



Addendum to the Risk Management Scope

for

Furan Compounds - Furfuryl alcohol and tetrahydrofuran in outdoor air

**Chemical Abstracts Service Registry Number
(CAS RN):**

**98-00-0
and
109-99-9**

Environment and Climate Change Canada

Health Canada

January 26, 2023

Summary of proposed risk management

This document outlines additional proposed risk management options for furfuryl alcohol and tetrahydrofuran under consideration to address risks outlined in the *Additional Risk Characterization Document in Support of the Draft Screening Assessment for Furan Compounds Group*. In particular, the Government of Canada is considering measures to reduce exposure of communities living in the vicinity of facilities in sectors of concern, that release furfuryl alcohol or tetrahydrofuran to air. These could include Pollution Prevention (P2) plans, voluntary actions by industry via mechanisms such as Memoranda of Understanding (MOUs), Environmental Performance Agreements (EPAs), or codes of practice, or regulatory actions under the Canadian Environmental Protection Act 1999 (CEPA).

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

Please note that the [Risk Management Scope for Furan Compounds](#) published in 2018 describes risk management options under consideration to address risks identified in the Draft Screening Assessment for Furan Compounds Group. Those risk management options remain under consideration; however, they will not be discussed in this document.

Moreover, because certain data gaps remain, facilities involved in the manufacture, import, use, and sale or offer for sale of these substances are invited to provide information which might further assist in the determination of risk management measures. Such information could include processing details, sources of releases, control technologies, alternatives, and monitoring data. This should be provided on or before 05-17-2023 to the contact details identified in section 6.1 of this document.

Note: The above summary is an abridged list of actions proposed to manage this substance. Refer to section 2 of this document for more complete details in this regard. It should be noted that the proposed risk management actions may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

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

The substance 2-furanmethanol, Chemical Abstracts Service Registry Number (CAS RN)³ 98-00-0, and furan, tetrahydro- (CAS RN) 109-99-9, hereinafter referred to throughout this document as furfuryl alcohol and tetrahydrofuran, respectively, as part of the screening assessment of the Furan Compounds Group, are included in the assessment of furan compounds, as part of the Chemicals Management Plan (Canada 2019).

2. Issue

2.1 Furfuryl alcohol and tetrahydrofuran outdoor air exposure and risk characterization

A draft [screening assessment for the Furan Compounds Group](#) was published on September 1, 2018. The *Additional Risk Characterization Document in Support of the Draft Screening Assessment for Furan Compounds Group* contains additional information to supplement the screening assessment for furfuryl alcohol and tetrahydrofuran, two of the four substances in the Furan Compounds Group. This includes data identified or generated since the publication of the draft screening assessment. Note that the proposed conclusion that furfuryl alcohol and tetrahydrofuran meet the criteria for toxicity to human health under paragraph 64(c) of CEPA, remains unchanged.

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, and products available to 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 does not preclude actions being taken under other sections of CEPA or other Acts.

³ CAS RN: Chemical Abstracts Service Registry Number. 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.

The scope of this addendum to the risk management scope is limited to addressing potential acute and chronic human health concerns from releases of furfuryl alcohol and tetrahydrofuran into air from certain facilities. In sectors of concern. For furfuryl alcohol, these are foundries and non-metallic product manufacturing facilities, and for tetrahydrofuran, they are facilities in the textile and fabric finishing and fabric coating sector. Since the publication of the draft screening assessment report, recent releases into air reported by certain facilities to the National Pollutant Release Inventory (NPRI) are more than double the releases reported for 2015 and 2016. As such, a thorough investigation of the NPRI data was undertaken, including use of Google maps to identify facilities located close to residences, and subsequently develop additional exposure scenarios for individuals living near facilities reporting releases of furfuryl alcohol or tetrahydrofuran. The results show potential human health concerns in addition to those identified in the draft screening assessment. Accordingly, on the basis of information presented in the Risk Characterization Document, the release of furfuryl alcohol and tetrahydrofuran into air by facilities found in certain sectors may be harmful to human health.

2.1.1 Identified risks from exposure sources

Specifically, the margins between estimated acute and chronic inhalation exposure to furfuryl alcohol in ambient air near certain foundries, particularly those using resin sand casting, and the critical cancer and non-cancer effect levels (acute and chronic), were considered inadequate to account for uncertainties in the health effects and exposure datasets used to characterize risk. In addition, the margins between estimated chronic inhalation exposure to furfuryl alcohol in the vicinity of a non-metallic mineral product manufacturing facility and critical non-cancer effects were also considered to be inadequate, and therefore of potential health concern. These results are summarized in Table 1.

Table 1. Summary of facilities releasing furfuryl alcohol into air near residential areas at levels that result in potential human health concerns

Exposure scenario	Critical effect	Sectors with inadequate MOEs
Chronic exposure	Cancer (nasal tumours)	Foundries
Chronic exposure	Non-cancer chronic effects (nasal tissue lesions)	Foundries Non-metallic mineral product manufacturing
Acute exposure	Non-cancer acute (decreased breathing)	Foundries

	rate and decreased body weight gain)	
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Therefore, the margins between the critical cancer and non-cancer (acute and chronic) inhalation effect levels and inhalation exposures to furfuryl alcohol for Canadians living near certain facilities, from foundries and non-metallic product manufacturing facilities releasing this substance to air, are considered inadequate to protect human health.

For tetrahydrofuran, a comparison of the critical non-cancer inhalation effect levels with estimated acute and chronic levels of exposure to this substance for Canadians living near certain facilities releasing tetrahydrofuran results in margins of exposure that are considered adequate for the protection of human health. However, the margins between chronic inhalation exposure to tetrahydrofuran for Canadians living near fabric coating facilities, and the critical cancer inhalation effect level, are considered inadequate to protect human health. These results are summarized in Table 2.

Table 2. Summary of facilities releasing tetrahydrofuran into air near residential areas at levels that result in potential human health concerns

Exposure Scenario	Critical effect	Sectors with inadequate MOEs
Chronic exposure	Cancer (liver adenoma/carcinoma)	Fabric coating facilities

Therefore, the release of furfuryl alcohol or tetrahydrofuran into air by certain facilities may be harmful to human health.

2.2 Recommendation under CEPA

On the basis of the findings of the draft screening assessment conducted pursuant to CEPA and the Risk Characterization Document supplementing the draft screening assessment, the ministers propose to recommend that furfuryl alcohol and tetrahydrofuran be added to the List of Toxic Substances in Schedule 1 of the Act⁴ as per section 77(2) of CEPA. According to section 91 of CEPA, a proposed regulation or instrument establishing “preventative control actions” must be published in the *Canada Gazette*, Part I within 24 months of the recommendation to add the substance to Schedule I. Once proposed, the ministers have a further 18 months to finalize the regulation or instrument

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.

(Environment Canada, 2004). If needed, additional regulations or instruments can be developed within that period or afterwards.

2.3 Public comment period on the Additional Risk Characterization and the Addendum to Risk Management Scope

The Draft Screening Assessment for the Furan Compounds Group and its associated Risk Management Scope document summarizing the proposed risk management options under consideration at that time were published on September 1, 2018 (Canada 2018). Since that time, new information became available which led to the preparation of the Additional Risk Characterization Document in Support of the Draft Screening Assessment.

Industry and other interested stakeholders are invited to submit additional comments on the *Additional Risk Characterization Document in Support of the Draft Screening Assessment for Furan Compounds Group* and the *Addendum to the Risk Management Scope* documents during a 60-day comment period. Comments received on these documents will be taken into consideration in the development of the final screening assessment of furfuryl alcohol and tetrahydrofuran, as well as the *Risk Management Approach* document.

3. Proposed risk management

3.1 Proposed human health objectives

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

The proposed human health objectives for furfuryl alcohol and for tetrahydrofuran is to reduce exposure of the general population to these substances to levels that are protective of human health.

3.2 Proposed risk management objectives

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 objectives for furfuryl alcohol and tetrahydrofuran for the protection of human health are to reduce inhalation exposures of people living in the vicinity of facilities releasing these substances to levels that are protective of human health.

3.3 Proposed risk management actions under consideration

The Government of Canada will consider measures to reduce levels of exposure to furfuryl alcohol or tetrahydrofuran in air in communities near facilities in sectors of concern. These could include P2 plans, voluntary actions for these facilities, such as MOUs, EPAs, or codes of practice, or regulatory actions under CEPA.

3.4 Risk management information gaps

In order to make informed decisions on proposed risk management, we are asking for specific information related to furfuryl alcohol and tetrahydrofuran. If your company undertakes an activity listed below, Environment and Climate Change Canada invites you to submit the information identified below within the timelines identified in section 6. The information requested includes, but is not limited to, facilities that release furfuryl alcohol and tetrahydrofuran where the margins between estimated acute and chronic inhalation exposure were considered inadequate for the protection of human health.

Activity	Information needs
<p>Manufacture, import, use, and sale or offer for sale of <u>furfuryl alcohol</u> for use in applications including:</p> <ul style="list-style-type: none"> • Ferrous metal foundries and non-ferrous metal foundries • Production of furan resins • Production of phenolic resins using furfuryl alcohol • Abrasives Manufacturing • Petroleum and Petroleum products Merchants and Wholesalers • Coating, engraving, cold and heat treatment activities • Other unidentified uses <p>Manufacture, import, use, and sale or offer for sale of <u>tetrahydrofuran</u> for use in applications including:</p> <ul style="list-style-type: none"> • Fabric coating • Petrochemical manufacturing 	<ul style="list-style-type: none"> • Description of the specific use of furfuryl alcohol or tetrahydrofuran products containing these substances in your activity, including their quantity and concentration • Primary sources of emission from the use of resin-based binders in ferrous metal foundries and non-ferrous metal foundries • Existing or available measures to reduce emissions of the substances • Known alternatives to furfuryl alcohol and tetrahydrofuran or products containing these substances • Cost and efficiency or suitability of alternatives • Available air monitoring data, i.e., fence line or other for both furfuryl alcohol and tetrahydrofuran • Suppliers of FA or THF or mixtures containing them. This

<ul style="list-style-type: none"> • Petroleum and petroleum products • Plastic film and sheet manufacturing • Mined oil sands extraction • Pharmaceutical manufacturing • Iron and steel mills and ferro-alloy manufacturing • Adhesive manufacturing • Automobile and light-duty motor vehicle manufacturing • Miscellaneous chemical product manufacturing 	<p>could include Information from safety data sheets containing supplier information.</p> <ul style="list-style-type: none"> • Available information on the manufacturing activity processes that lead to releases of FA or THF.
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Should stakeholders have further information to help address these gaps, they should provide it ideally on or before 05-17-2023. This will inform the risk assessment and management decision-making, and validate information for outdoor exposures and identified risks from exposure sources within the timelines (and to the contact) identified in section 5 of this document.

4. Exposure source and identified risk

Levels of furfuryl alcohol in ambient air attributable to on-site releases to air from facilities from various sectors releasing furfuryl alcohol as reported to the NPRI were estimated in order to determine chronic inhalation exposure for residents near these facilities. Annual levels were predicted to be between 0.006 mg/m³ and 0.695 mg/m³ for foundries. For these facilities, comparison of chronic inhalation exposure with chronic cancer and non-cancer inhalation effects in rodents resulted in margins of exposure as low as 2, which is considered to be inadequate for the protection of human health. In addition, for facilities specifically involving non-metallic mineral product manufacturing, annual levels were predicted to be 0.013 mg/m³. For these facilities, comparison of chronic inhalation exposures with that associated with the critical cancer effects and chronic non-cancer effects resulted in margins as low as 108, also considered to be inadequate.

In addition, Canadians may be exposed to higher concentrations of furfuryl alcohol emitted from facilities for short periods. These emissions may have effects on Canadians residing nearby; therefore, acute inhalation of ambient air was also considered. For foundries, a comparison of the estimated 1-hour maximum air concentration released from facilities located near residences, with the acute inhalation effect level in rodents, results in margins as low as 147, which is also considered inadequate.

Therefore, the release of furfuryl alcohol into air by certain facilities may be harmful to human health (Canada 2022).

Similarly, levels of tetrahydrofuran in ambient air attributable to on-site releases to air from various facilities releasing tetrahydrofuran, as reported from NPRI, were estimated in order to determine chronic inhalation exposure for residents near these facilities. Annual levels were projected to range from 0.014 mg/m³ to 0.121 mg/m³. For fabric coating and petrochemical manufacturing facilities releasing this substance, a comparison of the critical non-cancer (acute and chronic) inhalation effect levels with acute and chronic levels of exposure to tetrahydrofuran for Canadians living near these facilities results in margins of exposure that are considered adequate to account for the protection of human health. However, for fabric coating facilities releasing tetrahydrofuran, a comparison of chronic inhalation exposure of nearby residents with that associated with cancer effects in rodents, specifically liver adenoma or carcinoma, resulted in margins of exposure as low as 289. This margin of exposure is considered to be inadequate for the protection of human health. Therefore, the release of tetrahydrofuran into air by certain facilities may be harmful to human health (Canada 2022).

5. Risk management considerations

5.1 Socio-economic and technical considerations

Socio-economic factors will be considered in the selection of regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s) as per the guidance provided in the Treasury Board document [Assessing, Selecting, and Implementing Instruments for Government Action](#) (TBS 2007). In addition, socio-economic factors will be considered in the development of regulation(s), instrument(s) and/or tool(s) as to address risk management objective(s) as identified in the [Cabinet Directive on Regulation](#) (TBS 2018), [Red Tape Reduction Action Plan](#) (TBS 2012) and the [Red Tape Reduction Act](#) (Canada 2015).

Specific to furfuryl alcohol or tetrahydrofuran released from facilities, the Government will take into account best available technology for control of releases, economic aspects and implementation timelines in the determination of management measures.

6. Next steps

6.1 Public comment period

Industry and other stakeholders are invited to submit comments on the Addendum to the Risk Management Scope for Furan Compounds document or

other information that would help to inform decision-making. Please submit additional information and comments prior to 05-17-2023. 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, if required. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Additional Risk Characterization Document and the Addendum to the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada
 Chemicals Management Division
 Gatineau, Québec K1A 0H3
 Tel: 1-800-567-1999 | 819-938-3232
 Fax: 819-938-5212
 Email: substances@ec.gc.ca

6.2 Timing of actions

Action	Date
Submission of additional studies or information on furfuryl alcohol and tetrahydrofuran	On or before 05-17-2023
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 publication if required, of the proposed instrument(s)	At the latest, 24-months from the publication of the final Screening Assessment Report
Consultation on the proposed instrument(s), if required	60-day public comment period starting upon publication of each proposed instrument
Publication of the final instrument(s), if required	At the latest, 18 months from the publication of each proposed instrument

7. References

Canada. 1999. [Canadian Environmental Protection Act, 1999](#). S.C. 1999, c.33. Canada Gazette Part III, vol. 22, no. 3.

Canada. 2015. [Red Tape Reduction Act](#).

Canada. 2018. Dept. of the Environment, Dept. of Health. [Risk Management Scope for Furan Compounds](#).

Canada. 2019. Dept. of the Environment, Dept. of Health. [List of substances in the third phase of CMP \(2016-2021\): July 2019 update](#).

Canada. 2021. Dept. of the Environment, Dept. of Health. [Additional Risk Characterization Document in Support of the Draft Screening Assessment for Furan Compounds Group](#).

[TBS] Treasury Board of Canada Secretariat. 2007. [Assessing, Selecting, and Implementing Instruments for Government Action](#).

[TBS] Treasury Board of Canada Secretariat. 2012. [Red Tape Reduction Action Plan](#).

[TBS] Treasury Board of Canada Secretariat. 2018. [Cabinet Directive on Regulation](#). Ottawa (ON): Government of Canada.