Government of Canada | Gouvernement du Canada

Risk Management Approach

for

Ketones, *specifically*:

2-Butanone
(Methyl ethyl ketone; MEK)
2-Pentanone, 4-methyl-
(Methyl isobutyl ketone; MIBK)

Chemical Abstracts Service Registry Numbers

(CAS RNs):

78-93-3

108-10-1

Environment and Climate Change Canada

Health Canada

May 2026

Canada

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for methyl ethyl ketone (MEK) and methyl isobutyl ketone (MIBK) which have been found to be harmful to human health. For the purposes of subparagraph 77(6)(*c*)(*i*) of the *Canadian Environmental Protection Act, 1999* (CEPA), the Government of Canada is considering the following new risk management action:

Development of regulatory controls to help reduce inhalation exposures to MEK and MIBK from certain products available to consumers, including paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers.

If available, information on the following items should be provided to the contact identified in section 8 of this document, within 60 days following the publication of this document, to inform risk management decision-making:

1. Current quantities (kilograms [kg]) and concentrations (percent weight per weight [%w/w]) of MEK and/or MIBK used in do-it-yourself (DIY) products that are available to consumers in Canada, including but not limited to paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers;
2. Potential alternative substances to MEK and/or MIBK used in DIY products available to consumers in Canada, including but not limited to paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers; and
3. Socio-economic and technical barriers and benefits associated with the proposed risk management actions for MEK and MIBK.

The risk management actions outlined in this Risk Management Approach 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. In addition, the proposed risk management actions might evolve through consideration of additional information obtained from the public comment period, literature and other sources.

Table of Contents

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

The substances 2-Butanone, Chemical Abstracts Service Registry Number (CAS RN[3]) 78-93-3, referred to throughout this document as methyl ethyl ketone or "MEK," and 4-Methyl-2-pentanone, CAS RN 108-10-1, referred to throughout this document as methyl isobutyl ketone or "MIBK," were assessed under the Chemicals Management Plan (CMP) (Canada 2026).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of ketone substances, including MEK and MIBK, in Canada. A notice summarizing the scientific considerations of the assessment for these substances was published in the *Canada Gazette*, Part I, on May 16, 2026 (Canada 2026). For further information, refer to the final assessment for the Ketones Group.

2.1 Assessment conclusion

On the basis of the information available, the assessment concludes that MEK and MIBK are toxic under section 64(*c*) of CEPA as they are entering the environment

[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.

[3] The CAS RN 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.

in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (ECCC, HC 2026).

It is also concluded that MEK and MIBK 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 sections 64 (*a*) and (*b*) of CEPA, respectively (ECCC, HC 2026).

The draft screening assessment also proposed 2,4-pentanedione (2,4-PD) to be toxic under section 64(*c*) of CEPA (ECCC, HC 2019a). However, following the publication of the draft screening assessment and risk management scope, it was determined that 2,4-PD is not currently being used in products available to consumers. Therefore, the assessment concluded that 2,4-PD does not meet the toxicity criteria under section 64 of CEPA (ECCC, HC 2026).

The exposure sources of concern for MEK and MIBK identified in the assessment are from the use of certain products available to consumers (ECCC, HC 2026). To date, the following product types have been identified as a concern to human health: paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers. It is relevant to note that other products containing MEK and/or MIBK with similar uses and exposures could also pose a risk to human health; the Government of Canada may consider risk management actions applicable to these other products. As such, this document will focus on products available to consumers (refer to section 5).

The Government of Canada has a duty, in the administration of CEPA, to protect the right to a healthy environment as provided for under CEPA, subject to reasonable limits. An implementation framework sets out considerations to protect this right and uphold the principles described in the implementation framework.

Recognizing that CEPA decisions are informed by analyses and consultations that are often the result of years of work, the transition period is in place to allow the departments to support continued protection of the environment and human health. The objective of the transition period is to advance timely CEPA decisions and actions while consideration of the right to a healthy environment and relevant principles is being fully integrated into the administration of the Act. This risk management approach is proceeding under the transition period referenced in the implementation framework.

The risk management approach contributes to an environment that is protected from harmful substances. Although the work to inform the risk management approach was undertaken prior to the availability of the implementation framework, the risk management approach supports several elements identified in the

framework, such as participation in decision making through the public comment period on the proposed risk management options.

2.2 Recommendation under CEPA

CEPA sets out a 2-track approach for managing risks.

Under sub-section 77(3), the Ministers are required to propose recommending the addition of a substance that meets the criteria set out in paragraph (a), (b) or (c) to Part 1[4] of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment.

For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures.

On the basis of the findings of the assessment conducted pursuant to CEPA, the Ministers recommend that MEK and MIBK be added to Part 2 of Schedule 1 to CEPA.[5] Addition of a substance to Schedule 1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for ketones and its associated Risk Management Scope.

As the Ministers finalize the recommendation to add MEK and MIBK to Part 2 of Schedule 1, risk management instruments must be proposed, unless an exception in section 91 of CEPA applies, within 24 months from the date on which the Ministers recommended that MEK and MIBK be added to Schedule 1 to CEPA,

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[4] Under subsection 77(3), a substance must be recommended for addition to Part 1 of Schedule 1 to the Act when the substance is determined to be toxic and the ministers are satisfied that:

a) the substance may have a long-term harmful effect on the environment and
    i. is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies,
    ii. is persistent and bioaccumulative in accordance with the regulations,
    iii. is present in the environment primarily as a result of human activity, and
    iv. is not a naturally occurring radionuclide or a naturally occurring inorganic substance;
b) the substance may constitute a danger in Canada to human life or health and is, in accordance with the regulations, carcinogenic, mutagenic or toxic for reproduction; or
c) the substance is, in accordance with the regulations, a substance that poses the highest risk.

[5] After an assessment of a given substance under Part 5 of CEPA, other than section 83, the ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances in Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances). Adding a substance to Schedule 1 does not, in itself, restrict its use, manufacture, or import. Rather, it enables the Government of Canada to take risk management actions under CEPA.

Although risk to human health or the environment has not been identified at current levels of exposure, there may be a concern if exposure to 2,4-PD were to increase. As a result, this substance will be considered in future initiatives to track its commercial status or identify new uses or exposures. In addition, as the Ministers have reason to suspect 2,4-PD is capable of becoming toxic, this substance is being proposed for addition to the List of substances capable of becoming toxic described in section 75.1 of CEPA.

2.3 Public comment period on the draft screening assessment and the Risk Management Scope

The draft screening assessment for the Ketones Group (ECCC, HC 2019a) and the associated Risk Management Scope document for MEK, MIBK, and 2,4-PD (ECCC, HC 2019b) summarizing the proposed risk management options under consideration at that time were published on January 19, 2019. Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period. Comments received on the draft screening assessment report and the Risk Management Scope were taken into consideration in the development of this document. A summary of responses to public comments received is available.

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.

For MEK and MIBK, the proposed objective is focused on addressing the exposure sources of concern outlined in section 5 of this document. The proposed human health objective for MEK and MIBK is to reduce inhalation exposures of the general population to MEK and MIBK to levels that are protective of human health.

3.2 Proposed risk management objective

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 for MEK and MIBK is to reduce inhalation exposures to MEK and MIBK contained in certain products available to consumers to levels that are protective of human health.

3.3 Proposed risk management actions under consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, risk management actions are proposed.

For the purposes of subparagraph 77(6)(*c*)(*i*) of CEPA, the Government of Canada is considering the following new risk management action:

- Development of regulatory controls to help reduce inhalation exposures to MEK and MIBK from certain products available to consumers, including paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers.

Following the publication of this document, additional information obtained from the public comment period and from other sources will also be considered in the instrument selection and development process.[6] The risk management actions may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

The design of proposed risk management instruments will strive to keep administrative burden on industry low while continuing to address the protection of human health and the environment. This includes aligning requirements with those of other key jurisdictions wherever possible, keeping reporting requirements to those that are essential for effective administration, maintaining clear and streamlined processes and decision-making, enabling innovation and alternative methods where feasible, and leveraging modern tools and innovative process solutions.

[6] The proposed risk management regulations, instruments or tools 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 Regulation (TBS 2018a), the Red Tape Reduction Action Plan (TBS 2012), and, in the case of a regulation, the Red Tape Reduction Act (Canada 2015) as well as the objectives of the most recent federal Red Tape Review (TBS 2025).

3.4 Performance measurement and evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances.[7] Environment and Climate Change Canada and Health Canada have developed a Performance Measurement Evaluation Strategy that sets out the approach to evaluate the effectiveness of actions taken on substances found toxic under CEPA (ECCC, HC 2020). 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 those substances. Selection of a substance for performance measurement evaluation is conducted through readiness, prioritization and work planning as outlined in the Performance Measurement Evaluation Strategy. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time.

The Government of Canada may measure the effectiveness of the risk management action(s) and the progress towards meeting the risk management and human health objective for MEK and MIBK.

To do so, the Government of Canada may collect and analyze data on MEK and MIBK prevalence in products available to consumers in Canada.

When undertaken, the results of performance measurement and evaluation are used to inform whether further risk management action is warranted and are made available to people in Canada along with recommendations for further action, if applicable.

3.5 Risk management information gaps

Additional information is requested to inform risk management decision-making and to help in the early drafting of the proposed risk management actions. Information may also be used to help inform risk management performance evaluation. Where available, information on the following aspects may be

[7] Performance measurement can be performed at 2 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 (that is, 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 environment or human health (that is, evaluate whether human health and/or environmental objectives have been met).

For more information on performance measurement evaluation (including HC and ECCC's Performance Measurement Evaluation Strategy), please visit Performance measurement for toxic substances - Canada.ca.

submitted during the public comment period for this Risk Management Approach document or during stakeholder outreach activities that are anticipated to occur in the future.

Interested stakeholders are invited to provide information, such as outlined below, to inform risk management decision-making regarding MEK and MIBK:

1. Current quantities (kg) and concentrations (%w/w) of MEK and/or MIBK used in DIY products that are available to consumers in Canada, including but not limited to paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers;
2. Potential alternative substances to MEK and/or MIBK for use in DIY products available to consumers in Canada, including but not limited to paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers; and
3. Socio-economic and technical barriers and benefits associated with the proposed risk management actions for MEK and MIBK.

Stakeholders that have information to help address these gaps should provide it on or before July 15, 2026, to the contact identified in section 8.

4. Background

4.1 General information on MEK and MIBK

MEK and MIBK belong to the Ketones Group of substances characterized by a carbonyl group in which the carbon atom is joined to an oxygen atom by a double bond. The other 2 bonds are to other carbon atoms or to hydrocarbon radicals. Additionally, ketones are volatile organic compounds (VOCs).

MEK and MIBK are naturally occurring in plants and/or foods. They are also commercially produced and MEK is produced endogenously in humans.

4.2 Current uses and identified sectors

Manufacturing of MEK in Canada ceased in 2002 (Environment Canada 2001). The Canadian International Merchandise Trade Database shows that, in 2011, about 6 million kg of MEK was imported into Canada (CIMT 2017) and that, between 2011 and 2016, about 4.9 million kg of MEK, on average, was imported into Canada per year (CIMT 2017).

According to information reported to a survey issued pursuant to section 71 of CEPA, MIBK was not manufactured in Canada in 2011 (Environment Canada 2012). Total imports of MIBK in 2011 in Canada were reported to be 1 241 783 kg.

In general, ketones are primarily used as solvents in various products, including products available to consumers, and in numerous industrial applications as chemical intermediates and solvents, among other uses (O'Donoghue 2012a,b).

MEK and MIBK are used in products available to consumers including paint or coating removers or strippers (for example, lacquer removers), multipurpose solvents (for example, adhesive removers, degreasers, paint or coating thinners), liquid paints, spray products (for example, spray paints) and wood lacquers.

MEK is listed as a permitted food additive in natural extractives and in spice extracts as prescribed in Health Canada's List of Permitted Carrier or Extraction Solvents*,* incorporated by reference in its respective Marketing Authorization issued under the *Food and Drugs Act*. MEK and MIBK may be used as components in the manufacture of food packaging materials with no direct contact with food in Canada. MEK may also be used as a component in incidental additives[8] (cleaners) in food processing establishments with no direct contact with food. While there is no definitive information concerning the potential use of MEK and MIBK as food flavouring agents in Canada, since these substances are known to be used as food flavouring agents in the United States (US) and Europe, it is possible that they are present as flavouring agents in foods sold in Canada.

MEK is listed in the Natural Health Products Ingredients Database (NHPID)[9] with a medicinal role as a natural health product substance falling under Schedule 1, item 2 (an isolate) to the *Natural Health Products Regulations*, as well as with a non-medicinal role for topical use as denaturant (up to 1%) or oral use as flavour enhancer (up to 28.76 ppm). The NHPID also notes that MEK is subject to additional regulatory requirements in accordance with the *Precursor Control Regulations* since it is listed on Schedule VI of the *Controlled Drugs and Substances Act*. MIBK is also listed in the NHPID with a non-medicinal role for oral use as flavour enhancer (up to 25 ppm) or topical use as denaturant (up to 4%). MIBK is also associated in the NHPID with a permitted daily exposure as residual solvent of up to 45 mg/day, equivalent to a concentration limit of 4 500 ppm when

[8] While not defined under the *Food and Drugs Act*, incidental additives may be regarded, for administrative purposes, as those substances which are used in food processing plants and which may potentially become adventitious residues in foods (for example, cleaners, sanitizers).

[9] The NHPID provides an electronic tool which enables members of the public to access information on the following topics:

- medicinal and non-medicinal ingredients used in Natural Health Products;
- standard terminology used by the Natural Health Products Online System, known as "Controlled Vocabulary", referring to quality test methods, dosage forms, non-medicinal ingredient purposes, and so on; and
- pre-cleared information such as single ingredient monographs and product monographs.

assuming a product mass of 10 g administered daily, further indicating that this limit applies to all dosage forms and routes of administration. MEK and MIBK are listed in the Licensed Natural Health Products Database as being present as non-medicinal ingredients in a limited number of currently licensed topical natural health products in Canada (NHPID [modified 2022]; LNHPD [modified 2021]; personal communication, email from the Natural and Non-prescription Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated August 16, 2016, unreferenced). Based on notifications submitted under the *Cosmetic Regulations* to Health Canada, MEK and MIBK are used in certain cosmetics in Canada, primarily in nail care products.

MIBK is a formulant in pest control products registered in Canada (Canada 2022).

5. Exposure sources and identified risks

General population exposure to MEK and MIBK may occur from air and food (from its natural occurrence and possible use as a food flavouring agent), and from products available to consumers including cosmetics, markers (for MIBK), paints and DIY products, including paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers. MEK and MIBK were also reported to be released to air as a result of industrial activities. The assessment did not identify human health risks from exposures to MEK and/or MIBK from air, food (from its natural occurrence and possible use as a food flavouring agent), cosmetics, natural health products or markers. The assessment did identify exposure scenarios of potential concern to human health from inhalation of emissions from consumer use of certain products including paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints, spray products (for example, spray paints) and wood lacquers which contain MEK or MIBK. Dermal and oral exposures to MEK and MIBK from these consumer uses may contribute to the overall exposures; however, the exposures of concern occur by inhalation.

Exposures of concern to MEK and/or MIBK by inhalation can occur in the home during painting, renovations, maintenance and repairs through the use of the above noted products.

MEK

As identified in the assessment (ECCC, HC 2026), the critical health effects of MEK identified in laboratory animals were developmental effects and decreased body weight gain.

The calculated MOEs for inhalation exposure to MEK in certain paint or coating removers or strippers (for example, lacquer removers), adhesive removers, degreasers, paint or coating thinners, liquid paints and spray products (for

example, spray paints) were inadequate to account for uncertainties in the health effects and exposure databases based on the exposure scenarios[10] of potential concern included in the assessment (ECCC, HC 2026).

MIBK

The International Agency for Research on Cancer (IARC) considers MIBK to be in group 2B ("possibly carcinogenic to humans"), with "sufficient evidence" of carcinogenicity in laboratory animals (IARC 2013). For non-cancer effects, effects on the liver and kidney as well as developmental effects were observed in laboratory studies (ECCC, HC 2026).

The calculated MOEs for inhalation exposures to MIBK in certain liquid paints, spray products (for example, spray paints), and wood lacquers were inadequate to account for uncertainties in the health effects and exposure databases based on the exposure scenarios[11] of potential concern included in the assessment (ECCC, HC 2026).

6. Risk management considerations

6.1 Alternatives

Several alternatives and alternative technologies to solvent-based paints and coatings are available. These include water-based paints and coatings, plant-based paints, dry coatings and electrostatic coatings. As expected, there are pros and cons to employing these alternatives. Water-based and plant-based paints and coatings may offer lower concentrations of VOCs and reduced toxicity for the consumer. However, they may require the addition of more additives. Furthermore, they may require more preparation for use and longer drying time (TURI 1994). Industry is encouraged to make informed substitution when reducing the concentrations of MEK and MIBK in the consumer products of concern so that they are protective of human health and the environment.

Other VOCs may be used as alternatives to MEK and MIBK; however, existing and proposed Canadian risk management actions may limit the use of VOCs in certain applications. More details on current risk management actions related to VOCs can be found in section 7.1.

[10] Seven-hour time-weighted average (TWA) concentrations were derived for the product scenarios to match up with the exposure durations of the critical effects study used to characterize risk.
[11] Six-hour TWA concentrations were derived for all product scenarios to match up with the exposure durations of the critical effects study used to characterize risk.

6.2 Socio-economic and technical considerations

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objectives, as per the guidance provided in the Treasury Board document Policy on Regulatory Development (TBS 2018b).

In addition, socio-economic factors will be considered in the development of regulations, instrument(s) or tool(s) to address risk management objectives, as identified in the Cabinet Directive on Regulation (TBS 2018a), the Red Tape Reduction Action Plan (TBS 2012), and the *Red Tape Reduction Act* (Canada 2015) as well as in the objectives of the most recent federal Red Tape Review (TBS 2025).

7. Overview of existing risk management

7.1 Related Canadian risk management context

Existing risk management for MEK and MIBK in Canada is summarized below. In general, cosmetics and natural health products are regulated under the *Food and Drugs Act* and its regulations as follows:

Cosmetics: The human health risks of substances in cosmetics are primarily managed under the *Food and Drugs Act* and the *Cosmetic Regulations*. The addition or modification of the entries in the Cosmetic Ingredient Hotlist (Hotlist) inform stakeholders and the public about substances that, according to Health Canada, may contravene section 16 of the *Food and Drugs Act* or may contravene one or more provisions of the *Cosmetic Regulations* when they are present in a cosmetic. Section 16 of the *Food and Drugs Act* states, among other things, that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user."

Natural Health Products: Natural health products are regulated under the *Food and Drugs Act* and the *Natural Health Products Regulations* (NHPR) and undergo pre-market review in accordance with the NHPR. The risks to human health from substances in natural health products are primarily managed under section 7 of the NHPR, which provides for issuance or amendments to a product licence if the licence is not likely to result in injury to the health of a purchaser or consumer. The NHPID provides information on substances used as medicinal and/or non-medicinal ingredients in natural health products. The NHPID entries for substances can be revised to describe limits on the quantity and recommended uses of substances in natural health products to inform the public and stakeholders on potential health concerns. Natural health product applicants may access the information when completing a product licence application. Health Canada may access the information in the NHPID when reviewing a product licence application

which may inform how a product is managed under the provisions of the NHPR, such as section 7.

MEK and MIBK are VOCs and are reportable to the National Pollutant Release Inventory (Canada 2021).

The following are current VOC regulations that are applicable to VOC-containing products but are not specifically applicable to controlling these substances:

- The *VOC Concentration Limits for Architectural Coatings Regulations* for coatings were published in the *Canada Gazette*, Part II on September 30, 2009.

- The *VOC Concentration Limits for Certain Products Regulations* under CEPA were published in the *Canada Gazette*, Part II on January 5, 2022, and apply to Canadian manufacturers and importers. These regulations establish VOC concentration limits for approximately 130 product categories and subcategories. Several of the products of concern for ketones are also captured under these regulations. The regulations set a VOC concentration limit for the total amount of VOCs in a certain product.

MEK is listed as a permitted food additive in natural extractives and in spice extracts as prescribed in Health Canada's List of Permitted Carrier or Extraction Solvents (Canada 2022a). MEK and MIBK may be used as components in the manufacture of food packaging materials in Canada. Packaging materials in which food is sold must comply with safety provisions set out under Division 23 of the *Food and Drug Regulations* (Canada 2024a). MEK and MIBK are noted to be used as food flavouring agents. In Canada, the safety of food flavouring agents is subject to the provisions of section 4(1)(*a*) of the *Food and Drugs Act* (Canada. 2024b).

MEK may also be used as a component in incidental additives (cleaners) used in food processing establishments with no direct food contact. In Canada, incidental additives used in food processing facilities are subject to safety provisions set out under section 4(1)(*a*) of the *Food and Drugs Act* (Canada 2024b).

MEK and MIBK have also been identified to be present as non-medicinal ingredients in a limited number of currently licensed natural health products in Canada. Natural health products are subject to provisions of the NHPR (Canada 2023).

Certain ketones in consumer chemical products, including MEK and MIBK, are regulated by the *Consumer Chemicals and Containers Regulations, 2001* under the *Consumer Product Safety Act* (Canada 2022b). MEK and MIBK are regulated as dangerous goods and are subject to the *Transportation of Dangerous Goods*

Regulations (Canada 2001) and the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (Canada 2015b).

MIBK is a permitted formulant in pest control products regulated under the *Pest Control Products Act* (Canada 2022c).

7.2 Pertinent international risk management context

In the US, MEK and MIBK are subject to reporting requirements under the *Comprehensive Environmental Response, Compensation and Liability Act* and are considered hazardous waste under the *Resource Conservation and Recovery Act*. MIBK is also subject to reporting requirements under section 313 (Toxics Release Inventory) of the *Emergency Planning and Community Right-to-Know Act* (US EPA 2020). Also in the US, there are National VOC Emission Standards for Consumer and Chemical Products where MEK and MIBK are listed as VOCs in certain product categories (e-CFR 2021).

In the US and the European Union (EU), MEK is a permitted solvent used in the preparation of certain food additives (US FDA 2020a; EU 2012b). MEK and MIBK are permitted food flavouring agents in the US and the EU (US FDA 2020b; EU 2012a). In the US, MEK is also permitted as an indirect additive in certain adhesives, coatings and polymers while MIBK is a permitted indirect additive in certain adhesives and polymers (US FDA 2020c, 2020d). Both MEK and MIBK are also permitted in the manufacture of certain food contact materials in the EU (EC 2007).

MEK is listed in the International Council for Harmonization (ICH)'s Guideline for Residual Solvents (Q3C(R8)) as a Class 3 solvent, which is a solvent with low toxic potential, and should be limited by good manufacturing practices or other quality-based requirements. It is considered acceptable without justification at amounts of no more than 50 mg/day (corresponding to 5 000 ppm or 0.5 % when assuming a product mass of 10 g administered daily) (ECCC, HC 2026). MIBK is listed in the ICH's harmonized guideline as a Class 2 solvent, which is a solvent that should be limited, further associated with a permitted daily exposure of up to 45 mg/day (corresponding to 4 500 ppm or 0.45 % when assuming a product mass of 10 g administered daily) (ECCC, HC 2026).

Similar to Canada, MEK and MIBK are subject to various international transportation regulations.

8. Next steps

8.1 Public comment period

Industry and other interested stakeholders are invited to submit comments on the content of this document or other information that would help to inform decision-

making (such as outlined in section 3.2). Please submit additional information and comments prior to July 15, 2026.

Comments and information submissions on the Risk Management Approach should be submitted to the address provided below:

Substances Management Information Line
Chemicals Management Plan
Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-3231
Email: substances@ec.gc.ca

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

Stakeholders and members of the public who are interested in being notified of CMP publications are invited to subscribe for the latest news on the CMP. Stakeholders and members of the public who would like to receive CMP Publication Plans on a quarterly basis by email can contact: substances@ec.gc.ca.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instruments, where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instruments. Consultation will also take place as instruments are developed.

When the first regulation or instrument respecting preventative or control actions is published, a statement outlining the estimated timeframe for the development of subsequent proposed regulations or instruments will be made available.

8.2 Timing of actions

Electronic consultation on the Risk Management Approach: May 16, 2026 to July 15, 2026.

Publication of responses to public comments on the Risk Management Approach document: Concurrent to the publication of the proposed instrument.

Publication of the proposed instrument: At the latest, 24 months from the date on which the Ministers recommended that MEK and MIBK be added to Schedule 1 of CEPA.

Consultation on the proposed instrument: 60-day public comment period starting upon publication of the proposed instrument.

Publication of the final instrument: At the latest, 18 months from the publication of the proposed instrument.

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