



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

2-Propenamide

(Acrylamide)

Chemical Abstracts Service Registry Number (CAS RN):
79-06-1

Environment Canada
Health Canada

August 2009

Canada 

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This proposed risk management approach document builds on the previously released risk management scope document for acrylamide, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms; or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of “toxic” set out in section 64 of the Act.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance 2-Propenamide, Chemical Abstracts Service Registry Number (CAS RN)¹ 79-06-1, referred to throughout this document as “acrylamide”, is included in Batch 5 of the Challenge under the Chemicals Management Plan.

¹ 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.

1.2 Final Screening Assessment Report Conclusion for Acrylamide

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for acrylamide on August 22, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that acrylamide is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Based on the information presented in the draft screening assessment (Canada 2008), it is proposed that acrylamide is not 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 or that constitute or may constitute a danger to the environment on which life depends.

On the basis of the carcinogenicity of acrylamide, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margin of exposure for other health effects, it is proposed that acrylamide is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore proposed that acrylamide does not meet the criteria in paragraphs 64(a) and 64(b) of CEPA 1999, but it does meet the criteria in paragraph 64(c) of CEPA 1999.

The final screening assessment report also concluded that acrylamide does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of acrylamide in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for acrylamide, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_5_e.html.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of acrylamide to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that acrylamide meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, acrylamide will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

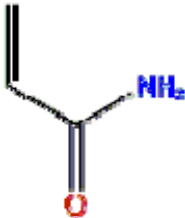
2. BACKGROUND

2.1 Substance Information

Acrylamide is part of the chemical grouping discrete organics and the chemical sub-grouping acrylamides and methacrylamides.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for acrylamide.

Table 1. Identity of Acrylamide

Chemical Abstracts Service Registry Number (CAS RN)	79-06-1
DSL name	2-Propenamide
Inventory names²	<i>2-Propenamide</i> (TSCA, AICS, ECL, SWISS, PICCS, ASIA-PAC, NZIoC); <i>Acrylamide</i> (EINECS, ENCS, ECL, PICCS); <i>Acrylamid</i> (EINECS, SWISS); <i>Acrilamida</i> (EINECS)
Other names	<i>2-Propene amide; Acrylamide monomer; Acrylic acid amide; Acrylic amide; Bio-Acrylamide 50; Ethylenecarboxamide; NSC 7785; Propenamide; UN 2074; UN 2074 (DOT); UN3426; Vinyl amide</i>
Chemical group	Discrete organics
Chemical sub-group	Acrylamides and methacrylamides
Chemical formula	C ₃ H ₅ NO
Chemical structure	
SMILES	O=C(N)C=C
Molecular mass	71.08 g/mol

²**Source:** National Chemical Inventories (NCI) 2008: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS

(European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Notified New Substances; Giftliste 1); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally upon the weight-of-evidence assessments of several international and national agencies (IARC 1994; US EPA 2001; EURAR 2002; NICNAS 2002; NTP 2005b), a critical effect for characterization of risk to human health for acrylamide is carcinogenicity, for which a mode of induction involving direct interaction with genetic material cannot be precluded (EURAR 2002; FAO/WHO 2006c). These classifications were based mainly upon the results of animal bioassays, as the limited number of epidemiological studies available indicated weak or no evidence of increased cancer risk with exposure to acrylamide. Consistently increased incidences of tumours at multiple sites (testes, thyroid, mammary gland) were observed in two drinking water assays with the same strain of rats. Acrylamide is genotoxic *in vivo*, testing positive in somatic cells in a wide range of assays in rodents and inducing transmissible genetic damage in male germ cells of mice.

Epidemiological studies have documented peripheral neuropathy in individuals and workers exposed to acrylamide, although data were insufficient for quantification of dose-response. The results of animal studies have been consistent with these observations, with lesions in peripheral nerves observed in rats following both subchronic and chronic exposure via drinking water. The lowest reported lowest-observed-effect level (LOEL) was 1 mg/kg-bw per day (Burek et al. 1980). Adverse reproductive and developmental effects have been reported in laboratory animals, generally at higher levels of exposure, although one recent assay reported reproductive effects in mice at the same level of exposure as the lowest LOEL for neuropathological effects (i.e., 1 mg/kg-bw per day).

Comparison of the critical non-neoplastic effect level for neurological and reproductive/developmental toxicity in rats (1 mg/kg-bw per day) with the estimated total daily intake of the general population (1.76 µg/kg-bw per day) results in a margin of exposure of approximately 570. In light of the profile of serious effects associated with exposure to acrylamide (i.e., carcinogenicity, genotoxicity, neurotoxicity, developmental and reproductive toxicity), this margin is considered to be inadequate to protect human health (Canada 2008).

3.2 Exposure of Children

Total intakes from food and environmental media ranged from 0.48 µg/kg body weight (kg-bw) per day in infants to 1.76 µg/kg-bw per day in children aged 6 months to 4 years. For most age groups, approximately 90% of the daily intake was from food. A significant association was observed between consumption of french fries and the level of urinary metabolites of acrylamide in children (i.e., 2–3 times higher concentrations of metabolites in children consuming french

fries more than 3 times a week compared with those who consume them less than once a month) (Canada 2008).

4. CURRENT USES AND INDUSTRIAL SECTORS

Acrylamide is largely used to produce polymers such as polyacrylamide, which finds use as a binding, thickening or flocculating agent in grout, cement, drinking water and wastewater treatment, pesticide formulations, cosmetics, food manufacturing and soil erosion prevention. The polymers of acrylamide are used in ore processing, food packaging and plastic products. Polyacrylamide is also used in crude oil production, coatings for home appliances, building materials, automotive parts, explosives, adhesives, printing inks, adhesive tapes and latex. It is also used in gelatin capsules, in the manufacture of dyes and in co-polymers used in contact lenses.

Based on information collected through a survey conducted pursuant to section 71 of CEPA 1999, between 1 million and 10 million kilograms of acrylamide were imported into Canada in 2006, whereas between 100 and 1000 kg of the substance were manufactured in Canada in 2006 (Environment Canada 2007).

Acrylamide has been identified in a wide variety of foodstuffs in many countries. The major pathway of acrylamide formation in those foodstuffs appears to be a high temperature-induced chemical reaction (above approximately 120°C), termed the Maillard reaction, between the amino acid asparagine and certain reducing sugars, both of which occur naturally in foods such as potatoes and grains.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

The breakdown of polyacrylamide into its monomer is energetically unfavourable and unlikely to occur (EURAR 2002). Acrylamide available for release from the polymer is residual (free) acrylamide.

Acrylamide may be released to wastewater during its production and use in the synthesis of dyes, in the manufacture of polymers, adhesives, paper/paperboard, textile additives, soil conditioning agents and permanent-press fabrics or in ore processing and oil recovery (Howard 1989). It may also be released in water treated with polyacrylamide as a flocculating agent. The largest end use is as a flocculant in facilitating liquid-solid separation for processing minerals in mining, waste treatment and water treatment. Other sources of release to water are acrylamide-based sewer grouting and recycling of waste paper. Acrylamide grouts generally consist of a 19:1 mixture of acrylamide and cross-linking agent. When the grout solidifies, it contains less than 0.05% free acrylamide (EURAR 2002).

In Canada, for the 2006 calendar year, fewer than 20 companies reported releases of acrylamide to air, water and land and/or transfer to an off-site hazardous or non-hazardous waste

management facility. This information included the substance contained in a mixture, in a product or in a manufactured item (NPRI 2008). One company reported a release to air of 30 kg. A number of companies reported releases to water from 0 to 85 kg and/or releases to land from 0 to 98 kg. Quantities transferred to an off-site waste management facility included 0–1018 kg for hazardous waste and 0–1224 kg for non-hazardous waste.

In 2006, the National Pollutant Release Inventory (NPRI) reported that 207 kg of acrylamide were released on-site (including 177 kg by a single facility to air), 45 kg were disposed of off-site (including 42 kg by a single facility) and 0 kg were recycled off-site (NPRI 2008). For facilities to report to the NPRI there is a 10-ton manufacturing, processing or use threshold. In 2007, total on-site releases were 50 kg (of which 5 kg were released to air), and disposal off-site was 40 kg (NPRI 2008). Although release and disposal quantities reported to the NPRI are relatively low, it should be noted that only certain industrial sectors are included in the inventory.

5.2 Exposure Sources

The major contributor to acrylamide exposure among Canadians is food. In Canada, the highest concentrations of acrylamide have been detected in french fries and potato chips. Acrylamide was also detected in breakfast cereals, pastries, cookies, breads, rolls, toast, cocoa products, coffee and coffee substitutes, although at lower concentrations than in french fries and potato chips. Acrylamide is not present in any ingredient of these food commodities prior to cooking and it is not a contaminant inadvertently added at any stage of food preparation. Although acrylamide is used in making some food packaging, this use has not been found to add a significant amount of acrylamide to foods. Intakes of acrylamide vary from 0.30 to 1.58 µg/kg bw/day when using mean consumption levels.

There is high confidence in the estimates of intake of acrylamide by the general population, as they were based mainly upon recent, well-conducted analyses by Health Canada, with supplementary data reported by the U.S. Food and Drug Administration and elsewhere. Furthermore, there was consistency between the concentrations of acrylamide in french fries and potato chips (foods which contribute the greatest single source of intake) reported by these two agencies (Canada 2008).

Acrylamide is a component of cigarette smoke (Urban et al. 2006). Smith et al. (2000) estimated that the acrylamide content in mainstream cigarette smoke is 1.1–2.34 µg/cigarette. Smoking could possibly be a source of acrylamide in indoor air (NTP 2005).

Other sources of potential exposure to acrylamide include the presence of residual acrylamide in polyacrylamide used in cosmetics, soil conditioners and coagulants and flocculants used in water treatment. There are currently no pest control products in Canada that contain either acrylamide or polyacrylamide as an active ingredient (2008 personal communication from Pest Management Information Service, Pest Management Regulatory Agency; unreferenced), although acrylamide may be present as a formulant impurity at < 0.01% (2008 personal communication from Review and Science Integration Division, Pest Management Regulatory Agency; unreferenced). Soil amendments that contain polyacrylamide must be registered as supplements under the *Fertilizers Act*, and the percentage of monomer must be specified (CFIA 1997). Several polyacrylamides

are currently registered in Canada for use in potting soils; the residual acrylamide content is 0.03–0.04% (2008 personal communication from Canadian Food Inspection Agency; unreferenced). Polyacrylamide is also used in the dewatering of sewage sludge; the amount of residual monomer is unknown.

In Canada, polyacrylamide is present as a non-medicinal ingredient in several licensed natural health products (e.g., skin cleansers, moisturizers) (NHPD 2008). Concentrations of polyacrylamide in licensed natural health products range from 0.8% to 3.375%. The concentration of acrylamide in polyacrylamide-containing formulations should not exceed 0.0005%.

While there may be some low concentrations of acrylamide monomer in the polyacrylamide found in cosmetics the concentrations of polyacrylamide in personal care products sold in Canada are generally less than 3%. Estimates of intake resulting from use of cosmetics (e.g., eye makeup, foundation, hand lotion) were found to be very low in comparison to foods.

Polyacrylamide is also present as a non-medicinal ingredient in several licensed topical therapeutic products, where concentrations range from 0.3% to 1.08% (TPD 2008). Although acrylamide can be used in gelatin capsules for rigidity, such use is infrequent (BPS 2008).

In Canada, acrylamide can be found as an impurity in paperboard, polystyrene, polyvinylidene chloride and epoxy coatings at concentrations ranging from 0.00045 to 29.8 mg/kg; the contribution to intake from this source is negligible (Health Canada 2005; FPIAS 2008).

Polyacrylamide flocculants are used to recover solids from wastewater produced during rendering, meat processing or fish processing (CFIA 2008).

Contributions to total intake from air, drinking water and soil, although based upon limited data and not including contribution from smoking, were negligible in comparison with that from food.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

- Acrylamide is subject to reporting under the National Pollutant Release Inventory.
- 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.
- Polyacrylamide-containing soil amendments must be registered as supplements under the *Fertilizers Act*, and the percentage of acrylamide monomer must be specified.
- As acrylamide-containing polymers can be used in drinking water treatment, Canada currently has voluntary health-based standards for additives that limit the amount of acrylamide residual that can be present in the finished drinking water (National Sanitation Foundation Standard 60/61) (NSF International 2005).

6.2 Existing International Risk Management

- Acrylamide is regulated in drinking water by the U.S. EPA at a level of 0.5 parts per billion.
- Acrylamide is listed on the *California Safe Drinking Water and Toxic Enforcement Act of 1986* (Proposition 65) which regulates substances listed by California as causing cancer or birth defects or other reproductive harm.
- Under the United States' *Food and Drugs Act*, polyacrylamide used as a film former for printing on soft-shell gelatin capsules must contain not more than 0.2% acrylamide (21CFR172.255).
- The European Union Cosmetics Directive (76/768/EEC) stipulates a maximum residual acrylamide level of 0.1mg/kg in body care and leave-on products and 0.5mg/kg in other rinse-off cosmetics products.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Recent studies with biopolymers for use in soil water retention and erosion control—such as charged polysaccharides, whey and industrial cellulose derivatives—introduce potential biopolymer alternatives to polyacrylamide; however, their performance characteristics are generally not as long lived. (Trimble 2008).

It is important to note that these substitutes have not undergone an assessment to determine whether they meet the criteria under section 64 of CEPA 1999.

7.2 Socio-economic Considerations

Socio-economic factors will be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

8. PROPOSED OBJECTIVES

8.1 Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for acrylamide is to minimize exposure to this substance to the extent practicable.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for acrylamide is to prevent increases in exposure to this substance due to environmental emergency situations in the manufacturing and industrial sector and to ensure, to the greatest extent possible, that Canadians' exposure to acrylamide from food sources is kept as low as possible.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Regulation and Instrument(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,³ and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulation and instruments were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health and environmental objectives, the risk management being considered for acrylamide is outlined below.

9.1.1 Polyacrylamide Manufacturing Sector

Industrial chemical uses are governed under provincial health and safety regulations and all workplace chemicals must comply with the *Controlled Products Regulations*, which includes Workplace Hazardous Materials Information System (WHMIS) labelling, supply of Material Safety Data Sheets (MSDSs) and worker training. While the polyacrylamide manufacturing sector is the largest user of acrylamide monomer in Canada, the exposures to the public from these products are negligible. The polyacrylamide manufacturing sector will therefore not be a candidate for risk management of acrylamide at this time.

9.1.2 Foods Sector

While further research on the human health effects of exposure to acrylamide from foods is needed before the risks can be fully understood, Health Canada's Food Directorate is acting to ensure that Canadian exposure to acrylamide from food sources is kept as low as possible. Since it was first discovered to be found in food in 2002, Health Canada's Food Directorate has been actively working with industry to reduce acrylamide in certain foods where it is known to occur

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal."

at higher levels. Health Canada has also participated in ongoing research to try to identify the health risks posed by acrylamide found in foods. This work includes numerous studies that examine acrylamide in food sold in Canada and an assessment of Canadians' levels of exposure to acrylamide from food. As well, Health Canada continues to provide recommendations and advice to Canadians on how to minimize their exposure to acrylamide in food.

The Government of Canada (Health Canada) is using the Chemicals Management Plan (CMP) process as another milestone to build on what has already been done and to update its risk management strategy to reduce exposure to food-borne acrylamide (http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/risk-management_gestion-risque-eng.php).

To achieve this, the following steps will be taken:

1. Health Canada will continue to press the food industry towards the development and implementation of acrylamide reduction strategies by food processors and the food service industry:
 - While Health Canada is aware of changes implemented by food processors that have already resulted in the reduction of acrylamide levels in certain foods, Health Canada will actively engage the food industry in the development of a guidance document outlining best practices for acrylamide reduction in prepackaged foods.
 - Health Canada will continue to support the development and implementation of additional tools that will minimize acrylamide formation in foods. This includes the use of the [enzyme asparaginase in food processing](#).
 - Health Canada will work with the Canadian food service industry to encourage the adoption of acrylamide reduction strategies.
 - Health Canada will also continue to update its [acrylamide monitoring program](#) to evaluate the effectiveness of these reduction strategies and to assess industry's compliance with identified acrylamide reduction best practices. This program could possibly lead to the development of reduction targets.
2. Health Canada will regularly update and reissue its consumption advice to consumers on how to reduce their exposure to acrylamide from food sources, based on the most up-to-date scientific and monitoring data.
3. Health Canada will coordinate its risk management efforts for acrylamide in food with key food regulatory partners in the United States, Europe, Australia, New Zealand and Japan. Where required, Health Canada will support targeted toxicology research to better understand possible chronic effects of acrylamide in food.

Health Canada will also update its food-related health risk assessment, based on emerging findings available internationally and stemming from its own research and monitoring activities related to acrylamide occurrence in food and its impacts on human health.

9.1.3 Cosmetics Sector

The government will add Acrylamide to the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

9.1.4 Natural Health Products Sector

Polyacrylamide is present as a non-medicinal ingredient in several licensed natural health products (e.g., skin cleansers, moisturizers). Concentrations of polyacrylamide in licensed natural health products range from 0.8% to 3.375%. The concentration of acrylamide in polyacrylamide-containing formulations should not exceed 0.0005%. As natural health products are regulated under the *Food and Drugs Act*, this sector will not be a candidate for risk management of acrylamide at this time.

9.1.5 Drugs Sector

Polyacrylamide is also present as a non-medicinal ingredient in several licensed topical therapeutic products, where concentrations range from 0.3% to 1.08%. Although polyacrylamide can be used in gelatin capsules for rigidity, such use is infrequent. Gelatin capsules containing polyacrylamide are not used for products intended for human consumption but rather for skin preparations. As drugs are regulated under the *Food and Drugs Act*, this sector will not be a candidate for risk management of acrylamide at this time.

9.1.6 Environmental Emergencies

The federal government has assessed acrylamide in the event that it were to enter the environment as a result of an environmental emergency and has concluded that the substance meets one of the criteria set out in section 200 of CEPA 1999. Therefore, the government intends to propose adding acrylamide to the *Environmental Emergency Regulations* with a proposed threshold of 9100 kg set through the Risk Evaluation Framework for sections 199 and 200 of CEPA 1999 (Environment Canada 2002).

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to acrylamide will be published in the *Canada Gazette*, Part I, no later than September 2011, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope for acrylamide, which summarized the proposed risk management under consideration at that time, was published on February 21, 2009. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the risk management approach will involve publication on August 22, 2009, and a 60-day public comment period.

The primary stakeholders include

- Food industry;
- Polyacrylamide manufacturing industry;
- Canadian Vehicle Manufacturers Association; and
- Health Canada – Health Products and Foods Branch.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	August 22, 2009 to October 21, 2009
Response to comments on the risk management approach	At time of publication of proposed instrument
Consultation on the draft instrument	Fall-winter 2009
Publication of the proposed instrument	No later than August 2011
Formal public comment period on the proposed instrument	No later than fall 2011
Publication of the final instrument	No later than February 2013

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to October 21, 2009, since the risk management of acrylamide will be moving forward after this date. During the development of regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and

information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division

Gatineau, Quebec K1A 0H3

Tel: 1-888-228-0530 / 819-956-9313

Fax: 819-953-7155

Email: Existing.Substances.Existantes@ec.gc.ca

REFERENCES

- [Canada]. 1999. *Canadian Environmental Protection Act, 1999*. S.C. 1999, c. 33. Canada Gazette. Part III, vol 22, no. 3. Ottawa: Queen's Printer. Available from <http://canadagazette.gc.ca/archives/p3/1999/g3-02203.pdf>.
- Canada, Dept of Environment, Dept of Health. 2008. Screening assessment for acrylamide, CAS No. 79-06-1. Available from: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_5_e.html
- [CFIA] Canadian Food Inspection Agency. 1997. Safety data requirements for the registration of polyacrylamide, acrylamide-acrylate copolymer and polyacrylate soil supplements as active ingredients under the Fertilizers Act. Trade Memorandum T-4-116. Ottawa (ON): Canadian Food Inspection Agency, Plant Production Division. Available from: <http://www.inspection.gc.ca/english/plaveg/fereng/tmemo/t-4-116e.shtml>
- [CFIA] Canadian Food Inspection Agency. 2008. Animal Feeds Division, personal communication.
- Environment Canada. 2002. Guidance Manual for the Risk Evaluation Framework for Sections 199 and 200 of CEPA 1999. Decisions on Environmental Emergency Plans Available at: http://www.ec.gc.ca/CEPARRegistry/documents/regs/e2_guidance/toc.cfm
- Environment Canada. 2007. Voluntary submission of data for Batch 5 substances collected under the Chemical Management Plan Challenge initiative. Data prepared by Environment Canada, Existing Substances Division.
- [EURAR] European Union Risk Assessment Report: CAS: 79-06-1: Acrylamide [Internet]. 2002. Luxembourg: Office for Official Publications of the European Communities. Report No.: EUR 19835 EN. [cited 2008 Feb]. 221 p. On the cover, European Commission Joint Research Centre. Available from: http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/acrylamidereport011.pdf
- [FPIAS] Food Packaging and Incidental Additives Section. 2008. Health Canada, Personal communication.
- Health Canada. 2005. Acrylamide and food. Ottawa (ON): Health Canada. [cited 2007 Nov 9]. Available from: http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/acrylamide_and_food-acrylamide_et_aliment-eng.php
- Howard PH. 1989. Handbook of environmental fate and exposure data for organic chemicals, vol. 1. Chelsea (MI): Lewis Publishers, Inc. p. 13-19.
- [NHPD] Natural Health Products Directorate. 2008. Health Canada, Personal communication.
- [NPRI] National Pollutant Release Inventory [database on the Internet]. 2008. Gatineau (QC): Environment Canada. [cited 2008 Aug]. Available from: http://www.ec.gc.ca/pdb/querysite/query_e.cfm
- [NTP] National Toxicology Program (US). 2005. NTP-CERHR monograph on the potential human reproductive and developmental effects of acrylamide. Research Triangle Park (NC): US Department of Health and Human Services, Public Health Service, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction. NIH Publication No. 05-4472. Available from: <http://cerhr.niehs.nih.gov/chemicals/acrylamide/acrylamide-eval.html>
- NSF International. 2005. NSF/ANSI Standard 60/61: Drinking Water Treatment Additives – health effects/Drinking Water System Components -- health effects. Ann Arbor, MI.
- Smith CJ, Perfetti TA, Rumble MA, Rodgman A, Doolittle DJ. 2000. "IARC group 2A Carcinogens" reported in cigarette mainstream smoke. Food Chem Toxicol 38(4):371-383. [cited in US EPA 2007].
- [TPD] Therapeutic Products Directorate. 2008. Health Products and Food Branch, Health Canada, Personal communication.

Trimble, SW. 2008. Encyclopedia of Water Science. vol. 1, 2nd ed. CRC Press, Los Angeles, (CA): p. 556.

Treasury Board of Canada Secretariat. 2007. Cabinet Directive on Streamlining Regulation, section 4.4.
<http://www.regulation.gc.ca/directive/directive01-eng.asp>

Urban M, Kavvadias D, Riedel K, Scherer G, Tricker A. 2006. Urinary mercapturic acids and a haemoglobin adduct for the dosimetry of acrylamide exposure in smokers and nonsmokers. *Inhal Toxicol* 18:831-839.