Government of Canada / Gouvernement du Canada

Risk Management Scope

for

Boric Acid, Its Salts and Its Precursors

Environment and Climate Change Canada

Health Canada

July, 2016

Canada

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for boric acid, its salts and its precursors (hereafter referred to as boric acid). In particular, the Government of Canada is considering the following primary actions to address human health concerns:

- Cosmetics: Measures to mitigate the potential risk of exposure to boric acid to infants and young children through the use of cosmetics (e.g., diaper and body creams). Action may be proposed after review of the List of Prohibited and Restricted Cosmetic Ingredients (Cosmetic Ingredient Hotlist), an administrative list published by Health Canada to communicate to manufacturers, importers and others, that cosmetics containing particular substances at particular concentrations are likely to contravene the *Food and Drugs Act* or the *Cosmetic Regulations.*

- Arts and Crafts Materials, and Toys: For home-made clays, doughs, slimes, putties, and other children's craft products made with boric acid, a public information document, outlining the potential health risks associated with boric acid and home-use of borax (as boric acid) in order to discourage consumers from this practice. For commercially available children's toys, compliance and enforcement of the existing prohibition on boron will continue as part of the regular enforcement of the *Toys Regulations* under the *Canada Consumer Product Safety Act* (CCPSA).

- Cleaning products: Measures which may include the preparation of public information material on the potential health implications of exposure to boric acid and investigation into the feasibility of product reformulation, guided by discussion with and information received from industry stakeholders.

- Swimming pool/spa water treatment chemicals: Investigation into the feasibility of limiting the concentration of boric acid in these products, guided by discussion with and information received from industry stakeholders.

The Government of Canada is also considering measures to reduce anthropogenic releases of boric acid to water from the metal mining sector to address ecological concerns:

- by working with a specific mill and the provincial authority to gather additional information on proposed actions to reduce releases of boric acid, and to determine appropriate risk management at this site, if required.

If available, information on the following items should be provided on or before September 21, 2016, to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Alternative substances to the use of boric acid in pool chemicals and in certain cleaning applications; and
- Details on actions proposed by a specific mill and the provincial authority to reduce boric acid releases to the aquatic environment.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of actions proposed to manage boric acid and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details.

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1. Context

The *Canadian Environmental Protection Act,* 1999 (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic[1,2] to human health and/or the environment as set out in section 64 of CEPA, and if so, to manage the associated risks.

As part of the second phase of the Government of Canada's Chemicals Management Plan (CMP), the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in 9 substance groupings (Canada 2011a). The Substance Groupings Initiative is a key element of the CMP. Fourteen boron-containing substances were identified as priorities for assessment, given that they met the categorization criteria under section 73 of CEPA. Subsequently, boron-containing substances that may transform into boric acid (i.e. boric acid precursors), with the exception of polymers, were included for assessment efficiency.

2. Issue

2.1 Draft Screening Assessment Report Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment relevant to the evaluation of boric acid, its salts and its precursors in Canada. There are many different salts of boric acid that dissociate to boric acid. There are also many substances that release boric acid as a result of relevant transformation pathways (e.g. hydrolytic, oxidative, digestive or metabolic) at environmentally or physiologically relevant conditions

[1]Section 64 [of CEPA: For the purposes of [Parts 5 and 6 of CEPA], except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

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

[2]A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of consumer products. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations* which is part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

(i.e. pH and concentration); these are considered to be precursors of boric acid. Boron-containing substances other than polymers, were evaluated for their potential to be precursors of boric acid. Precursors of boric acid include the following groups of boron-containing substances: oxygen compounds of boron (including boric acids, borates or boric acid salts and borate esters), boron halides, boranes (borohydrides) and organo-boron compounds. Not all boron-containing substances are precursors of boric acid; notable exceptions include elemental boron, borides (such as boron nitride or carbide) and inert substances (e.g. sodium borate silicates or borosilicate glass), which therefore fall outside the scope of this assessment.

A notice summarizing the scientific considerations of the draft Screening Assessment Report (dSAR) for this substance grouping was published in the *Canada Gazette*, Part I, on July 23, 2016 (Canada 2016a). Based on the information available, the dSAR proposes that boric acid, its salts and its precursors are toxic under section 64 *(a)* and *(c)* of CEPA as they are 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 and constitute or may constitute a danger in Canada to human life or health (Canada 2016b).

For the purposes of the human health screening assessment, “boric acid” refers to boric acid, its salts and its precursors and where relevant, specific substances containing boron have been explicitly identified by name or CAS Registry Number. The same nomenclature and approach is used in the Risk Management Scope.

For the environment, the dSAR has identified the release of boric acid in the effluent of a single mill that recovers precious and base metals from a range of feeds as the source of concern for aquatic organisms. Facilities with similar operations within the metal mining sector have also been identified as a potential risk. However, Environment and Climate Change Canada does not have information indicating that another facility within the sector could be releasing boron at harmful levels to the environment.

For human health, Canadians are exposed to boric acid from environmental media, food, drinking water and products. The dSAR exposure estimates indicate that naturally-occurring boron in food and to a lesser extent drinking water, represent primary sources of exposure. In addition, estimates of intake from uses of boric acid in some specific types of arts and crafts materials, toys, cosmetics, cleaning products, natural health products, and swimming pool and spa products indicate that these may also be important sources of exposure to boric acid for the general population. As such, this document will focus on anthropogenic exposure sources of concern (refer to sub-section 5.2).

The presence of boric acid in multi-vitamins/mineral supplements and multiple ingredient joint health products is currently subject to risk management under the *Natural Health Products Regulations* of the *Food and Drugs Act*.

Of note, the proposed risk management options described in this document (and the proposed conclusion outlined in the dSAR) are preliminary and may be subject to change. For further information on the dSAR for boric acid, its salts and its precursors refer to Draft Screening Assessment Boric Acid, its Salts and its Precursors.

2.2 Proposed Recommendation under CEPA

Based on the findings of the draft screening assessment conducted as per CEPA, and in anticipation of further deliberations regarding potential risk management, the Ministers propose to recommend that boron compounds, excluding borosilicates, borosilicate glass and borides, be added to Schedule 1 of CEPA.

The Ministers will take into consideration comments made and information provided by stakeholders during the 60-day public comment period on the dSAR and Risk Management (RM) Scope document, in the preparation of the final screening assessment Report (fSAR), and if required the RM Approach document. If boric acid, its salts and its precursors are concluded to meet one or more of the criteria under section 64 of CEPA and the Ministers recommend their addition to Schedule 1, risk management instrument(s) must be proposed and finalized within a set period of time, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

3. Proposed Risk Management

3.1 Proposed Environmental and Human Health Objectives

Proposed environmental and human health objectives are quantitative or qualitative statements of what should be achieved to address environmental and human health concerns.

For boric acid, the proposed objectives are focused on addressing the exposure sources of concern outlined in section 5 of this document. As such, the proposed environmental objective for boric acid is to reduce anthropogenic releases to water. The proposed human health objective is to minimize anthropogenic exposure to, and hence risks, associated with boric acid. If the fSAR concludes toxic, the proposed environmental and human health objectives may be revised in the RM Approach document that will be published concurrently with the fSAR for boric acid, its salts and its precursors, or in subsequent risk management

documents [(e.g., consultation document on the proposed instrument(s)], as the case may be.

3.2 Proposed Risk Management Objectives and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objectives for boric acid are 1) to reduce anthropogenic releases to water to the greatest extent practicable so as not to exceed the Canadian Council of Ministers of the Environment (CCME) Water Quality Guidelines, or the natural background concentration, whichever is higher, and 2) to reduce human exposure to boric acid from anthropogenic sources.

To achieve the proposed risk management objectives and to work towards achieving the proposed environmental and human health objectives, the risk management options under consideration for boric acid will focus on reducing its releases to water from sectors of concern identified in the dSAR, and on ways to reduce exposure of Canadians to boric acid from consumer applications identified in the dSAR. In addition, in order to inform Canadians as to the potential health risks associated with boric acid and steps they may take to decrease their risk, public information materials will be prepared. Specifically, the Government of Canada is considering risk management measures as described below.

3.2.1 Environment

Metal Mining

The dSAR has associated concentrations of boric acid in the aquatic environment above the predicted no-effect concentrations (i.e., 1.5 mg B/L) with the operations of a single facility that recovers precious and base metals from a range of feeds. This facility is subject to provincial government legislation, which prohibits the use, operation, establishment, alteration, extension or replacement of new or existing sewage work unless authorized by a permit. In recent years, a new permit was issued to the facility to reflect changes made to its tailings management area. Triggered by monitoring data submitted to the province under past certificates of approvals, the new permit outlined a Boron Reduction Strategy as a condition of the approval.

As part of its Boron Reduction Strategy, the facility has stopped processing feeds with high concentrations of boron. As a result, the tailings stored on site should now be the principal source of boric acid released to the environment. To further control these releases, the facility has proposed to cap sections of its tailing storage area with a clay liner while continuing to monitor its effluent. According

to information shared by the provincial authority, portions of the tailings pond were capped in 2015.

Communications with the provincial authority are ongoing to stay updated on the latest developments. This will inform the need for any further action by Environment and Climate Change Canada to achieve the risk management objective.

The dSAR also notes that if other facilities engage in similar activities they could release elevated concentrations of boric acid to the aquatic environment. Data submitted voluntarily to the Environment Effects Monitoring (EEM) Program, under the *Metal Mining Effluent Regulations* (MMER), indicate that boron is properly managed in the sector, as there is only one site with releases of concern and it is likely an isolated issue. Based on the available information, ECCC does not propose further actions for other facilities in the sector.

3.2.2 Health

Cosmetics: Measures to mitigate the potential risk of exposure to boric acid to infants and young children through the use of cosmetics (e.g., body creams). Action may be proposed following review of the current entry for boric acid on the List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient Hotlist), an administrative list published by Health Canada to communicate to manufacturers, importers and others, that cosmetics containing particular substances at particular concentrations are likely to contravene the *Food and Drugs Act* or the *Cosmetic Regulations*.

Arts and crafts materials, and toys: For home-made clays, doughs, slimes, putties, and other children's craft products made with boric acid a public information document, outlining the potential health risks associated with boron (as boric acid) and home-use of borax (a boric acid precursor) in order to discourage consumers from this practice. For commercially available children's toys, compliance and enforcement of the existing prohibition on boron will continue as part of the regular enforcement of the *Toys Regulations* under the *Canada Consumer Product Safety Act.*

Cleaning products: Measures which may include the preparation of public information material on the potential health implications of exposure to boric acid, and investigation into the feasibility of product reformulation guided by discussion with and information received from industry stakeholders.

Swimming pool/spa water treatment chemicals: Measures involving investigation into the feasibility of limiting the concentration of boric acid in these products, guided by discussion with and information received, from industry stakeholders.

In order to assist in determination of the effectiveness of risk management measures focused on boric acid, boron will be included in the biomonitoring program of the Canadian Health Measures Survey, specifically cycles 5 and 6 from 2016 to 2019. This will establish a baseline for comparison of boron levels in urine in future monitoring surveys. Boron has also been added to the Canadian Total Diet Study to measure levels in food.

Should the proposed conclusion for these substances be confirmed in the fSAR, comments received during the public comment period and additional information provided/obtained will be considered in the preparation of the RM Approach document. The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making[3].

3.3 Risk Management Information Gaps

In order to make informed decisions on proposed risk management, more information is needed on the following:

- Details on the actions proposed by the mill identified in the dSAR as being of concern and the provincial authority to reduce boric acid releases to the aquatic environment; and
- Alternative substances to the use of boric acid in pool chemicals and in certain cleaning applications.

4. Background

4.1 General Information on Boric Acid

Boron occurs naturally in the terrestrial crust in the form of borosilicate minerals, boric acid or borates (Gupta 1993, Cotton and Wilkinson 1999; Holleman and Wiberg 2001; Parks and Edwards 2005). The main sources of global natural emissions to the atmosphere include sea salt aerosols, soil dusts, volcanoes, biomass burning (e.g., forest fires) and plant aerosols (Park and Schlesinger 2002). Rock and soil weathering constitute another important source of boric acid to the environment (Park and Schlesinger 2002). The introduction of boric acid into surface water and soil as a result of these natural processes are reflected in the geochemical background concentrations in these media.

[3] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the Red Tape Reduction Act (Canada, 2015).

Anthropogenic sources are also significant and include the manufacture, import and use of boric acid, its salts and precursors in products and manufactured items. Other anthropogenic sources include the incidental production and subsequent release of boric acid as a result of activities such as coal-fired power generation, metal mining (including base metals, precious metals and uranium), base metals and precious metals smelting and refining, coal mining, oil sands extraction and processing, oil and gas extraction, and wastewater treatment (including the land application of biosolids) (Environment and Climate Change Canada, 2013; 2014a; 2014b; 2014c; 2014d; 2014e; 2014f).

4.2 Current Uses and Identified Sectors

Boric acid, its salts and its precursors are used for a wide variety of products and applications, including fibreglass insulation, agricultural products (e.g., fertilizers and pest control products), cellulose insulation, cleaning products (e.g., soaps and detergents, cleaning, polishing and toilet preparations), pharmaceutical products and preparations, various chemicals and chemical products (e.g., chemicals for metallurgy, antifreeze, brake fluids, buffers, and lubricants), gypsum board and wood products (e.g., veneer and engineered wood), paper and paper products and flame retardants (RPA 2008; Ball *et al*. 2012).

The use of boron in natural health products, drugs, cosmetics, pest control products, fertilizers, and toys is regulated in Canada. The use of boron in consumer chemical products is regulated under the *Consumer Chemicals and Containers Regulations 2001* (CCCR, 2001), based on acute hazard. The use of boron in natural health products is regulated under the *Natural Health Products Regulations* and the *Food and Drugs Act* (Canada 2003; Canada 1985a). Boric acid precursors are present as both medicinal ingredients and non-medicinal ingredients in these products. Boric acid precursors are also listed in the Drug Product Database (2015) as being present in human and veterinary drugs, for humans primarily as a non-medicinal ingredient in ophthalmic products and contact lens disinfectants, and for veterinary use, optic and topical products and injectable solutions (Health Canada 2015a; 2015b; 2015c).

Regarding cosmetics, boric acid may be present in a wide variety of these products and are most common in skin lotion/moisturizer and skin cleanser products. Boric acid and its salts (CAS RN 10043-35-3 and 11113-50-1, including sodium borate 1303-96-4) are included on the List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient Hotlist), an administrative tool that Health Canada uses to communicate to manufacturers and others that cosmetic products containing certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act*, or a provision of the *Cosmetic Regulations* (Canada 2014, Health Canada 2014a). The current listing for boric acid and its salts does not include all precursors of boric acid and it describes a concentration limit of 5% for boric acid and its salts, including sodium borate.

However current market data indicates that concentrations of boric acid in diaper creams, and other cosmetic baby products, sold in Canada are much lower than the maximum level of 5% (i.e., less than 0.1%). Also, under the *Cosmetic Regulations*, the label of cosmetics containing these substances, is required to carry a cautionary statement to this effect: ”Do not use on broken skin/not to be used by children under three years of age.”

In addition, several boron-containing substances are active ingredients in pest control products regulated under the *Pest Control Products Act* (2002), particularly in building applications, and for other pest control applications (Health Canada 2010). For example, some algaecide and sanitizer pool products regulated under the *Pest Control Products Act* contain boron as a formulant, which, when used according to label directions, results in a final concentration range in pool/spa water of 5 parts per trillion (ppt) to 1 part per million (ppm), depending on the use. Boron is also a recognized plant micronutrient and is regulated as a fertilizer under the *Fertilizers Act* (Canada 1985b). As well, the presence of boric acid and salts of boric acid in toys is regulated under section 22 of the *Toys Regulations* (Canada 2011b). Food packaging materials may also have boron present (2013 email from Food Directorate to Risk Management Bureau, Health Canada, unreferenced).

5. Exposure Sources and Identified Risks

The purpose of the Risk Management Scope is to present Environment and Climate Change Canada’s and Health Canada’s early proposal to manage the risks identified in the screening assessment. As such, only the exposure sources of concern are further discussed in this document. More information on other anthropogenic sources can be found in the screening assessment report.

5.1 Human Health

The draft human health assessment being conducted for boric acid, its salts and its precursors under CEPA indicates that boric acid adversely affects reproduction and development. Notwithstanding variations for recommended toxicological reference dose, the proposed conclusions set out in the draft screening assessment are similar to those of other jurisdictions. These findings are based on animal studies, as although some epidemiological studies in humans are available, collectively they were considered insufficient to demonstrate the absence of an adverse effect of boron exposure in humans, due to limitations in study design.

Canadians are exposed to naturally occurring and anthropogenic boric acid from environmental media, food, drinking water and products. Exposure to Canadians was characterized through the use of biomonitoring data from Canadian and European studies. Total boron measured in blood in individuals provides a measure of integrated exposure for individuals, from all routes (i.e., oral, dermal,

and inhalation) and all sources including environmental media, food, drinking water and the daily or frequent use of products. A comparison of estimates of intake predicted from biomonitoring data to critical health effect levels results in margins of exposure which are potentially inadequate to address uncertainties. Males have higher concentrations of boron in blood than females. For adults, there is a steady increase in the concentration of boron in blood with age; despite this trend in adults, blood boron concentrations are higher overall in children. Intake estimates from environmental media, food, drinking water and several products were generated to characterize important sources of exposure. As boron is an essential micronutrient for the growth of plants, these estimates indicate, as expected, that naturally occurring boron in fruits and vegetables and to a lesser extent, drinking water, are the primary sources of exposure. Estimates of intakes from uses of boric acid in specific types of arts and crafts materials, toys, cleaning products, cosmetics, natural health products, and swimming pool and spa products indicate that these may also be sources of exposure for the general population.

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to these substances. As part of the CMP, the Government asked industry and interested stakeholders to submit any information on the substances that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked if any of the products or manufactured items containing the substances were intended for or may be used by children. Given that the most critical health effects are reproductive and developmental toxicity, and that available information indicates that children may receive significant exposure in some instances involving products available to consumers, children should be considered a vulnerable population in management decisions.

5.2 Anthropogenic Releases to the Environment

Anthropogenic releases of boric acid to water from metal mining have been identified in the draft screening assessment report as posing a potential risk to aquatic organisms.

Boron compounds are not mined in Canada; however, boron is ubiquitous in nature meaning that it may be found in ores at varying concentrations. Additionally, boron is known to be frequently associated with "vein-type" gold mineralization (Boyle, 1974; Closs & Sado, 1981). Borates may also be used in precious metals recovery as they associate with metallic oxide contaminants to minimize the loss of precious metal (Borax, 2013). Therefore, boron could potentially be released as boric acid into the environment as a result of the mining and production of metal concentrates (e.g., base metals, precious metals and uranium) and diamonds.

In the ecological assessment of boric acid, its salts and its precursors, measured concentrations of boron in the receiving environment or effluent of metal mines across Canada were gathered and analyzed. This information was submitted to Environment and Climate Change Canada's Environmental Effects Monitoring Program under the *Metal Mining Effluent Regulations* (MMER). Monitoring data for boron in the aquatic environment (existing as boric acid) available for 72 sites representing approximately 60% of the sector. Among those sites, the majority showed low boric acid concentrations. While a few sites showed moderate to high concentrations of boron, only one site was associated with extremely high concentrations of boric acid in the receiving environment that exceeded the predicted no-effect concentrations for aquatic organisms.

The site of concern is a mill that processes a range of feeds for the purpose of concentrating precious metals. The process produces tailings that are stored on site for proper management. The effluent from the tailings storage area is monitored, treated, and discharged in an adjacent water body. Elevated concentrations of boric acid in the effluent of the mill have been confirmed in the monitoring data submitted to the province.

The high concentrations of boric acid entering the process and later released into the receiving environment have been linked to the feed processed by the Canadian facility. Through its permitting system, the provincial authority has requested the Canadian mill to develop a Boron Reduction Strategy. In its endeavor to reduce its releases of boric acid, the mill ceased receiving feeds with high boron concentrations in 2013. Therefore, current and future tailings produced at the site are not expected to result in important releases of boric acid. However, tailings produced before 2013 and stored on site are expected to continue releasing important quantities of boric acid until additional measures are taken.

6. Risk Management Considerations

6.1 Sources and Management Considerations

6.1.1 Food

Boron is present in food due to natural sources in the environment and is an essential micronutrient for the growth of plants. Health Canada has developed upper tolerable intake levels ranging from 3-20 mg/day for age groups 1 to 70 (Health Canada, 2007a). The highest levels of dietary boron are found in baking ingredients, nut butters, herbs and spices; however, the typically high consumption of fruits and vegetables result in these commodities contributing most overall dietary exposure to boron. Canadians should consume a balanced diet according to *Eating Well with Canada's Food Guide* (Health Canada 2011), which recommends the daily consumption of fruits, vegetables, grain products, and also lists other plant-based foods such as nuts as healthy food choices.

Considering this information, as well as the uncertainties in the dietary risk assessment of boron, food will not be a focus for risk management action.

6.1.2 Drinking Water

Boron is naturally present in drinking water due to sources in the environment. Potential management action could include a review and update of the current Canadian drinking water guideline for boron, to include a more in-depth assessment of treatment technology.

6.1.3 Cosmetics

Boric acid is used in cosmetic products, most commonly in skin moisturizers and skin cleansers. The screening assessment examined several exposure scenarios such as body creams, skin cleansers, mouthwashes and lipsticks considered to possibly represent high exposure scenarios or have the potential for frequent use. In addition, due to the potential for systemic exposure to boric acid following the use of certain baby care products (e.g. diaper creams and body creams) on abraded skin, these were also assessed. As identified in the screening assessment, of particular concern was the fact that infants (and to a lesser degree toddlers), have a high potential for dermal exposure to boric acid from some baby care products. Daily intake estimates were generated using the maximum concentration limit (this value reflects the maximum concentration of 5% boric acid, equivalent to 0.87% boron, outlined in the Cosmetic Ingredient Hotlist restriction) and frequency of use per day data. When relevant, dermal absorption estimates of 0.5 and 10% were incorporated for non-abraded skin, whereas absorption across broken or abraded skin and mucosal membranes was considered to be 100%. Although the Hotlist entry for boric acid describes a maximum limit of 5%, there are cosmetic products available to Canadians (such as powdered hand soaps) that contain 60–100% borax, equivalent to up to 65% boric acid (The Dial Corporation 2013; GoodGuide 2014; HPD 1993). It should be noted that current market data indicates that concentrations of boric acid in diaper creams sold in Canada are much lower than the concentration limit of 5% (email from email from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Accordingly management options may include review and update of the entry for boric acid on the Cosmetic Ingredient Hotlist, in order to limit the exposure of infants and young children to boric acid from cosmetic products.

6.1.4 Arts and Crafts Materials, and Toys

Boric acid may be a component of many arts and crafts materials including inks, glazes, artists' paints and craft glues. Boric acid can also be used in the home and school setting to make less expensive alternatives to commercial modeling clays, doughs and putties, slimes, and other children's craft materials. The screening assessment highlights potentially high oral and dermal exposures to boric acid for young children playing with home-made modeling clays. A priority

management action would be the preparation of public information material by Health Canada, outlining the hazards associated with boric acid and home-use of borax for craft-making in order to discourage consumers from this practice. For commercially available children's toys, compliance and enforcement of the existing prohibition on boron will continue as part of the regular enforcement of the *Toys Regulations* under the *Canada Consumer Product Safety Act*.

6.1.5 Cleaning Products

Boric acid may be found in a variety of cleaning products. Exposure would depend on several factors including amount of product used, concentration of boron in the product, duration and frequency of use, among other variables. The screening assessment considered several exposure scenarios involving ready-to-use spray cleaners, dishwashing detergents, floor cleaners, and hand washing laundry with detergent. These products and scenarios were considered to represent potentially high exposure scenarios or have the potential for frequent use. Among these, dermal exposure of adults using dishwashing liquids, general purpose cleaners and floor cleaners was somewhat higher than in other cleaning product applications. For toddlers, dermal and oral intake combined from floor cleaning liquids is also of concern. The range of possible management options could include the preparation of public information material, and investigation into the feasibility of product reformulation, guided by discussion with and information received from industry stakeholders.

6.1.6 Swimming Pool and Spa Products

Boric acid may be present in swimming pool and spa products. As pesticides, algaecide and sanitizer pool products containing boron, present as a formulant, are regulated under the *Pest Control Products Act* (Canada 2002). However, other swimming pool and spa products which are not pesticides, including performance products and water conditioners available to Canadians, may contain boron. Therefore the screening assessment focused on the latter products. Oral intake accounted for the majority of intake for infants and also to a lesser degree for toddlers and children, from boron in swimming pool water. If exposure is on a daily basis, this may elevate health concerns. Management options could entail measures involving investigation into the feasibility of limiting the concentration of boric acid or alternatives to boric acid, in these products, guided by discussion with and information received from industry stakeholders. Other options could involve publication of communications materials on the potential health risks associated with boric acid and exposure to boric acid from these products.

6.3 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for regulation(s) and/or instrument(s) respecting preventive or control actions, and in the development of the risk management objectives. Socio-economic factors will

also be considered in the development of regulation(s), instrument(s), and/or tool(s) as identified in the *Cabinet Directive on Regulatory Management* (TBS, 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS, 2007).

In order to address the potential socio-economic impact and feasibility of proposed risk management measures for boric acid, it would require further consultation with industry associations and a determination as to the availability and effectiveness of alternatives to boron in consumer applications highlighted in the screening assessment.

It is notable that boric acid increasingly appears to be substituted with sodium percarbonate in cleaning-type and other products, particularly in the United States and Europe. A site is available (http://www.goodguide.com/ingredients/255342-sodium-percarbonate?category_id=376387-laundry-detergent) which lists some mainstream brand names within a wide variety of products, where sodium percarbonate has replaced boric acid in the product. However, in other similar products, boric acid is still used. Therefore, it would be informative to approach major cleaning associations regarding present and future use of sodium percarbonate as a substitute for boric acid in cleaning products manufactured by their members.

7. Overview of Existing Risk Management

7.1 Domestic

7.1.1 Statutes

7.1.1.1 Metal Mining

The MMER, under the *Fisheries Act*, authorize the deposit of certain deleterious substances from metal mines into natural fish bearing waters at regulated limits. Schedule 4 of these regulations lists authorized release limits for deleterious substances as defined under the MMER. Schedule 5 of the regulations requires effluent characterization be conducted for some specific substances. However, neither boron, boric acid, nor any other of its compounds is listed in either schedule. As a result, the general prohibition of the *Fisheries Act* applies. Of note, the MMER apply to hydrometallurgical, milling, or mining facilities, as defined under the regulations, but can also apply to base metals smelters and refineries if their effluent is combined with one of those types of facilities.

7.1.1.2 Other (Acts and Regulations and Communications Products)

Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations (Canadian Environmental Protection Act, 1999) – This pertains to the export, import or conveyance in transit of a hazardous waste or hazardous

recyclable material. Under these regulations, boron is classified as a hazardous constituent and wastes and recyclables containing boron at or above the prescribed limit are subject to regulatory controls.

Environmental Emergency Regulations (Canadian Environmental Protection Act, 1999) – Under these regulations, Environment and Climate Change Canada (ECCC) requires any person who owns or manages certain hazardous substances (including some boron-containing substances) on a property, at or above the established thresholds, to notify ECCC when this quantity threshold is met or when the maximum container capacity meets or exceeds this threshold. If the total quantity and container capacity threshold are both met, there is an additional requirement to prepare and exercise an environmental emergency (E2) plan. The E2 plan ensures that any individual that owns or manages specific toxic or hazardous substances above a certain threshold has a plan for preparedness, prevention, response and recovery in the event of an environmental emergency. Environmental emergency occurrences must also be reported.

New Substances Notification Regulations (Chemicals and Polymers) (Canadian Environmental Protection Act, 1999) - These regulations require that the Minister of the Environment be notified before a chemical or polymer that is not on the DSL is manufactured or imported into Canada in order to determine whether it is toxic or capable of becoming toxic. Under this regulation, polymers that are 0.2% boron or more by weight are a reduced regulatory requirement polymer.

Transportation of Dangerous Goods Regulations (Transportation of Dangerous Goods Act) – These regulations specify rail transportation requirements for compressed boron trifluoride, classified as dangerous goods.

Cosmetic Regulations (Food and Drugs Act) – Boric acid is subject to the specifications of the List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient “Hotlist”). The Hotlist entry for boric acid describes a concentration limit of equal to or less than 5% and includes a cautionary statement to the effect: “Do not use on broken or abraded skin, not to be used by children under three years of age.”

Toys Regulations (Canada Consumer Product Safety Act) – These regulations specify that toys must not contain boric acid or boric acid salts if they could, under reasonably foreseeable circumstances, become accessible to a child or, if they are used as a filling, they could be released on breakage or leakage.

Consumer Chemicals and Containers Regulations 2001 *(Canada Consumer Product Safety Act)* – These regulations set out labelling and packaging requirements for chemical products to inform consumers of the potential acute (short-term) hazards that a product may pose during use. Labelling and packaging requirements are determined based on whether the product

formulation meets certain scientifically-derived classification criteria relating to toxicity, corrosiveness, flammability, aspiration, or skin bonding.

Science Education Sets Regulations (Canada Consumer Product Safety Act) – These regulations prohibit the inclusion of organic acids other than an aqueous solution of hydrochloric acid containing less than 5% of the acid.

Food and Drug Regulations (Food and Drugs Act) – Under these regulations, the labels of drugs that contain boric acid or sodium borate as a medicinal ingredient in drug products carry a cautionary statement to the effect that the drug should not be administered to a child under three years of age.

Natural Health Products Regulations (Food and Drugs Act) – Boric acid is present in a large number of licensed natural health products in Canada, both as a medicinal ingredient and a non-medicinal ingredient (Health Canada 2007b; 2014b; 2015a; 2015b; 2015c). It is most commonly used as a medicinal ingredient in multi-vitamin/mineral supplements, and at higher doses, in multiple ingredient joint health products. However these products are subject to ongoing management under the *Natural Health Products Regulations* of the *Food and Drugs Act*. The maximum daily dose currently permitted by the NNHPD's Multi-Vitamin/Mineral Supplements monograph and the Multiple Ingredient Joint Health Products monograph are 0.7 mg and 3.36 mg boron per day, respectively. The intended subpopulation listed for boron in these monographs, is adults only. The source ingredients listed are boric acid/orthoboric acid, Borax/disodium tetraborate/sodium biborate/sodium borate/sodium pyroborate/sodium tetraborate, Boron aspartate, boron citrate, boron glycinate, boron hydrolyzed animal protein (HAP) chelate, boron hydrolyzed vegetable protein (HVP) chelate, calcium borate/calcium pyroborate/calcium tetraborate, calcium borogluconate/calcium diboroglyconate, calcium fructoborate, and magnesium borate (Health Canada 2015c)

Fertilizers Regulations (Fertilizers Act) – These regulations describe labelling requirements in respect to boron.

Pest Control Products Regulations (Pest Control Products Act) – A proposed re-evaluation decision on the pesticidal uses of boric acid is in publication and includes proposed instructions for use on registered pesticide product labels. These include risk reduction measures to protect human and environmental health, and must be followed by law once a final re-evaluation decision has been issued. Note that this re-evaluation does not cover formulation uses of boric acid. Borax, disodium tetraborate, boric acid, boric acid disodium salt pentahydrate and sodium borohydrate are included on the Pest Management Regulatory Agency's list of formulants as List 3 formulants and thus may be present in other pest control products (Health Canada 2010).

The Guidelines for Canadian Drinking Water Quality - These guidelines, developed by the Federal-Provincial-Territorial Committee on Drinking Water, and published by Health Canada, have established a maximum acceptable concentration (MAC) of 5 mg/L for boron in drinking water.

The Canadian Environmental Quality Guidelines – These guidelines, published by the CCME, recommend limits for the protection of aquatic life, and water and soil for agricultural use.

7.1.2 Federal, Provincial and Territorial Water Quality Guidelines

Provinces and territories use the Guidelines for Canadian Drinking Water Quality as the basis to establish their own requirements for drinking water quality. These requirements may be established in policies, regulations or permits for individual treatment plants. Eleven of the provinces and territories have a mandatory limit for boron in drinking water, based on the maximum acceptable concentration of 5 mg/L established in the Guidelines for Canadian Drinking Water Quality.

Surface water quality guidelines for boron were found for many provinces, but not for territories. Most provinces refer to the CCME guidelines, which recommends 1.5 and 29 mg B/L (chronic and acute) for the protection of aquatic life in freshwater, 0.5 to 6 mg B/L (crop dependent) for irrigation, and 5 mg B/L for livestock feed water (Canadian Council of Ministers of the Environment, 2009). A few notable exceptions are British Columbia, Ontario, and Quebec. British Columbia developed a guideline of 1.2 mg B/L for the protection of aquatic life in freshwater. Ontario has set an interim criterion of 0.2 mg B/L for all surface waters. Quebec has established 5 and 28 mg B/L (chronic and acute) for the protection of aquatic life in freshwater (Nagpal, 2001; Ontario Ministry of the Environment, 1994; Gouvernement du Quebec, 2013).

The CCME guideline for the long-term protection of aquatic life (1.5 mg B/L) is used by Environment and Climate Change Canada as the predicted no-effect concentration in the assessment of boric acid, its salts and its precursors.

7.2 International

7.2.1 United States

7.2.1.1 Statutes

Over 130 boron compounds (comprised entirely/predominantly of precursors of boric acid) are regulated in the United States under different statutes, with legal requirements ranging from reporting and notifications to restrictions. Of relevance to the ecological risk characterized in the dSAR is the *Clean Water Act* (CWA).

Under the CWA the discharges of oil or hazardous substances into or upon navigable waters as well as contiguous waters and areas of the United States is prohibited. Zinc borate (CAS RN 1332-07-6), lead fluoroborate (CAS RN 13814-

96-5), and ammonium fluoroborate (CAS RN 13826-83-0) are all listed as hazardous substances under the CWA (United States Environmental Protection Agency, 2015).

Under the *Dietary Supplements Health and Education Act* of 1994 (DSHEA), there is no mandatory pre-market review for dietary supplements containing boron, but they are not permitted to be labelled or advertised with claims to treat any disease.

In 2001, the Institute of Medicine U.S. Food and Nutrition Board determined an upper limit of 20 mg /day of boron in a 70 kg adult.

The United States Environmental Protection Agency (US EPA) has established a chronic oral reference dose (RfD) of 200 µg B/kg bw/d (Integrated Risk Information System, 2007). As well, the Agency for Toxic Substances and Disease Registry (ATSDR) set an oral Minimal Risk Level of 200 µg B/kg bw/d for intermediate-duration (Agency for Toxic Substances and Disease Registry, 2010).

7.2.1.2 Federal and States Guidelines

The US EPA guidelines/standards for air, drinking water, pesticides. Pursuant to Section 304(a) of the *Clean Water Act* (CWA), the US EPA publishes national recommended water quality criteria. The US EPA published a criterion of 0.75 mg B/L for boron in irrigation water to protect sensitive crops during long-term exposure (United States Environmental Protection Agency, 2002).

Some states have also published their own guidelines. For example, Illinois State has established an acute (40.1 mg B/L) and chronic (7.6 mg B/L) water quality standard for the protection of aquatic organisms (Illinois Pollution Control Board, 2014). New York State also developed chronic standards for the protection of aquatic life of 1 mg B/L for fresh groundwaters and saline surface waters, and 10 mg B/L for fresh surface waters (New York State Department of Environmental Conservation, 2015).

7.2.2 European Union

7.2.2.1 Statutes

The European Commission has added several boron compounds to List of Dangerous Substances and in the European Union, some form of risk management exists or is being recommended for 11 boric acid precursors.

Boric acid (CAS RN 10043-35-3, CAS RN 11113-50-1), boron oxide (CAS RN 1303-86-2), borax (CAS RN 1303-96-4), boron sodium oxide (CAS RN 1330-43-4), perboric acid, sodium salt (CAS RN 7632-04-4), tetraboron disodium heptaoxide, hydrate (CAS RN 12267-73-1), diboron trioxide (CAS RN 1303-86-

2), lead bis(tetrafluoroborate)(CAS RN 13814-96-5), and sodium perborate, perboric acid, sodium salt (CAS RN 15120-21-5) have been identified by the European Union (EU) as Substances of Very High Concern (SVHC) for their reproductive toxicity. As a result, these substances have been listed on the Candidate List of the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (European Chemicals Agency, 2014). Being listed on the Candidate List may imply legal obligations for producers, importers, and suppliers of those substances (European Chemicals Agency, 2015a). More importantly, substances on the Candidate List can be recommended for inclusion in the Authorisation List. This is the case for nine of these boron-containing substances. If added to the Authorisation List, substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation (European Chemicals Agency, 2015b).

Dibutyltin hydrogen borate (CAS RN 75113-37-0) is listed on the List of Restrictions. Restricted substances (on their own, in a mixture or in an article) are substances for which manufacture, placing on the market or use is limited or banned in the EU (European Chemicals Agency, 2015c). In the case of dibutyltin hydrogen borate, it cannot be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0.1 % by weight. An exemption exists for conversion into articles.

Regarding nutritional supplements, The European Food Safety Authority (2004) set a Tolerable Upper Intake Level (UL) for boron as boric acid or borates, of 10 mg/person/day for adults and stated that on the basis of safety boric acid and sodium borate are suitable for use in foods for particular nutritional purposes, food supplements and foods intended for the general population providing the UL is not exceeded. In 2013, EFSA re-evaluated their scientific opinion of boric acid and borax as food additives and determined an acceptable daily intake of 11.2 mg/day in adults.

7.2.2.2 Guidelines

In 2008, the EU published Directive 2008/105/EC on Environmental Quality Standards. Annex I of the directive establishes limits on concentrations of certain pollutants in surface waters. However, none of the targeted pollutants is boron or a boron-containing substance (European Commission, 2015).

7.2.3 Other Jurisdictions

In Australia, the Therapeutic Goods Administration licensed 14 oral boron-containing over-the-counter supplements providing doses of less than or equal to 3 mg boron/day for osteoporosis. At least one listed medicine authorized for osteoarthritis in 2014 provides 13.32 mg of borax per day (Government of Australia, 2014a). Another multi-vitamin mineral supplement was authorized in 2014 that provides 8.82 mg of borax (Government of Australia 2014b). A

combination multi-vitamin mineral product with joint health claims was authorized in 2011 with 8.8 mg of borax

In the United Kingdom, boron is present in a number of multi-vitamin and mineral food supplements at levels up to 10 mg, but not in licensed medicines (European Food Safety Authority, 2004). A recommended limit of 6 mg/day has been set for supplemental intake (Expert Group on Vitamins and Minerals, 2003).

7.2.4 International Organizations

- World Health Organization drinking water quality guideline (provisional, 0.5 mg/L)
- World Health Organization Tolerable Daily Intake of 160 µg B/kg bw/d (World Health Organization, 2003)

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this RM Scope or other information that would help to inform decision-making (such as outlined in section 6). Please submit additional information and comments prior to September 21, 2016. The RM Approach document, if required, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the fSAR. At that time, there will be further opportunity for consultation.

Comments and information submissions on the RM Scope should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 |819-956-9313
Fax: 819-953-7155
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in boron are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding boron and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the Risk Management Scope: July 23, 2016 to September 21, 2016.

Submission of additional studies or information on boric acid, its salts and its precursors: on or before September 21, 2016.

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before July, 2017.

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: on or before July, 2017.

Publication of responses to public comments on the Risk Management Approach and, if applicable and if required, the proposed instrument(s): at the latest, 24 months from the publication of the final Screening Assessment Report.

Consultation on the proposed instrument(s), if required: 60-day public comment period starting upon publication of each proposed instrument(s).

Publication of the final instrument(s), if required: at the latest, 18 months from the publication of each proposed instrument(s).

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