Risk Management Scope

for:

Parabens Group, *specifically:*

Benzoic acid, 4-hydroxy-, methyl ester (Methylparaben)

Benzoic acid, 4-hydroxy-, propyl ester (Propylparaben)

Benzoic acid, 4-hydroxy-, butyl ester (Butylparaben)

Benzoic acid, 4-hydroxy-, 2-methylpropyl ester (*Iso*-Butylparaben)

Chemical Abstracts Service Registry Numbers (CAS RNs):

99-76-3; 94-13-3; 94-26-8; 4247-02-3

Environment and Climate Change Canada

Health Canada

March 2020

Summary of proposed risk management (RM)

This document outlines the risk management options under consideration for methylparaben, propylparaben, butylparaben and *iso*-butylparaben, which have been proposed to be harmful to human health.

In particular, the Government of Canada is considering the actions below to address the health concerns:

Cosmetics

- Communicate measures to reduce exposures to butylparaben and *iso*-butylparaben from certain cosmetics by describing butylparaben and *iso*-butylparaben as prohibited or restricted ingredients on the Health Canada Cosmetic Ingredient Hotlist.

Non-prescription drugs

- Measures to reduce exposures (to levels that are protective of human health) of butylparaben and *iso*-butylparaben in non-prescription drugs by modification of applicable databases, in accordance with the *Food and Drugs Act.*

Natural Health Products (NHPs)

- Measures to reduce exposures (to levels that are protective of human health) of methylparaben, propylparaben, butylparaben and *iso*-butylparaben in NHPs by modification of applicable databases in accordance with the *Food and Drugs Act.*

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

Note: The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

The Parabens Group:

Methylparaben, propylparaben, butylparaben and *iso*-butylparaben are four of the seven substances referred to collectively as the Parabens Group under the third phase of the Chemicals Management Plan and have been proposed to be harmful to human health (Canada, 2016).

In addition, the three remaining substances in this grouping, ethylparaben, *iso*-propylparaben, and benzylparaben, are proposed not to meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

All seven substances in this assessment were identified as having low potential to be causing ecological harm, according to information considered under the Ecological Risk Classification of organic substances (ERC) approach (ECCC 2016), it is proposed to conclude that methylparaben, ethylparaben, propylparaben, butylparaben, benzylparaben, iso-propylparaben, and iso-butylparaben do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada1999) 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 to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2], and if so, to manage the associated risks.

As part of the third phase of the Chemicals Management Plan (CMP), the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada 2016).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of seven parabens including methylparaben, propylparaben, butylparaben and *iso*-butylparaben, in Canada. A notice summarizing the scientific considerations of the draft screening assessment for these substances was published in the *Canada Gazette*, Part I, on February 29, 2020. (Canada 2019). For further information on the draft screening assessment for parabens, refer to [https://www.*canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-parabens-group.html*].

2.1 Draft screening assessment conclusion

On the basis of the information available, the draft screening assessment proposes that methylparaben, propylparaben, butylparaben and *iso*-butylparaben meet the criteria under section 64(*c*) of CEPA because they are entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2019). However, it is proposed to conclude that these substances do not meet the criteria under paragraphs 64(*a*) or 64(*b*) of CEPA as they are not entering the environment in a quantity or

[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 products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

The draft screening assessment also proposes that methylparaben, propylparaben, butylparaben and *iso*-butylparaben do not meet the criteria for persistence and/or bioaccumulation, as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada, 2000).

The exposure sources of concern, identified in the draft screening assessment, are based on the potential absorption of butylparaben and *iso*-butylparaben from the use of cosmetics; butylparaben and *iso*-butylparaben from non-prescription drugs; and methylparaben, propylparaben, butylparaben, and iso-butylparaben from NHPs. As such, this document will focus on these exposure sources of concern (refer to section 5).

2.2 Proposed recommendation under CEPA

Based on the findings of the draft screening assessment conducted under CEPA, the Ministers propose to recommend that methylparaben, propylparaben, butylparaben and *iso*-butylparaben be added to the List of Toxic Substances in Schedule 1 of the Act[3].

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and its associated RM Scope document.

If the Ministers finalize the recommendation to add methylparaben, propylparaben, butylparaben and *iso*-butylparaben to Schedule 1, risk management instruments 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 human health objective

Proposed human health objectives (HMO) are quantitative or qualitative statements of what should be achieved to address human health concerns.

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the Ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

For methylparaben, propylparaben, butylparaben and *iso*-butylparaben, the proposed objective is focused on addressing the risks and exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective for methylparaben, propylparaben, butylparaben and *iso*-butylparaben is to decrease exposure of the general population to these substances from certain cosmetics, NHPs, and non-prescription drugs, to levels that are protective of human health.

3.2 Proposed risk management objective

Proposed risk management objectives (RMO) set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances.

In this case, the proposed risk management objectives for methylparaben, propylparaben, butylparaben and *iso*-butylparaben for the protection of human health, are to:

- reduce consumer exposures to butylparaben and *iso*-butylparaben from certain cosmetic products
- reduce consumer exposures to butylparaben and *iso*-butylparaben from certain non-prescription drugs
- reduce consumer exposures to methylparaben, propylparaben, butylparaben and *iso*-butylparaben from certain NHPs.

The proposed risk management objectives may be revised in the RM Approach document that will be published concurrently with the screening assessment for these substances, or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

3.3 Proposed risk management options under consideration

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the risk management options under consideration for methylparaben, propylparaben, butylparaben and *iso*-butylparaben are:

- Communication of measures to reduce exposures to butylparaben and *iso*-butylparaben from certain cosmetics by describing butylparaben and *iso*-butylparaben as prohibited or restricted ingredients on the Health Canada Cosmetic Ingredient Hotlist

- Measures to reduce exposures (to levels that are protective of human health) of butylparaben and *iso*-butylparaben in certain non-prescription drugs by modification of applicable databases, in accordance with the *Food and Drugs Act.*

- Measures to reduce exposures (to levels that are protective of human health) of methylparaben, propylparaben, butylparaben and *iso*-butylparaben in certain NHPs, by modification of applicable databases, in accordance with the *Food and Drugs Act.*

Following the publication of this RM Scope document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[4]. 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.

3.4 Risk management information gaps

At this time, the following additional information is being requested from interested stakeholders to help fill any information gaps and to inform risk management decision-making regarding methylparaben, propylparaben, butylparaben and *iso*-butylparaben use in Canada:

- Ranges of concentrations of butylparaben and *iso*-butylparaben used in non-prescription drugs in Canada

- Ranges of concentrations of methylparaben, propylparaben, butylparaben and *iso*-butylparaben used in NHPs, in Canada.

Should stakeholders have such further information, they should provide it ideally on or before April 29, 2020, within the timelines (and to the contact) identified in section 8 of this document.

3.5 Performance measurement and evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[5]. The aim is to determine

[4] 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)

[5] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (*i.e.*, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the

whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review, on a regular basis, the effectiveness of the risk management actions for methylparaben, propylparaben, butylparaben and *iso*-butylparaben.

To this end, over time, the Government of Canada plans to collect and analyze data, such as biomonitoring data from the Canadian Health Measures Survey (CHMS) on the presence of methylparaben, propylparaben, butylparaben and *iso*-butylparaben due to exposures to these substances from cosmetic products, non-prescription drugs, and NHPs.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

4. Background

4.1 General information on the Parabens Group

Parabens are a family of alkyl esters of *para*-hydroxybenzoic acid, the word paraben being a contraction of "*para*-hydroxybenzoic acid". Different parabens differ in the chemical substitutions in the para position of the benzene ring.

All seven parabens in the parabens group are synthetically produced. However, some also occur naturally in certain fruits such as blueberries, strawberries, grapes, olives, yeast and barley.

4.2 Current uses and identified sectors

According to information submitted in response to surveys under section 71 of CEPA (Canada 2012), methylparaben was reported to be manufactured in Canada in 2011 at a volume of 981 kg, and reported to be imported into Canada at a volume of 563,000 kg. Butyl-, propyl-, and *iso*-butylparaben were not reported to be manufactured in Canada.

In response to CEPA Section 71 survey (Canada, 2017), propylparaben was reported to be imported, in 2016, at a volume of 8,526 kg, butylparaben at a volume of 100-1000 kg, and *iso*-butylparaben at a volume of 232 kg.

environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

In Canada, as per the draft screening assessment (Canada 2019) parabens are widely used as preservatives or antimicrobials against yeast, moulds and bacteria, in various cosmetic products, prescription and non-prescription drugs, NHPs, as well as in products available to consumers. They are also used in pest control products. Methyl- and propylparaben are approved food additives, which may be used as preservatives in certain foods and beverages sold in Canada.

The results from the 2014 and 2015 Canadian Health Measures Survey (CHMS) showed that 93% of Canadians aged 3 to 79 had at least one detectable paraben in their urine (methylparaben, ethylparaben, propylparaben or butylparaben). Detectable paraben levels reflect recent exposure only and do not necessarily indicate the possibility of an adverse event occurring (Statistics Canada 2016).

Cosmetic products

Based on notifications submitted under the *Cosmetic Regulations* to Health Canada from 2014 to 2017, methyl-, propyl-, butyl-, *iso*-propyl and *iso*-butylparabens are used in a wide range of cosmetic products in Canada.

As per the draft screening assessment (Canada, 2019), methylparaben and propylparaben were not identified as concerns in cosmetic products. Levels of butylparaben and *iso*-butylparaben were identified as a concern in some cosmetics products.

Prescription drugs

Methyl-, and propylparaben are reported as non-medicinal ingredients in some prescription drug products. Propylparaben was not identified as a concern in prescription drug products[6]. As per the draft screening assessment (Canada 2019), oral and dermal exposures to methylparaben in prescription drugs were not addressed in the assessment as the level of methylparaben in Canadian-approved pharmaceutical products is within standard use.

Non-prescription drugs

Methyl-, propyl-, butyl-, and *iso*-butylparaben are reported as non-medicinal ingredients in some over-the-counter (non-prescription) drug products.

As per the draft screening assessment (Canada, 2019), levels of methyl-, and propylparaben were not identified as a concern in non-prescription drug products,

[6] Personal communication, email from Health Canada Risk Assessment to Health Canada Risk Management, dated March 20, 2019; unreferenced.

whereas levels of butyl-, and *iso*-butylparaben were identified as a concern in certain non-prescription drug products.

NHPs

Methyl-, propyl-, butyl-, and *iso*-butylparaben are also reported as non-medicinal ingredients in several NHPs. They are of concern in certain NHPs.

5. Exposure sources and identified risks

The purpose of the RM Scope is to present Environment and Climate Change Canada's (ECCC) and Health Canada's (HC) early proposal to manage the risks identified in the screening assessment. As such, the exposure sources of concern are further discussed in this document.

Methylparaben

According to the draft screening assessment (Canada 2019), the critical effect for methylparaben includes clinical signs of ill-health, stomach erosion, and spleen and thyroid atrophy. The margins of exposure for oral exposure to some NHPs: (anti-diarrheal medication, heartburn medication, radiological contrast media); were considered potentially inadequate to address uncertainties in the health effects and exposure databases.

Propylparaben

In the draft screening assessment (Canada 2019), the critical effect level was based on an NOAEL (no observed adverse effect level) at the highest dose tested in a study of reproduction, reproductive development, or prenatal development. However, the possibility of adverse effects at high doses could not be excluded. The margins of exposure for oral exposure to a NHP (heartburn medication) were considered potentially inadequate to address uncertainties in the health effects and exposure databases.

Butylparaben

The draft screening assessment (Canada 2019) indicated that the critical effect for butylparaben is reduced anogenital distance in both sexes, reproductive organ weight, sperm count and motility. The calculated margins of exposure to some cosmetics (hair dye); some NHPs (herbal cough medicine, sunscreen); and some non-prescription drugs (children's analgesic suspension, antacid) are considered potentially inadequate to address uncertainties in the health effects and exposure databases.

Iso-butylparaben

As per the draft screening assessment (Canada 2019), the critical effect is reduced sperm count and motility. The calculated margins for exposure to the following cosmetic products: body lotion, body oil, body scrub, face make-up face lotion, eye lotion, sunless tanning product, shampoo, hair conditioner, body cleanser, as well as NHP (analgesic cream) and non-prescription drug (sunscreen) are considered potentially inadequate to address uncertainties in the health effects and exposure databases.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

There are several alternatives to the parabens being used in cosmetics, prescription and non-prescription drugs and NHPs in Canada.

6.2 Socio-economic and Technical Considerations

No information on socio-economic or technical considerations was identified. We ask that stakeholders submit information on these considerations, if known.

Socio-economic factors will be considered in the selection process for a regulation and/or instrument 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 regulations, 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).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

There are no specific restrictions for the use of parabens in cosmetic products in Canada. Parabens are restricted in Canada in NHPs to an oral upper limit of 10 mg/ kg bw/day exposure of the sum of methyl-, ethyl-, and propylparaben.

Methyl- and propylparaben are on the List of Permitted Preservatives (Lists of Permitted Food Additives) for use at up to 1000 ppm (0.1%) in certain foods and beverages. Butylparaben and *iso*-butylparaben are not permitted for use as food additives.

7.2 Pertinent International Risk Management Context

The EU has set the maximum concentration in cosmetics of 0.4% (w/w) for methylparaben as single ester and a total maximum concentration of 0.8% for mixtures of esters (w/w). It has also set the maximum concentration for butylparaben and propylparaben (and their salts) in cosmetics as: 0.14% (as acid) for the sum of the individual concentrations; and 0.8% (as acid) for mixtures of methyl-, butyl-, propyl-, and ethylparaben, and their salts (including maximum 0.14% for the mixture of butyl- and propylparaben). *Iso*-butylparaben is prohibited in cosmetics in the EU. (EU, 2009, 2014).

For food additives, methylparaben and its sodium salt is included in the parabens group ADI (Acceptable Daily Intake) of 0-10 mg/kg body weight per day (applicable to the sum of methyl and ethylparaben) established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Propylparaben was originally included in the group ADI but was withdrawn in 2006 due to new information of adverse effects. Methylparaben is permitted in the European Union as a food additive. (JECFA, 2017).

In the U.S., methylparaben and propylparaben are recognized as direct food substances affirmed as "Generally Recognized as Safe" (GRAS) when either of them is used as an antimicrobial agent in food at levels not to exceed a maximum level of 0.1 percent (1000 ppm) in food. Methylparaben and propylparaben are also approved for use as synthetic flavouring substances and adjuvants. (USA, 2018).

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. Please submit additional information and comments prior to April 29, 2020.

The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final Screening Assessment Report. 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
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in methylparaben, propylparaben, butylparaben and *iso*-butylparaben are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding methylparaben, propylparaben, butylparaben and *iso*-butylparaben and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the draft Screening Assessment Report and Risk Management Scope: February 29, 2020 to April 29, 2020

Submission of public comments, additional studies and information on methylparaben, propylparaben, butylparaben and iso-butylparaben: On or before April 29, 2020

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: On or before February 2021

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: On or before February 2021

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instruments: At the latest, 24-month from the publication of the final Screening Assessment Report

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

Publication of the final instruments, if required: At the latest, 18-month from the publication of each proposed instrument

9. References

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