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**Risk Management Approach
for**

**Crude tall oil (CTO)
in the Resins and Rosins Group**

**Chemical Abstracts Service Registry Number
(CAS RN):
8002-26-4**

Environment and Climate Change Canada

Health Canada

July 2022

Summary of Proposed Risk Management

This document outlines the proposed risk management action for crude tall oil (CTO), which has been found to be harmful to the environment.

Under the *Domestic Substances List*, tall oil (CAS RN 8002-26-4) covers both CTO and distilled tall oil (DTO). Exposure scenarios for the co-production of CTO indicate that there is a potential risk to aquatic organisms. However, DTO was not identified as posing risks at levels of exposure considered in the assessment. As such, the proposed risk management measure focuses on potential releases of CTO from its incidental co-production in the kraft pulping process. More information on the [screening assessment](#) is available.

In particular, the Government of Canada is proposing to include CTO in amendments to the *Pulp and Paper Effluent Regulations* under the *Fisheries Act*.

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 substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of actions proposed to manage this substance. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management action 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 harmful to human health as set out in section 64 of CEPA^{1,2}, and if so to manage the associated risks.

Crude tall oil, Chemical Abstracts Service Registry Number (CAS RN³) 8002-26-4, referred to throughout this document as CTO, is included in the third phase of the Chemicals Management Plan (CMP) as part of the Resins and Rosins Group (Canada 2016).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of CTO in Canada. A notice summarizing the scientific considerations of the screening assessment for this substance was published in the *Canada Gazette*, Part I, on July 23, 2022 (Canada 2022). For further information, refer to the [screening assessment for the Resins and Rosins Group](#).

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 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.

2.1 Screening Assessment Conclusion

Tall oil (CAS RN 8002-26-4) includes both CTO and distilled tall oil (DTO), and both are unknown or variable composition, complex reaction products, or biological materials (UVCBs). In 1994, CAS RN 8002-26-4 was added to the *Domestic Substances List* (DSL) with the DSL name “tall oil”. This substance as nominated to the DSL may refer to both CTO and DTO. As a result, where possible, distinction between these two substances is made in the assessment. However, given that this distinction was not made during the original DSL nomination and CTO and DTO share a common CAS RN, instances may remain where it is not possible to accurately distinguish between CTO and DTO.

Exposure scenarios for the co-production of CTO indicate that there is a risk to aquatic organisms (ECCC, HC 2022). On the basis of the information available, the screening assessment concludes that tall oil (CAS RN 8002-26-4), specifically due to CTO, is toxic under section 64 of CEPA because it is 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 (Canada 2022). More specifically, CTO was found to be a risk to the environment based on co-production and associated activities. As such, proposed risk management described in this document focuses on CTO co-production.

Considering there may be a concern to the environment if exposure to DTO were to increase, follow-up activities to track changes in exposure or commercial use patterns are under consideration.

Most components of CTO are moderately persistent in water, and are expected to be moderately to highly persistent in sediments. CTO representative components show low to moderate bioconcentration overall, while certain CTO components are predicted to have a high bioaccumulation potential. However, components of CTO also occur naturally from plants; and thus, near continuous background exposure is likely present in many aquatic environments (ECCC, HC 2022). For more information on persistence and bioaccumulation potential for CTO components, please refer to the [screening assessment for the Resins and Rosins Group](#).

2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment conducted as per CEPA, the ministers recommend that CTO be added to the *List of Toxic Substances* in Schedule 1 of the Act⁴.

The ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for resins and rosins and the associated Risk Management Scope document for Crude Tall Oil.

As the ministers finalize the recommendation to add CTO to Schedule 1 of CEPA, a risk management instrument must be proposed within 24 months from the date on which the recommendation is made, and finalized within 18 months from the date on which the risk management instrument is proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

2.3 Public Comment Period on the Draft Screening Assessment and the Risk Management Scope

The draft screening assessment for the Resins and Rosins Group (ECCC, HC, 2019a) and the associated Risk Management Scope document for Crude Tall Oil (ECCC, HC, 2019b) summarizing the proposed risk management options under consideration at that time, were published on June 22, 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 and the Risk Management Scope document were taken into consideration in the development of this document. A [summary of responses to public comments received](#) is available.

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 substances, add the substance to the *Priority Substances List* for further assessment, or recommend the addition of the substance to the *List of Toxic Substances* in Schedule 1 of the Act.

3. Proposed Risk Management

3.1 Proposed Environmental Objective

Proposed environmental objectives are quantitative or qualitative goals to address environmental concerns.

For this substance, the proposed environmental objective addresses the exposure source of concern outlined in section 5 of this document. The proposed environmental objective for CTO is to prevent or minimize adverse effects from anthropogenic releases of CTO on the aquatic environment. The predicted no-effect concentration (PNEC) based on representative chemicals of CTO in surface water may be used as a goal to achieve this objective.

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, instruments and/or tools for a given substance or substances. In this case, the proposed risk management objective for CTO is to limit its release in the final effluent of pulp and paper facilities to concentrations that are protective of the aquatic environment, taking into account technical and economic feasibility, consideration of socio-economic factors, and natural background concentrations.

These objectives will be refined on the basis of stakeholder consultation and new information, the proposed risk management, and socio-economic and technical considerations (refer to section 6).

3.3 Proposed Risk Management Action

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management action being considered for CTO is to include the substance in a planned amendment to the *Pulp and Paper Effluent Regulations* (PPER) under the *Fisheries Act*.

Currently, the PPER sets regulatory limits on mill effluent suspended solids (SS), biochemical oxygen demand (BOD), and acute lethality. To further improve environmental protection, the modernization of the PPER proposes to lower effluent limits for parameters currently subject to the PPER, add effluent limits for chemical oxygen demand (COD), nitrogen, phosphorus, temperature, and pH, as well as include mandatory water quality monitoring and effluent characterization requirements. It is also proposed to add certain resin acids and fatty acids, among other components of CTO, to the list of required chemicals to be measured through water quality monitoring and effluent characterization for all Canadian kraft mills. The lowering of current regulated parameters along with the addition of the

proposed COD limit would help to reduce the level of CTO components in mill effluent, as this parameter captures more mill effluent constituents, particularly organic compounds, when compared to BOD alone. Imposing a limit on COD would encourage mills to better control their processes, which would contribute to achieving the risk management objective. Information received through mill effluent monitoring activities will be considered to determine if additional risk management actions for CTO components would be needed in the future.

In addition, all Canadian mills currently subject to the PPER are required to perform Environmental Effects Monitoring (EEM) studies. These mandatory studies require mills to identify effects on receiving environments of mill effluent, as well as causes and solutions of/to these effects. To improve the efficacy and efficiency of EEM requirements, it is proposed under the modernization of the PPER to reduce the time spent by regulatees on investigation studies and require the implementation of solutions identified in EEM studies. Following the implementation of the PPER amendments, if EEM studies indicate any effect on the receiving environment attributed to the release of CTO, mills would be required to identify this effect, identify possible solutions, and implement a solution.

Note that the proposed risk management action is preliminary and subject to change. 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 development process⁵. The risk management action 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.

3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances⁶. 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. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time. To achieve

⁵ The proposed risk management regulation, instrument or tool is 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 2018), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015a).

⁶ Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (i.e., evaluate whether risk management objectives have been met); and
- Performance measurement evaluation 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 (i.e., evaluate whether human health and/or environmental objectives have been met).

this, the Government of Canada plans to review the effectiveness of the risk management action for CTO.

The Government of Canada plans to measure the effectiveness of the risk management action by collecting and analyzing data such as the percentage of regulatory tests meeting regulatory acute lethality requirements, data from environmental effects monitoring from pulp and paper mills, and measured concentrations of components of CTO in kraft mill effluent to measure progress towards meeting the risk management objective.

In addition, the Government of Canada may collect and analyze data on the presence of the substance in surface water periodically, in order to establish a baseline environmental presence and to measure progress towards meeting the environmental objective.

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

4. Background

4.1 General Information on tall oil and CTO

Tall oil is a generic term which refers to a resinous liquid obtained as a co-product in the manufacture of chemical wood pulp using the kraft pulping process. Under the DSL, tall oil (CAS RN 8002-26-4) covers both CTO and DTO. CTO and DTO are considered to be UVCBs (ECCC, HC, 2022).

CTO is a dark oily liquid with 26-42% resin acids (represented by abietic acid, isopimaric acid, and dehydroabietic acid), 36-48% fatty acids (e.g., linoleic acid), and 10-38% neutral compounds (represented by β -sitosterol, abietinol, and abietinal) (Huibers 2000). Variability in composition may be due to both the pulpwood variability (e.g., tree species used) and the process/operational conditions. Canadian CTO typically contains a higher amount of neutral compounds compared to that from the United States (U.S.) (ECCC, HC, 2022).

4.2 Current Use and Identified Sector

According to information submitted in response to a CEPA section 71 survey in 2012 (Canada 2012, EC 2013) and subsequent voluntary surveys in 2016 and 2017 (ECCC 2016a, 2016b, 2017), It was reported that 10,000,000 – 100,000,000 kg of CTO was incidentally co-produced in Canada and that 10,000 – 100,000 kg of CTO was imported into Canada. The export of CTO is not known to occur in Canada.

As mentioned in section 4.1, CTO is a co-product of kraft pulping of coniferous wood. CTO may serve as a source material for several downstream products manufactured through fractional distillation of CTO. CTO refining is not known to occur currently in Canada; however, the downstream products of CTO are imported into Canada. Based on information received during stakeholder engagement, some facilities sell the resulting CTO while others burn it onsite for fuel (ECCC, HC 2022).

In addition, CTO that is imported into Canada may have various commercial and industrial applications, and may be used as raw material for oil and gas drilling applications (ECCC, HC 2022).

5. Exposure Source and Identified Risk

The major sources of release for CTO to the environment are related to co-production and industrial uses in Canada. Potential releases of concern occur primarily to surface water.

Exposure scenarios were developed for the co-production and industrial use of CTO. Risk quotient analyses were conducted to compare estimated aquatic concentrations of the components of the UVCBs in aquatic organism for different exposure scenarios.

Based on the analysis of sources and use information along with relevant monitoring data, CTO is anticipated to be released to water from the CTO co-production process at kraft pulping manufacturing facilities in Canada. Releases of concern from this source may occur primarily to surface water where certain components may transfer to sediments via partition from overlying water (ECCC, HC 2022).

Exposure scenarios for the industrial uses of CTO did not indicate that there is a risk to aquatic organisms.

Components of CTO could have non-specific (i.e. narcotic) or compound-specific effects on benthic and aquatic organisms at low concentrations of exposure.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

No alternative technologies were identified for CTO co-production from tall oil soap (acidulation process) at kraft pulping facilities.

As CTO is a co-product that is formed during the kraft pulping process, consideration of alternatives is not relevant.

6.2 Socio-economic and Technical Considerations

At the time of this document's publication, there are 90 active and idled pulp and paper mills. Twenty-eight of these mills are kraft mills with the potential to produce CTO. Of the 28 kraft mills, five plants are confirmed producers of CTO in Canada (ECCC 2019). Kraft mills are distributed throughout the country.

Canada is the third largest producer of wood pulp (9.5% of global production) and the eighth largest producer of printing and writing paper (3.0% of global production) (Natural Resources Canada 2019). In 2018, Canadian chemical mills produced a total of approximately 18.5 million tonnes of pulp, and exported 14.8 million tonnes of chemically produced pulp for a total export value of US\$ 11.4 billion. In addition, Canada imported 675,000 tonnes of chemically produced pulp, for a total import value of US \$5 million in 2018 (FAO 2019).

Pulp and paper mills routinely follow best practices, such as the Forest Products Association of Canada Best Management Practices Guide for Nutrient Management in Effluent Treatment (FPAC 2008).

Socio-economic factors have been considered in the selection process for a regulation respecting preventive or control actions, and in the development of the risk management objective 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 the regulations to address the risk management objective, as identified in the [Cabinet Directive on Regulation](#) (TBS 2018), [Red Tape Reduction Action Plan](#) (TBS 2012) and the [Red Tape Reduction Act](#) (Canada 2015a).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

As described in section 3.3, pulp and paper mills are subject to the PPER under the *Fisheries Act*, which does not currently address releases of CTO specifically.

The pulp and paper sector is subject to other risk management actions that are not specific to CTO. Further information on these actions is available from the [Management of Toxic Substances: Pulp and Paper Sector](#) webpage (Canada 2015b).

7.2 Pertinent International Risk Management Context

7.2.1 United States

In the U.S., tall oil has active commercial status under the *Toxic Substances Control Act* Inventory. In addition, tall oil is also listed on the U.S. High Production Volume Challenge Program List and under the High Production Volume / Voluntary Children Chemical Evaluation Program Information (US EPA 2019a). Furthermore, tall oil is listed under the *Federal Insecticide, Fungicide, and Rodenticide Act* as an inert ingredient authorized for food and non-food uses (US EPA 2019b).

Pulp and paper mills are subject to the Pulp, Paper, and Paperboard Effluent Guidelines (40CFR430). These guidelines, which are incorporated into mill permits or other control mechanisms, are not specific to CTO. Instead, they establish release limits for BOD, total suspended solids (TSS), pH, and other chemical pollutants of concern (US EPA 2018). Furthermore, bleached kraft mills are subject to best management practices to control leaks and spills and to control intentional diversion of spent pulping liquor, tall oil soap (the precursor to CTO) and turpentine (US eCFR 2020).

7.2.2 European Union

Tall oil is registered under the European Union (EU)'s Registration, Evaluation, and Authorization of Chemicals (ECHA 2020).

Pulp and paper mills in the EU are required to implement best available technologies (BAT) as per the BAT conclusions established in EU/2014/687 (EU 2014). Specific technologies included in the conclusions are not prescriptive, but there is a requirement for pulp and paper mills to implement technologies that have equivalent or better environmental protection. These conclusions include techniques to reduce pollutants in wastewater effluent, including the accidental release of tall oil and turpentine.

7.2.3 Risk Management Alignment

As described earlier, Canada, the U.S. and the EU have all implemented risk management for pulp and paper mills; however controls in the U.S. and EU do not specifically address releases of CTO to pulp and paper effluents from its co-production. Canada would be the first to implement risk management requirements that are specific to CTO.

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 Approach or other information that would help to inform decision-making (such as outlined in section 3.5). Please submit additional information and comments prior to September 21, 2022.

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

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

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

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument, where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the development of this instrument. Consultations with implicated stakeholders take place as the instrument is developed.

8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: July 23, 2022 to September 21, 2022.

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 CTO 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.

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

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