

## Summary of Public Comments received on the Challenge substance 2-nitropropane (B8- 79-46-9) Proposed Risk Management Approach document for Batch 8

Comments on the proposed risk management approach document for 2- nitropropane to be addressed as part of the Chemicals Management Plan Challenge were provided by Inuit Tapiriit Kanatami, Canadian Society of Microbiologists, and Canadian Environmental Law Association. The table contains a condensed version of each comment and a response in non-technical terms.

A summary of comments and responses is included below, organized by topic:

- Persistence
- Significant New Activity (SNAc) Approach
- Exposure
- Reporting to National Pollutant Release Inventory (NPRI)
- Uses and Releases
- Alternatives

TOPIC	COMMENT	RESPONSE
Persistence	The screening assessment and the risk management approach offer contradictory conclusions in the determination of persistence for 2-nitropropane.	The Risk Management Approach document was corrected to reflect the conclusion in the final screening assessment report which notes that 2-nitropropane is not persistent.
Significant New Activity (SNAc) Approach	Given 2-nitropropane is being recognized as a non-threshold carcinogen, a requirement for the government to be notified of changes in use-pattern under SNAc provisions is inadequate as a risk management tool.	The final screening assessment concluded that 2-nitropropane poses a potential risk to human health because of its hazardous properties, but the general population's exposure is expected to be low based on current uses in Canada (as most products are intended for industrial or commercial applications). Risk management measures are focussed on keeping exposures low. This includes a requirement for the Government to be notified of changes in use pattern (which allows for further risk management actions, if necessary) as well as the delisting of 2-nitropropane from the approved food additives table, Division 16 (food

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		additives) of the <i>Food and Drug Regulations</i> .
Exposure	Currently, in Canada, 2-nitropropane is permitted for use in the fractionation of vegetable oils intended for human consumption under the Food and Drug Regulations. However, the final assessment report indicates that this substance is not used in vegetable oil processing in North America and that its use as a food processing solvent is discouraged internationally. If the use of 2-nitropropane has changed, there needs to be evidence of any changes followed by public reporting.	Following consultation with stakeholders, Health Canada is now in the process of delisting 2-nitropropane from the approved food additive tables of Division 16 of the <i>Food and Drug Regulations</i> . This process of delisting will involve a public consultation step as per the Cabinet Directive on Streamlining Regulations. Once delisted, the addition of 2-nitropropane in vegetable oil processing will no longer be permitted in oils intended for sale in Canada.
	The risk management focus needs to be expanded to address the volume of 2-nitropropane already in commerce and its potential presence as an impurity in various products.	Most of the products identified containing 2-nitropropane as part of the final screening assessment were intended for industrial applications resulting in negligible exposure to the Canadian general population. Therefore, risk management activity focuses on the requirement for notification of any changes in use pattern under SNAc (Significant New Activity Approach).
	To prevent future use of 2-nitropropane in cosmetics products, a commitment should be made to prohibit its use in such products.	There are no indications that 2-nitropropane is considered to have a foreseeable use as a possible cosmetic ingredient for products sold in Canada. As a consequence, there are currently no plans to add 2-nitropropane to the Cosmetic Ingredient Hotlist (which is used by Health Canada to inform manufacturers and importers of substances Health Canada considers to be a violation of the <i>Food and Drugs Act</i> ).
Reporting to	The threshold for reporting to the NPRI is not	Substances meeting the criteria for posing a potential risk to

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National Pollutant Release Inventory (NPRI)	adequate to reflect the release values of 2-nitropropane to the environment. The government needs to recommend a far more appropriate threshold for reporting to NRPI.	human health (under section 64, <i>Canadian Environmental Protection Act 1999</i> ) are given high priority in NPRI consultations. Updates to the substance list result from the NPRI consultations process and may include the addition, modification or removal of substances, as well as changes in the thresholds at which they must be reported.
Uses and Releases	The facility and product disposal of 2-nitropropane needs to be examined and be subject to further research since there is no available data.	The Government conducts research, evaluates findings from new studies, collects information, and investigates potential releases of harmful substances from waste management (e.g. landfills), and recycling facilities in Canada to determine risk management activities. Based on findings, the Government of Canada will implement further risk management activities, if warranted.
Alternatives	Government needs to include a substantial focus on alternatives to 2-nitropropane (e.g. in the pharmaceutical sector).	Alternatives are considered as part of the development of risk management approaches and instruments. The Government of Canada welcomes input from stakeholders in this area.
	The final assessment report noted 2-nitropropane was being replaced by other alternative solvents in food packaging applications. No information was provided on such alternates including whether they were assessed or found safe. The risk management strategy should pursue substitution with safer alternatives, including stringent methods to assess safety and making plans accessible to the public.	At this time, there are no indications that 2-nitropropane is still being used in food packaging or that the food packaging industry is actively searching for alternatives. Health Canada continues to provide opinions on the safety of food packaging formulations on request. Note, however, under Section 23 of the <i>Food and Drug Regulations</i> , the manufacturer is ultimately responsible for ensuring the food packaging will not impart materials to the food that may be injurious to human health.