamine.html).</u>

Footnote 18

The Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals is available on the <u>Canadian Environmental</u> Assessment Agency website (https://www.canada.ca/en/environmental-assessment-agency/programs/strategic-environmental-assessment/cabinetdirective-environmental-assessment-policy-plan-program-proposals.html).

Government of Canada activities and initiatives

Apology to LGBTQ2 Canadians