# Risk Management Scope

# for

# Alcohols Group

# Methanol, 1-Butanol,

# and Benzenemethanol (Benzyl Alcohol)

# Chemical Abstracts Service Registry Numbers (CAS RNs):

# 67-56-1, 71-36-3, and 100-51-6

Environment and Climate Change Canada

Health Canada

March 2022

# Summary of Proposed Risk Management

This document outlines the risk management options under consideration for methanol, 1-butanol, and benzenemethanol (hereinafter refered to as benzyl alcohol), included in the Alcohols Group of the Chemicals Management Plan (CMP). In particular, the Government of Canada is considering:

1. Methanol:
   - Regulatory or non-regulatory action to help reduce inhalation exposure to methanol from paint/varnish remover products available to consumers to levels that are protective of human health.

2. 1-Butanol:
   - Regulatory or non-regulatory actions to help reduce inhalation exposure to 1-butanol from lacquer products available to consumers to levels that are protective of human health. Actions may aim to lower the concentration of 1-butanol in lacquer products to 1%.

3. Benzyl alcohol:
   - Measures to help reduce dermal exposures to benzyl alcohol from certain natural health products and non-prescription drugs by revising the listing for benzyl alcohol in the Natural Health Products Ingredients Database (NHPID); and

   - Measures to help reduce dermal exposures to benzyl alcohol from certain cosmetics by describing benzyl alcohol as a prohibited or restricted ingredient on Health Canada's Cosmetic Ingredient Hotlist.

Information on the following items should be provided (on or before May 11, 2022, to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Current quantities and concentrations of methanol used in paint/varnish remover products that are available to consumers;
- Potential alternative substances to methanol for use in paint/varnish remover products available to consumers;

- Current quantities and concentrations of 1-butanol used in lacquer products that are available to consumers;
- Potential alternative substances to 1-butanol for use in lacquer products available to consumers;
- Current concentrations of benzyl alcohol in sunscreens, body moisturizers/creams, deodorants, and face creams;
- Potential alternative substances to benzyl alcohol for use in sunscreens, body moisturizers/creams, deodorants, and face creams; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for methanol, 1-butanol, and benzyl alcohol.

The risk management options outlined in this risk management scope may evolve through consideration of assessments and risk management options published for other 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 this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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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 harmful or dangerous to the environment or human health as set out in section 64 of CEPA[1,2]; and if so, to manage the associated risks.

The substances methanol, 1-butanol, and benzenemethanol (hereinafter refered to as benzyl alcohol), Chemical Abstracts Service Registry Numbers (CAS RNs)[3] 67-56-1, 71-36-3, and 100-51-6, respectively, are included in the Alcohols Group of the Chemicals Management Plan (CMP; Canada 2022).

# 2. Issue

## 2.1 Draft Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of 21 substances that are part of the Alcohols Group. A notice summarizing the scientific considerations of the draft screening assessment for these 21 substances was published in the *Canada Gazette*, Part I, on March 12, 2022 (Canada 2022). Based on the information available, the draft screening assessment proposes that methanol, 1-butanol, and benzyl alcohol are toxic under section 64(*c*) of CEPA because they

[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 of CEPA 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, 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 *Hazardous Products Regulations*, which are 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 1999 does not preclude actions being taken under other sections of CEPA or other Acts.

[3] Chemical Abstracts Service Registry Number (CAS RN). The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2022).

It is proposed that methanol, 1-butanol, and benzyl alcohol 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 under paragraphs 64(*a*) or (*b*) of CEPA, respectively (Canada 2022). The draft screening assessment proposes that the other 18 substances in the Alcohols Group do not meet any of the criteria set out in section 64 of CEPA.

The draft screening assessment also proposes that methanol meets the persistence, but not the bioaccumulation criteria, and that 1-butanol and benzyl alcohol do not meet the criteria for persistence or bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

According to the draft screening assessment, the exposure sources of concern for the general population to methanol and 1-butanol are based on the release of methanol and 1-butanol into air from certain do-it-yourself (DIY) products (e.g., paint/varnish removers and lacquers, respectively) and dermal exposure to benzyl alcohol from certain cosmetics (e.g., body creams/moisturizers, deodorants/antiperspirants, and face creams), natural health products and non-prescription drugs (e.g., sunscreens). As such, this document will focus on these specific exposure sources of concern (refer to section 5).

Although one substance, 2-propanol, 1,3-dichloro (common name 1,3-dichloro, 2-propanol or 1,3-DCP) (CAS RN 96-23-1), is not considered to be harmful to human health or the environment at current levels of exposure, this substance is associated with health effects of concern on the basis of its International Agency for Research on Cancer (IARC) carcinogenic to humans Group 2B designation. There may be a potential risk to human health if use patterns were to change. For this reason, follow-up activities to track changes in exposure and/or commercial use patterns for 1,3-DCP are being considered.

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft screening assessment are preliminary and may be subject to change. For further information, refer to the draft screening assessment for the Alcohols Group.

## 2.2 Proposed Recommendation Under CEPA

Based on the findings of the draft screening assessment conducted pursuant to CEPA, the ministers propose to recommend that methanol, 1-butanol, and benzyl alcohol be added to Schedule 1 of the Act[4].

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and risk management scope. If the ministers finalize the recommendation to add these substances to Schedule 1 of CEPA, 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 are quantitative or qualitative statements of what should be achieved to address human health concerns.

The proposed human health objective for methanol, 1-butanol, and benzyl alcohol is to reduce exposure of the general population to these substances to levels that are protective of human health.

[4] 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 substance, 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.

## 3.2 Proposed Risk Management Objective and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective is to reduce inhalation exposure of the general population to methanol and 1-butanol in paint/varnish removers and lacquers, respectively, and to reduce dermal exposure of the general population to benzyl alcohol in sunscreens and certain other leave-on natural health products, non-prescription drugs, and cosmetics.

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management options under consideration are:

1. Methanol:
   - Regulatory or non-regulatory action to help reduce inhalation exposure to methanol from paint/varnish remover products available to consumers to levels that are protective of human health.

2. 1-Butanol:
   - Regulatory or non-regulatory actions to help reduce inhalation exposure to 1-butanol from lacquer products available to consumers to levels that are protective of human health. Actions may aim to lower the concentration of 1-butanol in lacquer products to 1%.

3. Benzyl alcohol:
   (1) Revising the listing for benzyl alcohol in the NHPID by lowering the maximum allowable concentration in leave-on products containing benzyl alcohol as a non-medicinal ingredient from 3 to 1% in order to help reduce dermal exposures to benzyl alcohol from sunscreens and certain other leave-on natural health products and non-prescription drugs; and
   (2) Measures to help reduce dermal exposures to benzyl alcohol from certain cosmetics by describing benzyl alcohol as a prohibited or restricted ingredient on Health Canada's Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

Following the publication of this risk management scope, 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[5]. 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 Risk Management Information Gaps

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

- Current quantities and concentrations of methanol used in paint/varnish remover products that are available to consumers;
- Potential alternative substances to methanol for use in paint/varnish remover products available to consumers;
- Current quantities and concentrations of 1-butanol used in lacquer products that are available to consumers;
- Potential alternative substances to 1-butanol for use in lacquer products available to consumers;
- Current concentrations of benzyl alcohol in sunscreens, body moisturizers/creams, deodorants, and face creams;
- Potential alternative substances to benzyl alcohol for use in sunscreens, body moisturizers/creams, deodorants, and face creams; and
- Socio-economic and technical impacts and benefits associated with the proposed risk management for methanol, 1-butanol, and benzyl alcohol.

## 3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[6]. The aim is to determine 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 the effectiveness of the risk management action(s) for methanol, 1-butanol, and benzyl alcohol.

The Government of Canada plans to measure the effectiveness of the risk management action(s) by collecting and analyzing data to measure progress towards meeting the risk management objective(s).

[5] 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).

[6] Performance measurement strategy available online at https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/performance-measurement-evaluation-strategy.html

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

Methanol is a naturally occurring substance that is commonly produced in anaerobic environments by bacteria. However, production of methanol is mainly from anthropogenic sources. Canada is estimated to produce 600 000 - 700 000 tonnes of methanol and import 250 000 tonnes annually. It is predominantly used to produce formaldehyde. It is also used in automotive products, cosmetics, natural health products, non-prescription and prescription drugs, cleaning agents, adhesives, and paint/varnish remover products. It is a permitted food additive and may be used as a component in the manufacture of certain food packaging materials, such as polymer-based materials and printing inks.

1-Butanol occurs in nature through fermentation processes, but consumers are largely exposed to the substance from anthropogenic sources. It is used in cosmetics, as a non-medicinal ingredient (NMI) in natural health products, non-prescription and prescription drugs, and several consumer products such as cleaning agents, lacquers, automotive care products, epoxy adhesives and as a solvent in paint and ink products. It may also be used as a component in the manufacture of food packaging materials and as a food flavouring agent. From a survey issued pursuant to section 71 of CEPA, there was no reported manufacture of 1-butanol and 68 000 kg of 1-butanol were imported in Canada in 2011 (Environment Canada 2013).

Benzyl alcohol is found in nature (e.g., derived from plants), but consumer exposure to the substance is mainly from anthropogenic sources. Based on information submitted in response to a CEPA section 71 survey, 5 000 kg of benzyl alcohol was manufactured in and 735 000 kg imported to Canada in 2011 (Environment Canada 2013). This substance is found in a wide variety of products available to consumers such as household cleaning products, automotive products, and home improvement products, as well as in cosmetics, as an NMI in natural health products, non-prescription and prescription drugs. Benzyl alcohol is also a permitted food additive, and may be used as a food flavouring agent.

# 5. Exposure Sources and Identified Risks

## 5.1 Methanol

The draft screening assessment considered the possible risks from long-term exposure to indoor air containing methanol. There were no health risks from long-term inhalation exposures from indoor or outdoor air as determined by the levels of methanol obtained by general air monitoring, which were lower than the reference concentration (RfC) for inhalation of methanol of 20 mg/m$^3$ based on developmental effects derived by the United States Environmental Protection Agency (US EPA). There were also no health risks from oral exposures (e.g., from food, uses in natural health products, non-prescription and prescription drugs) or dermal exposures (e.g., from cosmetics, natural health products, and non-prescription and prescription drugs).

However, the assessment did identify short-term inhalation exposure scenarios associated with risks to human health for methanol. These scenarios considered exposures to paint/varnish remover products available to consumers containing 10 or 35% methanol concentrations for small (≤500 g of product) or large (>4500 g of product) projects. These scenarios resulted in estimated 24-hour average concentrations of methanol from 37 to 72 mg/m$^3$ from use of paint remover with 35% methanol in small projects or 92 to 611 mg/m$^3$ for larger projects with products containing 10 to 35% methanol, respectively. The estimated mean concentration of methanol for bathtub resurfacing in a bathroom ranged from 130 to 458 mg/m$^3$ for 10 and 35% methanol containing products, respectively. All of these exposure estimates exceeded the RfC of 20 mg/m$^3$ based on developmental effects derived by the US EPA and were therefore identified as a concern for human health.

## 5.2 1-Butanol

The draft screening assessment considered the possible risks from long-term exposure to indoor air containing 1-butanol from all household sources (including cosmetics, natural health products, household cleaning products and other home use products which may lead to the release of 1-butanol in air). There were no health risks from long-term inhalation exposures from indoor air as determined by the levels of 1-butanol obtained by general indoor air monitoring. There were also no health risks from oral exposures (e.g., from food, natural health products, prescription and non-prescription drugs) or dermal exposures (e.g., cosmetics, natural health products, and prescription and non-prescription drugs).

The assessment, however, did identify one short-term inhalation exposure scenario associated with neurodevelopmental and developmental risk to human health for 1-butanol. This scenario considered inhalation exposure to lacquer products available to consumers that are used by adults in the home. Estimated

inhalation exposures were compared to a lowest-observed-adverse-effect level (LOAEL) for developmental effects and the resulting margin of exposure (MOE) was considered potentially inadequate.

## 5.3 Benzyl alcohol

The assessment considered possible risks to Canadians from the environment and food, but concluded that potential risk, if any, from exposure to these sources would be less than that from products available to the consumer since benzyl alcohol exposure via environmental media is expected to be less than its exposure from products available to consumers. There were no health risks from dermal or inhalation exposures due to the use of cleaning products or air fresheners. The assessment did identify health risks from dermal exposure to sunscreens, body creams/moisturizers, deodorants/antiperspirants, and face creams.

Chronic dermal exposure scenarios were considered for the use of cosmetics (e.g., body creams/moisturizers, deodorants/antiperspirants, and face creams) as well as natural health products and non-prescription drugs (e.g., sunscreens) by both children and adults. The estimated dermal exposures were compared to an oral no-observed-adverse-effect level (NOAEL) for neurotoxic effects resulting in potentially inadequate MOEs.

# 6. Risk Management Considerations

## 6.1 Alternatives and Alternate Technologies

No publicly available information on alternatives to methanol or 1-butanol was identified for paint/varnish remover products or lacquer products, respectively. There were also no known alternatives identified for benzyl alcohol in cosmetics, natural health products, and non-prescription drugs. Follow-up information from stakeholders is requested, if known.

The US EPA's Safer Choice Criteria for Specialized Industrial Products and a report from the State of California on alternatives identified benzyl alcohol as an acceptable substitute for other chemicals that function as a solvent in paint strippers (EPA 2012, Jacobs *et al*., 2015).

## 6.2 Socio-economic and Technical Considerations

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(s). 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 Regulation* (TBS 2018) 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

### 7.1.1 Methanol

Domestically, methanol is listed on the Pest Management Regulatory Agency (PMRA) formulant list for pest control products currently registered in Canada under the *Pest Control Products Act* and Regulations (PMRA, 2010).

It is also listed as a Volatile Organic Compound (VOC) by National Pollutant Release Inventory (NPRI).

In Canada, the safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the *Food and Drug Regulations* and section 4(1)(a) of the *Food and Drugs Act*.

Methanol is a permitted food additive on the *List of Permitted Carrier or Extraction Solvents,* incorporated by reference into its respective Marketing Authorization issued under the *Food and Drugs Act.*

Methanol is listed as an ingredient restricted for use in cosmetic products. No person can sell a cosmetic containing an amount of methanol equal to or greater than 5 mL unless it is packaged in a child-resistant container as a result of section 15.2 of the *Cosmetic Regulations*. Containers, that contain an amount of methanol equal to or greater than 5 mL, must meet the requirements set out in subsection 28.2 of the *Cosmetic Regulations*. The NHPID entry for methanol refers to the presence of this ingredient as restricted on the Cosmetic Ingredient Hotlist and indicates that this ingredient must be used in accordance with the restrictions set out on the Hotlist when included in natural health products, unless additional evidence for safety is submitted.

The *Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations* were published in the *Canada Gazette*, Part II, on January 5, 2022 under CEPA and apply to Canadian manufacturers and importers. They establish total VOC concentration limits for approximately 130 product categories and subcategories, including paint or coating removers or strippers. The regulations set a VOC concentration limit for the total amount of VOCs in a certain product but do not include a specific limit for a single VOC.  For further information visit: Certain products and volatile organic compounds – Canada.ca.

In addition, a paint/varnish remover product containing methanol is considered a consumer chemical product, which is regulated by the *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001) under the *Canada Consumer Product Safety Act* (CCPSA).

### 7.1.2 1-Butanol

Domestically, 1-butanol is listed on the Pest Management Regulatory Agency (PMRA) formulant list for pest control products currently registered in Canada under the *Pest Control Products Act* and Regulations (PMRA, 2010).

In Canada, the safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the *Food and Drug Regulations* and section 4(1)(a) of the *Food and Drugs Act*. In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act*.

It is also listed as a VOC by the NPRI.

The *Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations* were published on September 30, 2009 in *Canada Gazette*, Part II. The regulations set mandatory VOC concentration limits on products such as paints, stains, varnishes, lacquers and other types of coatings applied to a wide variety of stationary structures in residential, commercial, institutional and industrial settings. The regulations apply to manufacturers, importers and sellers of architectural coatings, as well as to users of traffic marking coatings. Under these regulations, there are 53 product categories of architectural coatings, each having a specific VOC maximum concentration limit. The regulations set a VOC concentration limit for the total amount of VOCs in a product but do not include a specific limit for a single VOC, such as 1-butanol. For further information visit: Architectural coatings products and volatile organic compounds - Canada.ca

In addition, a lacquer product containing 1-butanol is considered a consumer chemical product, which is regulated by the *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001) under the CCPSA.

### 7.1.3 Benzyl alcohol

Benzyl alcohol is listed in the NHPID with an acceptable daily intake up to 5 mg/kg bw/day, expressed as benzoic acid equivalents. It is also listed with a non-medicinal role for use as flavour enhancer, fragrance ingredient, preservative antimicrobial, or solvent. It must be declared as a medicinal ingredient in throat lozenges at daily doses at or above 100 mg/day, and in anorectal products in concentrations at or above 1% w/w. For topical use as NMI, it is allowed up to 10% in rinse-off products and up to 3% in leave-on products.

Benzyl alcohol is a permitted food additive on the *List of Permitted Carier or Extraction Solvents*, incorporated by reference into its respective Marketing Authorization issued under the *Food and Drugs Act* where it is permitted as a carrier solvent in unstandardized flavouring preparations and in one type of standardized flavouring preparation. It may also be used as a food flavouring agent, the safety of which is subject to the provisions under section 4(1)(a) of the *Food and Drugs Act*.

## 7.2 Pertinent International Risk Management Context

### 7.2.1 Methanol

United States

- Under the Federal Food, Drug, and Cosmetic Act, methanol is listed under Food Additives. Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid (Cis-9, Trans-11 and Trans- 10, Cis-

12-Octadecadienoic Acids) as a reactant with refined sunflower oil to produce fatty acid methyl esters.

- Under Title 21: Food and Drugs, Part 184—Direct Food Substances Affirmed as Generally Recognized as Safe, §184.1259 Cocoa butter substitute, residual methanol must be 5 ppm maximum.
- Under PART 172—Food Additives Permitted for Direct Addition to Food for Human Consumption, Subpart I—Multipurpose Additives, §172.859 Sucrose fatty acid esters, methanol cannot exceed 10 ppm in sucrose fatty acid esters.
- Listed under Title 21: Food and Drugs, Subpart B—Substances for Use Only as Components of Paper and Paperboard, Part 176—Indirect Food Additives: Paper and Paperboard Components §176.210 Defoaming agents used in the manufacture of paper and paperboard.

European Union

- Listed under Dangerous Substances in Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, PART 2: Named dangerous substances.
- Under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, 3.1.1. Packaging to be fitted with child-resistant fastenings, methanol has a concentration limit of ≥ 3 % in packaging.
- Under 2006/257/EC: Commission Decision of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products, methanol is listed as a cosmetic ingredient.
- Listed in Directive 2009/32/EC (Consolidated-2016-11-09): Extraction solvents used in the production of foodstuffs and food ingredients.

### 7.2.2 1-Butanol

United States

- *Food and Drug Act*, Title 21 of the Code of Federal Regulation (CFR):
    - Part 172 – Food additives permitted for direct addition to food, where 1-butanol may be safely used as a flavouring agent or as a

modified hop extract flavouring to no more than 50 ppm (US eCFR, 2017a).
    - Part 175 – Indirect food additives in adhesives and components of coatings, where 1-butanol is safely used in adhesives and coatings for polyolefin films in food packaging
    - Part 176 – Indirect food additives in paper and paperboard components, where the substance is safe to use in articles intended for packaging, transporting or holding food; and
    - Part 177 – Indirect food additives in polymers
- The United States Food and Drug Administration (US FDA)'s Inactive Ingredient Search for Approved Drug Products list a *maximum potency per unit dose* of 0.02 mg *for tablet, extended release*.
- *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), US EPA Regulations. 1-Butanol is classified as List 4B - an inert ingredient in pesticides based upon the 'reasonable certainty of no harm' safety finding. It is cleared for use in food and non-food as a dye. This inert ingredient is used pre-harvest with exemptions from the requirement of a tolerance when used in accordance with good agricultural practice. To be exempt from the requirement of a tolerance, it must be limited to not more than 0.005% of the pesticide formulation. It is also an inert ingredient applied to animals (with exemption from the requirement of a tolerance) (US EPA, 2005; US eCFR 2017d).
- *Clean Air Act,* EPA Regulations. 1-Butanol is designated a VOC subject to compliance with 40 CFR Part 60 – Standards of Performance for New Stationary Sources.

<u>European Union</u>

- 1-Butanol is included in Annex I, list of monomers authorized in plastics production intended for food contact, of European Commission Regulation No 10/2011 (EC, 2011)
- Listed in the Register of Flavouring Substances under European Commission Regulation No 2232/96 (EC, 1996), where 1-butanol is safe for use as a food flavouring substance
- Listed in Directive 2009/32/EC (Consolidated-2016-11-09): Extraction solvents used in the production of foodstuffs and food ingredients
- Listed as an existing active substance in biocidal products in accordance with European Commission Regulation No 1451/2007 (EC, 2007)

### 7.2.3 Benzyl alcohol

United States

- *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), US EPA Regulations: classified as List 3 – inert ingredient of unknown toxicity
- *Food and Drug Act*, Title 21 of the Code of Federal Regulation (CFR):
    - Part 73 – allowed as a colour additive in drugs
    - Part 172 – Food additives permitted for direct addition to food where benzyl alcohol may be safely used as a synthetic flavouring agent (US eCFR, 2017a).
    - Part 175 – Indirect food additives in adhesives and components of coatings, where benzyl alcohol should not exceed 4% of the resin for coatings intended for repeated use in contact with food
    - Part 177 – Indirect food additives in polymers allowing up to 1% benzyl alcohol in closures for food containers
- The US FDA's Inactive Ingredient Search for Approved Drug Products gives a *maximum potency per unit dose* for benzyl alcohol (US FDA 2019).
- Listed as approved for fragrance use on the EPA Fragrance Ingredient List

European Union

- Listed in the Regulation No 872/2012 as allowed as a flavouring substance
- Listed in Regulation (EU) No 10/2011 (Consolidated-2018-02-08): Plastic materials and articles intended to come into contact with food
- Listed in Regulation (EU) No 1333/2008) on food additives and Regulation (EU) No 231/2012 (Consolidated-2018-08-12): Specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008
- Listed in the Regulation No 1223/2009 on cosmetic products where benzyl alcohol must be listed on the ingredient list if concentrations are >0.001% in leave-on products or >0.01% in rinse-off products (Annex III)
- Also under Regulation No 1223/2009, allowed as a preservative in cosmetic products up to 1% (Annex V)

# 8. Next Steps

## 8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this risk management scope or other information that would help to inform decision-making (such as outlined in sections 3.2 or 3.3). Please submit additional information and comments prior to May 11, 2022.

The risk management approach, 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. At that time, there will be further opportunity for consultation.

Comments and information submissions on the risk management scope should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819-938-3232
Email: substances@ec.gc.ca

Companies who have a business interest in methanol, 1-butanol, and/or benzyl alcohol are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding methanol, 1-butanol, and/or benzyl alcohol and may be contacted for further information.

## 8.2 Timing of Actions

Electronic consultation on the draft screening assessment and risk management scope: March 12, 2022 to May 11, 2022. This should include the submission of public comments, additional studies, and/or information on methanol, 1-butanol, and/or benzyl alcohol.

Publication of responses to public comments on the draft screening assessment and risk management scope: concurrent to the publication of the screening assessment and, if required, the risk management approach.

Publication of responses to public comments on the risk management approach, if applicable and if required, the proposed instrument(s): At the latest, 24 months from the date on which the ministers recommended that methanol, 1-butanol, and/or benzyl alcohol be added to Schedule 1 of CEPA.

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

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

These are planned timelines, and are subject to change. Please consult the schedule of risk management activities and consultations for updated information on timelines.

# 9. References

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