

Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report on Naphthalene (CAS RN 91-20-3)

Comments on the draft screening assessment report on naphthalene, a substance included in Batch 1 of substances to be addressed as part of the Chemicals Management Plan Challenge under the *Canadian Environmental Protection Act 1999* (CEPA 1999), were provided by the Canadian Petroleum Products Institute, NOVA Chemicals Corporation, Canadian Consumer Specialty Products Association, the Naphthalene Council, Inc., Nalco Canada Company, Recochem Inc., BASF Canada, Dow Chemical Canada Inc., and the Canadian Environmental Law Association during the 60 day public comment period that took place from January 19, 2008 to March 19, 2008. A summary of the comments that relate specifically to the draft assessment on naphthalene, along with responses, is presented in the table below. Comments related to subsequent risk management of the substance are addressed separately.

Comment	Response
<p>The opinion was expressed by several commenters that the data on naphthalene do not support a non-threshold mode of action for tumourgenicity (e.g. genotoxicity studies, histology results, lack of tumours in metabolic tissues).</p>	<p>Health Canada recognizes that there is a potential linkage between non-cancer effects and the observed cancer effects; however, this potential linkage has not been fully elucidated.</p> <p>In the absence of a fully elucidated mode of action it cannot be precluded that tumours observed in experimental animals resulted from direct interaction with genetic material.</p>
<p>The opinion was expressed by commenters that the representation of the genotoxicity results was not consistent with the conclusions of other international or national assessments (International Agency for Research on Cancer (IARC), the European Union (EU)).</p> <p>Also, commentators expressed the opinion that the genotoxicity results and how they were used to support the conclusion of the draft screening assessment report were not discussed.</p>	<p>It is recognized that other international assessments indicate that naphthalene is not likely to be genotoxic. In the context of a Challenge screening assessment, in the absence of a fully elucidated mode of action analysis it cannot be precluded that tumours observed in experimental animals resulted from direct interaction with genetic material.</p>
<p>The opinion was expressed that tumours observed in experimental animals due to naphthalene exposure were not believed to be relevant to humans.</p>	<p>In the absence of a fully elucidated mode of action analysis, it cannot be precluded that tumours observed in experimental animals are relevant to humans.</p>
<p>The opinion was expressed by multiple commenters that further research is required on naphthalene genotoxicity, tumourgenicity and human relevance. A research program focussing on the mode of action of tumorigenicity, currently in progress until 2011 was mentioned as well.</p>	<p>It is recognized that there is uncertainty in these areas of the dataset.</p>

<p>The opinion was expressed that the draft screening assessment report did not mention excessive doses used in mouse and rat bioassays as uncertainties.</p>	<p>This uncertainty will be noted in the screening assessment. The publications critiquing these bioassays were published after the cut-off date for inclusion of literature.</p>
<p>The opinion was expressed by commenters that a worst-case approach was taken for the exposure evaluation in the draft screening assessment report</p>	<p>Reasonable upper bound intakes and not worst case scenarios were calculated in the screening assessment (i.e. non-smoking homes were considered in studies; simulated indoor air studies with homes containing mothballs were not used to estimate intake).</p>
<p>The opinion was expressed that the draft screening assessment report relies on data that are not publicly available; that the description of uses is incomplete and presents inaccurate naphthalene source information; and that the assessment report fails to identify specific sources of concern with regard to naphthalene.</p> <p>Another commenter believed that the uses of naphthalene need to be clarified in the draft screening assessment report, especially to make the distinction between petroleum stream uses and products such as moth repellents.</p>	<p>The presentation of the uses in the challenge screening report has been modified to enhance clarity.</p>
<p>A commentator requested that the internal reports (Ottawa and Windsor indoor air surveys) be made publicly available.</p>	<p>The Ottawa indoor air survey (Zhu et al. 2005) is publicly available. Information pertaining to naphthalene from the Windsor study (Health Canada 2008) is available on request and the study will be published by Health Canada when finalized.</p> <p>Zhu J, Newhook R, Marro L, Chan CC. 2005. Selected volatile organic compounds in residential air in the City of Ottawa, Canada. Environ Sci Technol 39:3964-3971.</p> <p>Health Canada 2008. Windsor Ontario Exposure Assessment Study 2005, 2006: VOC Sampling Data Summary (Draft). Fuels and Exposure Assessment Section, Air Health Sciences Division.</p>

<p>A concern was raised by a commenter regarding the statistical relevance of the indoor air result (144.44 µg/m³) used in the draft screening assessment report.</p>	<p>The maximum indoor air value from the study conducted in Windsor, Canada (158.050 µg/m³) was used in the final version of the assessment report. This number was significantly higher than the mean or 90th percentile values from this study. However, this value was not considered an outlier. Additionally, this value was measured in a non-smoking home, and higher values may be expected in smoking homes as cigarette smoking is an additional source of naphthalene. It was considered that this represented a reasonable upper bounding estimate of exposure for the general population.</p>
<p>A commenter expressed the opinion that further review and analysis is required on the attached garage study described in the draft screening assessment report.</p>	<p>It is recognized that further research identifying specific sources contributing to naphthalene in indoor air maybe required.</p> <p>This study was not used to quantify upper-bounding estimates of exposure.</p>
<p>A commenter remarked that the estimates of general exposure in environmental media and indoor air were more conservative compared with those of other agencies, specifically the Agency for Toxic Substances and Disease Registry (ATSDR).</p>	<p>The challenge screening assessments use most current Canadian data, where available, to quantify upper bounding estimates of intake.</p>
<p>Commenter expresses opinion that further evaluation of risk can be conducted on the evaluation (probabilistic risk assessment, derivation of daily intake or practical exposure limit)</p>	<p>Although beyond the scope of a Challenge screening assessment, further characterization of risk, along with other factors, could be used to inform risk management of this substance, as appropriate.</p>

<p>A commenter expressed the opinion that the draft screening assessment report hazard portrayal is misleading (possibility of harm at any level while deriving Margin of Exposure).</p>	<p>Both cancer and non-cancer effects were considered when characterizing the risk to human health of naphthalene. For non-cancer effects, when the uncertainties of both the exposure and hazard databases are taken into consideration, the margin of exposure (derived from the lowest inhalation effect value and the upper-bounding indoor air measurement in the screening assessment) is considered to be potentially inadequate for the protection of human health. With regard to cancer, which was one of the critical effects of this screening assessment of naphthalene, it is considered that there is a probability of harm at any level of exposure as the mode of action for the induction of tumours has not been fully elucidated. The potential inadequacy of the margin of exposure, in addition to the cancer conclusion, is also supportive of the conclusion under section 64(c) of the <i>Canadian Environmental Protection Act, 1999</i>.</p>
<p>Commenters expressed the opinion that the draft conclusion based on a screening assessment and application of precaution is inappropriate.</p>	<p>A critical effect for naphthalene (i.e. Carcinogenicity) is considered to present a probability of harm at any level of exposure; therefore the conclusion is that naphthalene “may be entering the environment in a quantity or concentration or under conditions that constitute a danger in Canada to human life or health.” The application of a precautionary approach is required by CEPA.</p>
<p>The opinion was expressed that guidance is needed on assessment criteria and standard of evidence to overturn the presumption of toxic and that a guideline and/or procedure to implement precaution decisions made under Chemical Management Plan following the Government of Canada framework is needed.</p>	<p>Consistent with the Ministers' Notice of Intent (December 9, 2006), Health Canada considers that evidence of carcinogenicity (i.e., classification by one or more international/national agencies), in the absence of a fully elucidated mode of action analysis, is sufficient to propose a conclusion that there is a probability of harm at any level of exposure and that the criterion in paragraph 64c of CEPA is met. The application of a precautionary approach is required under CEPA.</p>
<p>A commentator recommended a more transparent peer-review process.</p>	<p>Information concerning the nature of external peer review of the sections relevant to assessment of risk to human health will be included in the revised draft.</p>

<p>A commentator requested a review of Health Canada's genotoxic carcinogen policy in light of the Advisory Panel's comments on the January 11, 2008 meeting.</p>	<p>Information regarding the assessment of non-threshold toxicants under the Existing Substances Programme is available at http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/approach/index_e.html</p> <p>The report of the January 11, 2008 meeting of the Challenge Advisory Panel is available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/meetings-reunions_e.html</p>
<p>A commenter expressed the need for a clear understanding of the process for incorporating new information into the final and/or draft screening assessments in the Challenge program and Chemical Management Plan.</p>	<p>Health Canada (HC) considers all information submitted by stakeholders and its inclusion in the screening assessment is based on factors such as its relevance within the scope of the screening assessment and confidentiality of the information.</p>
<p>The opinion was expressed by a commenter that naphthalene should undergo a Priority Substances List (PSL) assessment that would consider new research, a thorough review of genotoxicity data and a refined exposure evaluation.</p>	<p>The Government of Canada considers that it has sufficient information on this substance at this time to support the conclusion of "toxic" under section 64 of the <i>Canadian Environmental Protection Act, 1999</i> (CEPA) 1999.</p>
<p>A commenter requested deferral of the finalization of the screening assessment report until a Health Canada air study is made publicly available and an in-progress research program is carried-out.</p>	<p>The health Canada air study is available upon request.</p>
<p>A commenter requested that Health Canada review the genotoxic classification of naphthalene based on new science, in the form of the US Environmental Protection Agency Reregistration Eligibility Decision (US EPA RED) (February 2008).</p>	<p>Due to the preliminary nature of the US EPA preliminary Reregistration Eligibility Decision (RED), scheduled for publication in July 2008, it is not possible to use the RED at this time.</p>
<p>A commenter expressed confidence that the Pesticide Management Regulatory Agency (PMRA) will come to a similar conclusion as the US Environmental Protection Agency Reregistration Eligibility Decision (US EPA RED) with respect to pesticidal application re-evaluation.</p> <p>However, the commenter also expressed concern that different conclusions from Health Canada and the PMRA will confuse Canadian consumers.</p>	<p>It should be noted that the PMRA has not completed its re-evaluation of naphthalene, and therefore, one cannot predict the outcome at this time.</p>

<p>A commenter provided supplementary information [presentations to Health Canada, the PMRA and prepared meeting notes; posters on the population screening risk assessment of nasal tumours due to naphthalene; evaluation on toxicity and metabolism and relationship to tumorigenicity; Naphthalene (the five-year research program by the Naphthalene Coalition); and the overview of a preliminary draft Reregistration Eligibility Decision (confidential) from the US EPA]</p>	<p>The submitted information was considered. Only data key to the screening assessment was cited in the assessment. Due to the current preliminary nature of the US EPA RED, (scheduled for publication July 2008), it is not possible to use the RED at this time.</p>
<p>A commenter expressed the opinion that as exposures values were not greater than the critical threshold value (CTV) there is difficulty in recommending risk management actions.</p>	<p>Both cancer and non-cancer effects were considered when characterizing the risk from naphthalene to human health. For non-cancer effects, the margin of exposure derived from the lowest inhalation effect value and the upper-bounding indoor air measurement in the screening assessment is considered to be potentially inadequate for the protection of human health when the uncertainties of both the exposure and hazard databases are taken into consideration. With regard to cancer, which was one of the critical effects of this screening assessment of naphthalene, it is considered that there is a probability of harm at any level of exposure, as the mode of action for the induction of tumours has not been fully elucidated.</p>
<p>A commenter expressed the opinion that the inclusion of the aggregate use of and exposure to naphthalene should be considered by the Government of Canada as it prepares to conduct an assessment of petroleum uses and releases. It was also stated that the assessment of the petroleum sector stream substances should consider the cumulative impact of the other substances found in use and the release of substances relevant to the petroleum sector.</p>	<p>The primary focus of the screening assessment report on naphthalene under the Challenge was on the uses of naphthalene as a discrete substance rather than its presence in complex mixtures such as petroleum-based streams and products. Naphthalene is used in a variety of commercial applications, and exposures to the general population may be quite different from those associated with the petroleum stream uses of naphthalene and related exposures.</p> <p>The petroleum sector stream approach is anticipated to look at substances within the petroleum sector, which are mainly complex mixtures. The methodology for assessment of petroleum sector streams is in development.</p>

Summary of Public Comments Received on the Government of Canada's Risk Management Scope Document for Batch one substance naphthalene [CAS 91-20-3] on the *Domestic Substances List*

The table below presents a summary of the comments received during the 60-day public comment period that took place from January 19, 2008 to March 19, 2008. Comments summarized below were received by one or more of the stakeholders listed.

Comments on this publication were provided by:

1. Johnson & Johnson Inc.
2. Dow Chemical Canada Inc.
3. Nalco Canada Company
4. NOVA Chemicals
5. Canadian Petroleum Products Institute
6. Canadian Environmental Law Association
7. Stiefel Canada Inc

Comment	Response
<p>Coal tar was included in the risk management scope document. Coal Tar should be removed from the risk management of naphthalene and should be evaluated separately.</p> <p>Coal tar use meets an unmet medical need and has not been shown to exhibit the toxicities associated with overexposure to naphthalene. The product should remain on the market in Canada as exposure and environmental impact is likely to be at a minimum and within agreed limits.</p>	<p>Issues pertaining to naphthalene in therapeutic products fall under the regulatory area of the <i>Food and Drugs Act</i>. This would encompass medicated toiletries such as coal-tar based shampoos. The risk management approach document discusses Health Canada's current management approach for coal-tar based shampoos.</p>
<p>The government is urged to develop a CEPA Guideline for consumer products identifying conditions for which consumer products are not allowed.</p>	<p>Health Canada will undertake investigations to better characterize controllable sources of naphthalene in indoor air in order to design effective risk management measures.</p>
<p>The government should examine if a regulatory instrument made under an Act other than CEPA can fulfill the requirements of the Chemicals Management Plan</p>	<p>The risk management process considers regulations, instruments and / or tools under CEPA 1999 and other Acts.</p>
<p>Since there are already risks in place for naphthalene (as it is a naturally occurring, non-threshold toxic), it would be inappropriate to address non-indoor air conditions that represent less than 1% of the intake exposure.</p> <p>Developing a risk management instrument for facilities should not be required and should not be a priority.</p>	<p>It should be noted that many non-threshold carcinogens are naturally-occurring, as well as anthropogenic. Risk management being considered for naphthalene pertains to minimization of naphthalene in indoor air, particularly potential contributions from consumer products.</p> <p>The risk management approach does not reference industrial facilities as being a source of exposure.</p>
<p>There is an error in section 1.4. The maximum indoor air value was 144.44 µg/m³ and not 140 µg/m³</p>	<p>The value has been changed.</p>
<p>Industrial facilities were not mentioned as a source of exposure in the draft screening assessment report but is mentioned in the risk management scope as a</p>	<p>As the final screening assessment report does not identify industrial emissions as a significant source of exposure, the risk management</p>

Comment	Response
source of potential exposure.	approach does not propose any new risk management actions for industrial facilities.
There is a reference to the use of naphthalene in food packaging as something that may require risk management however, there is nothing in draft screening assessment about food packaging.	<p>Issues pertaining to food packaging fall under the regulatory area of the <i>Food and Drugs Act</i>.</p> <p>Information obtained subsequent to the scope document confirms that naphthalene is used as a solvent in food packaging coatings and would volatilize and thus would not be expected to be present in the food product. Health Canada will review future submissions for the use of naphthalene as a solvent in coatings of food cans toward the objective that residual levels in finished materials are as low as possible and accordingly that potential migration of naphthalene into food is negligible.</p>
Multiple risks from naphthalene were identified for potential management, whereas, more than 95% of the total daily intake of Canadians was attributed to the inhalation of indoor air in the draft screening assessment report. Risk management should focus on the risks identified in the screening assessment report.	Risk management being considered for naphthalene pertains to minimization of naphthalene in indoor air, particularly potential contributions from consumer products. Health Canada will undertake investigations to better characterize controllable sources of naphthalene in indoor air in order to design effective risk management measures.
The government should ensure that naphthalene is prohibited in consumer products such as mothballs, room deodorizers and cleaning products.	<p>The risk management approach considers the releases of naphthalene from consumer products.</p> <p>The risk management being considered for naphthalene pertains to minimization of naphthalene in indoor air, particularly potential contributions from consumer products. Additional actions are focused on moth repellents, foods, food packaging, therapeutic products, homeopathic preparations, and cosmetics.</p>
The government should identify alternatives to naphthalene in its various uses, and conduct an assessment for their toxicity to ensure their safety. Finding safer alternatives will support the production of consumer products that are naphthalene free.	Alternatives are investigated, where possible, in the risk management process.
Under the Chemicals Management Plan, the government's management approach should require the phase out of naphthalene as a pesticide active ingredient due to its health impacts.	Naphthalene is subject to the <i>Pest Control Products Act</i> , under which it is currently listed as an active ingredient, and is undergoing reassessment.