Summary of Public Comments received on the Challenge substance Acrylamide (CAS RN 79-06-1) Proposed Risk Management Approach document for Batch 5

Comments on the proposed risk management approach document for acrylamide to be addressed as part of the Chemicals Management Plan Challenge were provided by North American Polyelectrolyte Producers Association, Dow Chemical Canada, Chemical Sensitivities Manitoba, Canadian Environmental Law Association and Inuit Tapiriit Kanatami. 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:

TOPIC	COMMENT	RESPONSE
Risk management	The risk management approach states that "The Government of Canada will not require risk management activities from industrial facilities using acrylamide…" However, the Government of Canada proposes adding acrylamide to the *Environmental Emergency Regulations* which is a type of risk management.	While this may appear to be contradictory, in that adding acrylamide to the *Environmental Emergency Regulations* is a form of risk management, this activity is a proactive measure to prevent emergencies that might reasonably occur, including both on-site and off-site consequences, and the associated prevention, preparedness, response and recovery issues. It does not restrict how acrylamide is used by those same industries.
	The risk management approach states that one of the criteria set out in section 200 of the *Environmental Emergency Regulations* has been met. Please disclose this criterion in the risk management discussion.	Due to the length of section 200 of the *Environmental Emergency Regulations* it was not included in its entirety in the risk management approach. A weblink to the Environmental Emergency website was included in the references section. It is also included below: http://www.ec.gc.ca/ee-

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	As an amendment to the *Environmental Emergency Regulations* is currently in progress, it is suggested acrylamide be added to the list of substances controlled by the Regulation.	It is proposed that acrylamide be added to the list of substances under the *Environmental Emergency Regulations.*
	Using the *Food and Drugs Act* to control acrylamide in food would allow the Government of Canada to avoid placing acrylamide on Schedule 1 of CEPA 1999.	As acrylamide has met one or more criterion under section 64 of CEPA 1999, it has been added to Schedule 1. This does not preclude risk management actions being taken under acts such as the *Food and Drugs Act* where appropriate.
	An action plan to reduce or prevent residual acrylamide in consumer products and food sources should be developed. Safe substitutes to polyacrylamide polymers, particularly for the cosmetic industry, should be investigated with full public disclosure.	Risk management for acrylamide will focus on minimizing exposure from foods, which are the greatest source of acrylamide for Canadians. Additional risk management includes the addition of acrylamide to the *Cosmetic Ingredient Hotlist*, which is an administrative tool to communicate to manufacturers and others that certain substances, when used in a cosmetic, may cause injury to the health of the user in contravention of section 16 of the *Food and Drugs Act.* Given the chemical nature of the substance, the breakdown of polyacrylamide into its monomer is energetically unfavourable and unlikely to occur. As a result, exposure to acrylamide from products containing polyacrylamide, such as cosmetics, is negligible.
	Eliminate the use of additives in drinking water that contain acrylamide. Voluntary health-based standards for drinking water should be replaced by a regulation to ensure that acrylamide in drinking water is not permitted.	Polyacrylamide resin flocculants play an important role in ensuring safe drinking water. They aid in removing particles that would not be removed by filtration alone. Exposure to residual acrylamide from the use of polyacrylamide resins to treat drinking water is expected to be negligible.

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	Regardless of the evidence that industrial sources are not the main source of exposure for humans, the Government of Canada should not avoid taking action on industrial sources, since this places the burden on consumers to effectively protect themselves from exposure to acrylamide.	As foods is the most significant source of acrylamide exposure to Canadians, the Government of Canada has chosen the *Food and Drugs Act* as the most effective means to protect Canadians. Pursuant to the *Environmental Emergency Regulations*, the Government of Canada will also require facilities that use greater than 9100 kg to prepare an Environmental Emergencies Plan, which will protect human health and the environment from spills of acrylamide.
	The Government of Canada should impose a mandatory requirement on the food industry to eliminate acrylamide in pre-packaged foods within a specified timeframe.	Acrylamide in pre-packaged foods is formed naturally during baking or frying. As a result, it is possible to reduce but not eliminate its production from foods The Government of Canada is working with both the European Union and the United States to align actions and share information in order to reduce the inadvertent production of acrylamide in foods.
	The development of a guidance document outlining best and safe practices for acrylamide reduction in pre-packaged foods is one of the key elements for eliminating acrylamide in pre-packaged food. This guidance document should be made publicly available, and should be part of a larger strategy to support the reduction of acrylamide in the food industry.	A document is available on Health Canada's website at: http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/risk-management_gestion-risque-eng.php
	Data from acrylamide monitoring must continue to be available to the public in an understandable format and include a summary	Health Canada will continue to monitor acrylamide levels in foods on a periodic basis. Results that include plain-language summaries will be published once available at:

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	of findings. The monitoring results should inform the level of progress made towards the management goals for acrylamide.	http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/monitoring-prog-surveillance-eng.php
	The use of the enzyme asparaginase should be evaluated for its safety to the environment and human health. The data regarding the use of the enzyme asparaginase to reduce acrylamide in food should be made available for public comment.	Health Canada undertook public consultation on its intention to permit the use of asparaginase in food processing. In response to the large volume of questions that were received, Health Canada has prepared a document entitled "Questions and Answers Regarding Health Canada's Proposal to Amend the *Food and Drug Regulations* to Permit the Use of the Enzyme Asparaginase in Certain Food Products", which is available at: http://www.hc-sc.gc.ca/fn-an/securit/addit/asparaginase_qs_as-eng.php This document provides responses to the most common questions that were posed during the consultation period, including human health concerns. In addition, it attempts to address the misconceptions and correct the inaccuracies that may have been reported about Health Canada's proposal. Additionally, ongoing results of Health Canada's acrylamide monitoring program will be made available online at: http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/monitoring-prog-surveillance-eng.php
	Advances made in the reduction of acrylamide in pre-packaged food in Canada and in conjunction with other countries should be made available on Health Canada's website.	Health Canada scientists collaborate with the Joint FAO/WHO Expert Committee on Food Additives. New information relevant to consumers on acrylamide in foods will be published on Health Canada's website.
	The proposed management objectives for	In addition to preventing exposures to environmental

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	acrylamide are not supported because they do not adequately protect human health from exposure to this substance and focus on only emergency situations. The Government of Canada is urged to expand its management objectives to seek to eliminate acrylamide and prevent exposure to from all sources.	emergency situations, the risk management objective for acrylamide proposes, to the greatest extent possible, that Canadians' exposure to acrylamide from food sources is kept as low as possible. As acrylamide is naturally produced during the baking and frying process, it cannot be eliminated from food. The Government of Canada has also added acrylamide to the *Cosmetic Ingredient Hotlist*, which is an administrative tool to communicate to manufacturers and others that certain substances, when used in a cosmetic, may cause injury to the health of the user in contravention of section 16 of the *Food and Drugs Act*. Other sources of acrylamide are deemed to have levels of exposure that do not require risk management.
	The addition of acrylamide to the *Cosmetic Ingredient Hotlist* should be as a prohibited substance in cosmetics and personal care products.	Acrylamide has been added to the *Cosmetic Ingredient Hotlist*. Polyacrylamide is listed on the Natural Health Products Ingredients Database as a non-medicinal ingredient, where the concentration of acrylamide in polyacrylamide-containing formulations should not exceed 5 ppm.
	It was recommended that the Government of Canada eliminate polyacrylamide, hence acrylamide, from natural health products.	The concentrations of residual-free acrylamide in natural health products are negligible. Polyacrylamide is listed on the Natural Health Products Ingredients Database and the Licensed Natural Health Products Database as a non-medicinal ingredient.
	Support was expressed for the addition of acrylamide to the list of chemicals under the *Environmental Emergency Regulations*. However, it was suggested that the threshold of	The threshold for acrylamide was developed after a risk assessment in accordance with the methodology described in the Environment Canada document entitled: "Rationale for the Development of a List of Regulated Substances under

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	9100 kg should be removed to ensure that all facilities using or releasing acrylamide are required to prepare environmental emergency plans regardless of volume thresholds. The environmental emergency plans should also address potential stockpiles of acrylamide.	CEPA 1999 section 200 and their Threshold Quantities" available at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=8BA5E950-1 Environmental emergency plans will be required of any company whose stockpiles trigger the quantity threshold.
	The proposed addition of acrylamide to the *Cosmetic Ingredient Hotlist* is appropriate, but polyacrylamide should not be added.	Acrylamide has been added to Health Canada's *Cosmetic Ingredient Hotlist* as referenced by chemical's CAS registration number (79-06-1), to avoid any confusion with polyacrylamide compounds.
Releases to the environment	The release and disposal quantities of acrylamide reported to the National Pollutant Release Inventory (NPRI) do not give a complete picture of releases to the environment. Only certain industrial sectors are included in the inventory and the threshold for reporting releases of acrylamide to the NPRI (10 tonnes manufactured, produced or otherwise released) is inappropriate and inadequate to provide information on releases of this substance to the environment. Somewhat different information on environmental releases was obtained under the section 71 notice of CEPA1999, but this information is confidential, so the public has to rely on the NPRI for specific facility information.	The NPRI is meant to capture the major release sources and smaller users (<10 tonnes) are not included as they are considered minor. Food producers (e.g. bakeries and potato chip fryers) also release acrylamide to the air in their vented steam however they are not users of acrylamide; rather, the acrylamide is produced unintentionally in the cooking process. Results generally indicate that there is a widespread microbial ability to degrade acrylamide and the substance is considered to not persist in the aquatic environment which is the primary environmental compartment to which it is likely released. Based on the empirical and modelled data, acrylamide does not meet the persistence criteria in air, water, soil and sediment.

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Releases	There is no consideration to how the many products containing acrylamide will be disposed of, to releases from industrial processes such as ore extraction and crude production and to treatment of wastewater. This is particularly an issue for communities where resource extraction is dominant in their regions, such as the Arctic, and where communities lack treatment facilities. Pollution prevention strategies should be given consideration, including the implementation of substitutes.	The Government of Canada considers a wide variety of risk management options, including waste disposal of a substance. However, when exposure risks are low, the Government of Canada develops risk management to control the primary source(s) of exposure to protect the environment and human health. In the case of acrylamide, exposure to the general population from waste sources is negligible.
Alternatives	The Government of Canada should expand its efforts to identify alternatives to acrylamide. A process to determine the safety of all appropriate substitutes for polyacrylamide (in effect, acrylamide) should be undertaken under CEPA before the substitutes are used as replacements.	Due to its chemical nature, the breakdown of polyacrylamide into its monomer is energetically unfavourable and unlikely to occur. As a result, exposure to acrylamide from products containing polyacrylamide is negligible, and therefore, substitutes for polyacrylamide were not considered.
Vulnerable Populations	Exposure estimates did not include vulnerable populations, but relate to general populations. These estimates have not taken into account that vulnerable populations, whether due to diet, cultural foods and/ or products, may have greater exposure levels than the general population. Because of the presence of acrylamide in commonly eaten fried foods and other food items, the likelihood of exposure may be quite variable for many diverse	Challenge screening assessment reports are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada. However, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment.

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	Young children may have a greater susceptibility to acrylamide due to a larger intake than other age groups. There was no further information on children's exposure other than to general population data based on age. Also, no data on acrylamide in breast milk has been identified in Canada.	Health Canada considers the conservative exposure estimates of Canadian children as represented in Appendix 2 of the screening assessment report for acrylamide as sufficient to represent the intakes for vulnerable populations. According to international studies, acrylamide in breast milk ranges from non-detectable levels to extremely low.
	Potential adverse effects on pregnant women need to be addressed. Food advisories must account for this diversity.	Canada's Food Guide advises Canadians to consume fried foods in moderation. Fried foods high in starch (such as potatoes) contain the highest concentrations of acrylamide. The Government of Canada has an advisory guide on what Canadians can do to reduce exposure to acrylamide, which is available at: http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/acrylamide_rec-eng.php