October 25, 2011

Office of the Auditor General of Canada
Commissioner of the Environment and Sustainable Development
Attention: Petitions
240 Sparks Street
Ottawa, Ontario
K1A 0G6 *transmission by email: petitions@oag-bvg.gc.ca*

Dear Commissioner,

The following petition is being submitted to the Office of the Auditor General of Canada in accordance with section 22 of the *Auditor General Act* by the Canadian Environmental Law Association and Chemical Sensitivities Manitoba.

The Canadian Environmental Law Association (CELA) (www.cela.ca), is a non-profit legal aid clinic based in Ontario. Since 1970, CELA has provided legal representation to individuals and groups with problems caused by environmental pollution and by working to change policies and laws to prevent such problems in the future. This includes a specific focus on protecting vulnerable populations such as children, the elderly, people of low income and workers, who are exposed to toxic substances.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic substances on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic substances in the home and the environment and advocates for the safe substitution of toxic substances.

A. Purpose of Petition

Since 1999, we have been reviewing and responding to government proposals focused on the assessment and management of substances under the *Canadian Environmental Protection Act 1999* (CEPA). The following petition seeks to obtain responses to questions (see Section F) by Environment Canada and Health Canada, the principal departments that have authority to implement CEPA, along with other federal departments that could contribute to the implementation of CEPA including Industry Canada.

The federal approach under CEPA commits to "virtually eliminate the most persistent and bioaccumulative toxic substances…."[1] However, it fails to include a specific goal to *eliminate or reduce* the use of substances that cause specific health effects such as cancer, reproductive or developmental or mutagenic impacts. We consider this an omission in the current federal program.

[1] Government of Canada. Canadian Environmental Protection Act, 1999. Preamble. http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=24374285-1&offset=1&toc=show.

Our petition aims to seek information on cosmetics and personal care products that would provide evidence if government commitments are warranted for the reduction or elimination of specific toxic substances that cause health effects listed above, particularly cancer causing substances. Although this petition does not focus on toxic substances in other consumer products and industrial sources, we are of the view that such an inquiry is necessary. In effect, the overarching purpose of this petition is to assess how effective federal government measures have been in the elimination or reduction of toxic substances in cosmetic and personal care products. In addition, this petition seeks to promote the view that such information is needed for transparency in the government's decision making process and accountability of manufacturers and importers to ensure the safety of personal care and cosmetic products available in Canada.

As a result, the questions below focus on the Cosmetic Ingredient Hotlist (Hotlist) under the Cosmetic Regulation of the *Food and Drug Act*, the main tool used by the government to address the utilization of toxic substances in cosmetic and personal care products. Furthermore, we focus on the government's efforts to manage toxic substances identified on the basis of carcinogenicity. In order to assess whether the use of the Hotlist is an effective strategy to protect the health of Canadians from exposure to toxic substances on the basis of carcinogenicity, the public requires evidence that the Hotlist is effectively keeping these substances out of cosmetics and personal care products available in the Canadian market, including those products intended for export to other countries.

B. Canadian cancer statistics

Cancer is the cause of thousands of deaths each year in Canada. According to the Canadian Cancer Statistics 2011 report, published by the Canadian Cancer Society, Public Health Agency of Canada, Statistics Canada, and the Provincial/Territorial Cancer Registries: "An estimated 177,800 new cases of cancer (excluding 74,100 non-melanoma skin cancers) and 75,000 deaths from cancer will occur in Canada in 2011. Furthermore, approximately one out of every four Canadians will die from cancer."[2]

This report also indicates that increases in the incidence rate of new cancer cases are due mainly to an aging population. However, it also noted there are many types of cancer with increasing incidence rates, such as testicular cancer in young men that cannot be attributed to aging. In addition, the report does not address how exposure to cancer causing substances from the environment (via industrial or consumer products) may contribute to the current cancer statistics.

[2] Canadian Cancer Society, Public Health Agency of Canada, Statistics Canada, and the Provincial/Territorial Cancer Registries **Canadian Cancer Statistics 2011: Featuring Colorectal Cancer.** Accessed at http://www.cancer.ca/Canada-wide/About%20cancer/~/media/CCS/Canada%20wide/Files%20List/English%20files%20heading/PDF%20-%20Policy%20-%20Canadian%20Cancer%20Statistics%20-%20English/Canadian%20Cancer%20Statistics%202011%20-%20English.ashx.

Improving our understanding about the effects of both acute and chronic exposure to cancer causing substances, both individually or in combination, as well as addressing how exposure can be prevented, will have significant impacts on health care services and other social services that are required to meet the growing demands of cancer care patients on the medical system in Canada.

C. Background

The risk-based approach practiced by the federal government to manage toxic substances does not adequately incorporate a precautionary approach when there is evidence of harm from toxic substances, including carcinogens or suspected carcinogens. This approach does not require testing of all hazardous endpoints (including endocrine disruption and neurodevelopmental toxicity) for each substance in the Canadian market. Management measures are generally reactionary and are considered only after widespread exposure to toxic substances occurs, in order to then document epidemiological evidence of health effects in the population. As a result, we consider that the threshold for seeking elimination strategies on these toxic substances is too high and unacceptable to protect human health and the environment. The risk based approach is also limited because it:

- inadequately considers the full life cycle of a toxic chemical including its safe disposal and destruction;
- applies a chemical by chemical approach rather than the grouping of similar substances with similar properties for assessment and management; and
- fails to consider synergistic effects between these substances or groups of substances.

Canada's approach to regulating substances that are known or possible carcinogens has led to a decline in the use of some toxic substances (e.g. PCBs and hexachlorobeneze). However, the continued presence of toxic substances, particularly carcinogens, in cosmetics and personal care products does not appear to be effectively addressed under CEPA. Indeed, the government manages toxic substances in cosmetic products and personal care products by relying on provisions of other federal statutes such as the *Food and Drug Act* and the new *Canada Consumer Products Safety Act* (CCPSA), which entered into force in June 2011.

As noted below, and based on our experience with CEPA, it is our view that the federal approach to management of toxic substances in cosmetics and personal care products, and in particular carcinogens, is not sufficiently protective of human health and the environment. Our organizations seek a legislative commitment to prohibit the use of carcinogens and other toxic substances in cosmetic and personal care products.

Consider the following information relevant in Canada.

i) Toxic substances detected in the environment and Canadian population

Due to improved monitoring procedures in the Great Lakes and northern regions of Canada, a greater number of substances are being detected and tested in these ecosystems. The International Joint Commission, a binational agency that provides advice to the US and Canadian governments regarding the implementation of the Great Lakes Water Quality Agreement, identified a number of substances that are emerging as concerns for the Great Lakes basin. Many substances being detected in the waters of the Great Lakes are from consumer, personal care and pharmaceutical products. Some of these substances have been identified as toxic and may be linked to specific health effects (i.e., carcinogenicity, reproductive and developmental toxicity, etc.).[3]

Effective removal of these substances via sewage treatment plants may not always be possible prior to the wastewater effluent being discharged to receiving waters. In addition, there are jurisdictions across Canada that do not have sewage treatment systems in place to address wastewater effluents.[4]

In the past few years, Canada has taken steps to address data gaps in the monitoring and surveillance of substances that are considered to be of concern. This includes the launch of the Canadian Health Measures Survey (CHMS) in 2007, which is aimed at collecting key information relevant to the health of Canadians, including a survey to collect blood and urine samples from 5,000 people to test for chronic and infectious diseases, as well as nutritional and environment markers.

The results of such monitoring programs are a source of valuable information that should inform and support the federal approach to assess and manage substances, provide better understanding about the extent of uptake of substances by people and the potential sources for these substances. However, the results from these monitoring programs that show the presence of toxic substances in the Canadian population have yet to result in the government taking immediate action to implement precautionary measures on toxic substances.

ii) Chemicals Management Plan

Under Canada's Chemicals Management Plan (CMP), the assessment of almost 200 substances considered high priority substances is almost complete. Under the CMP, a total of 51 substances

[3] Work group report on chemicals of emerging concern. *Great Lakes Water Quality Agreement Priorities 2007-09 series*. Accessed at http;//www.ijc.org.

[4] Canadian Environmental Law Association and Lowell Center for Sustainable Production (University of Massachusetts). June 2009. *The Challenge of Substances of Emerging Concern in the Great Lakes Basin: A review of chemicals policies and programs in Canada and the United States*, A report prepared for the International Joint Commission Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes Basin. p 19.

were identified as priority for assessment based on human health in Batches 1 to 9 of the Industry Challenge.[5]

Based on the results of the final screening assessments of these substances, approximately 34 substances were found to be toxic under CEPA, meeting the criteria as outlined in section 64 of CEPA. Twenty eight of the 34 substances were CEPA toxic on the basis of carcinogenicity[6]. (see Table 1) The findings of CEPA toxicity for the remaining substances were based on other health impacts such as reproductive and developmental toxicity. Sixteen of the 34 CEPA toxic substances have been listed on Schedule 1 of CEPA as of March 2, 2011.[7] Many of the 34 CEPA toxic substances are used in a wide range of cosmetics and personal care products available in Canada. Not all CEPA toxic substances have been prohibited in Canada.

Table 1: Categorized health substances from Batches 1 – 9 of the Chemicals Management Plan, Industry Challenge Program – summary of analysis

Summary	Number of substances
Categorization for human health	51
CEPA toxic	34
CEPA toxic & possible or known carcinogen	28
CEPA toxic, known or possible carcinogen & prohibited/restricted/proposed* on the Cosmetic Ingredient Hotlist	22

*Source Proposed Risk Management Approach document for each of the CEPA toxic substances

Table 2 provides a listing of CEPA toxic substances from Batches 1-9 that are listed or proposed for listing to the Hotlist. These toxic substances are prohibited or restricted in cosmetic or personal care products in Canada.

[5] Note: The Industry Challenge of the CMP, introduced in December 2006, was established to collect data and complete risk assessments of 200 substances considered high priority by the government. The government used mandatory and voluntary tools to collect data on these substances. The substances were released in batches of up to 19 substances, every 3 months. A total of 12 batches of chemicals were released under the Industry Challenge since 2007. Final assessments have been completed for Batches 1-10. Development and implementation of risk management options for substances meeting the criteria of toxic under CEPA section 64 are underway.

[6] Note: The number presented includes butane or isobutene provided that they contain the already assessed 1,3-butadiene.

[7] Canadian Environmental Protection Act, 1999. Toxic Substances List (Schedule 1) dated July 6, 2011. http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0DA2924D-1&wsdoc=4ABEFFC8-5BEC-B57A-F4BF-11069545E434.

Table 2: List of substances considered human health priorities in Batches 1-9 of the Chemicals Management Plan, Industry Challenge and are CEPA toxic substances, identified with known or possible carcinogens effects, and listed or proposed to be added to the Cosmetic Ingredient Hotlist.**[8]

Chemical name and Chemical Abstract Service Registration Number (CAS RN)	Batch Number Industry Challenge of the Chemicals Management Plan	Cosmetic Ingredient Hotlist (prohibited/restricted/proposed)
Oxirane, methyl- 75-56-9 (listed as propylene oxide – monomer)	1	Prohibited
Napthalene 91-20-3	1	Prohibited
Oxirane, ethyl- (ethyloxirane) 106-88-7	1	Prohibited (listed as 1,2 epoxybutane)
1,2 –benzenediol (Catechol) 120-80-9	1	Prohibited
1,4-benzenediol (Hydroquinone) 123-31-9	1	Restricted
Benzene, 1,3-diisocyanatomethyl- (TDIs) 26471-62-5	1	Prohibited
Benzene, 1,3-diisocyanato-2-methyl (TDIs) 91-08-7	1	Prohibited
Benzene, 2,4-diisocyanato-1-methyl (TDIs) 584-84-9	1	Prohibited
Thiourea 62-56-6	2	Restricted
1,3-Butadiene, 2-methyl- (Isoprene) 78-79-5	2	Prohibited (listed as isopropene)
Oxirane, (chloromethyl)- (Epichlorohydrin) 106-89-8	2	Prohibited (listed as epichlorohydrin)
C.I. Pigment 34 1344-37-2	2	Restricted (listed as Lead (7439-92-1) and its compounds)
C.I. Pigment Red 104 12656-85-8	2	Restricted (listed as Lead (7439-92-1) and its compounds)
Sulfuric acid, diethyl ester (Diethyl Sulfate) 64-67-5	4	Prohibited
Sulfuric acid, dimethyl ester (Dimethyl Sulfate) 77-78-1	4	Prohibited
Butane * 106-97-8	4	Restricted (Prohibited containing equal to or more than 0.1% w/w of 1,3-butadiene (106-99-0 – carcinogenicity for 1,3-butadiene))
Propane, 2-methyl (Isobutane) * 75-28-5	4	Resticted (Prohibited when containing equal to or more than 0.1% w/w of 1,3-butadiene (106-99-0))
2-Propenamide (Acrylamide)	5	Prohibited (listed as acrylamide

[8] Health Canada. Cosmetic Ingredient Hotlist. March 2011. Access: http://www.hc-sc.gc.ca/cps-spc/alt_formats/hecs-sesc/pdf/cosmet-person/indust/hot-list-critique/hotlist-liste_2011-eng.pdf.

79-06-1		monomer)
Benzene, chloromethyl- (Benzyl Chloride) 100-44-7	6	Prohibited
Methanone, bis[4-(dimethylamino)phenyl]- (Michler's ketone) 90-94-8	7	Prohibited
Benzene, 1,2- dimethoxy-4-(2-propenyl)- (methyl eugenol) 93-15-2	9	Restricted (listed as Methyl eugenol)
Bromic acid, potassium salt (Potassium bromate) 7758-01-2	9	Prohibited
Total number of substances in Batches 1-9 of Industry Challenge that are CEPA toxic on the basis of carcinogenicity and listed or proposed to be added to the Cosmetic Ingredient Hotlist = 22 (includes CI Pigments 34 and 104)		

Notes:

*designated CEPA toxic only if substance contains 1,3 butadiene

**CEPA toxic – listed under Schedule 1 (Toxic Substances List) or proposed as CEPA toxic according to Screening Level Risk Assessment Report for specified substance

*** CI Pigment 34 and CI Pigment 104 – Considered to be on the Cosmetic Ingredient Hotlist under the listing of "lead and its compounds," based on the Risk Management Document for these substances. Accessed at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=EF4ED98F-1 and http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5EC834E2-1

iii) Status of CEPA toxic substances under the CMP

Under CEPA, risk management strategies are under development for many of the CEPA toxic substances assessed in the Industry Challenge. However, these strategies are not focused on elimination or phase out of these substances using regulatory instruments. Instead, there has been a significant focus on the use of non-regulatory tools to address these CEPA toxic substances. For example, several of the toxic substances that are carcinogenic may be managed through the Hotlist, an administrative tool under the Cosmetic Regulations of the *Food and Drug Act*. The listing of Diethyl sulphate (CAS RN: 64-67-5) and Dimethyl sulphate (CAS RN: 77-78-1) (Batch 4) to the Hotlist represents one management option proposed by the government for these CEPA toxic substances. Another proposed measure for these two substances is future use notification, another non-regulatory requirement for which the government has yet to provide additional details but is expected to require manufacturers to submit new forms identifying new uses for specific CEPA toxic substances. This latter measure does not require changes to the current use level of these substances and in effect, requires no substantial changes to the current practices by industry. Hence, we are concerned about the effectiveness of the Hotlist as it relates to the risk management of these toxic substances.

iv) Cosmetic Ingredient Hotlist

The Hotlist is implemented under the Cosmetic Regulations of the *Food and Drug Act (FDA)* and is administered by Health Canada. Compliance with the Hotlist is achieved by requiring mandatory notification provisions under section 30 of the *Cosmetic Regulations* of the *FDA*. The regulations require that all "cosmetics must be notified to the Cosmetic Program of Health Canada within the first 10 days a cosmetic is available for sale".[9] This requires manufacturers

[9] Health Canada. June 2009. Guide for Completing Cosmetic Notification Forms (Version 2.0). pages 3-4.

and importers to provide a list of the cosmetic's ingredients through the Cosmetic Notification Form.

The Hotlist is considered "an administrative list of substances that are restricted and prohibited in cosmetics" but it is not "exhaustive". Manufacturers are responsible for meeting obligations and requirements under the *FDA* and the Cosmetic Regulations.[10] The requirements under the Cosmetic Regulations create a situation where cosmetic and personal care products that may contain substances that violate the Hotlist are available to the public.

In Batches 1-9 of the Industry Challenge of the CMP, 22 CEPA toxic substances identified on the basis of carcinogenicity, are currently listed on the Hotlist for prohibition or restrictions (including butane and isobutene once they contain 1,3-butadiene). Specifically, these CEPA toxic substances were considered carcinogenic on the basis that "there may be a probability of harm at any level of exposure" to these substances.[11] The government's conclusions on these substances provide some basis to justify the need for a more protective management approach. Public interest organizations, including our respective organizations, continue to express concerns about the presence of toxic substances in cosmetics and personal care products, regardless of concentration levels, since some products may be used by children, babies and pregnant women. There are on-going concerns about relying on the Hotlist to prohibit or restrict substances for which there are no safe levels.

Similarly, the current approach does not require the identification and promotion of safe alternatives for toxic substances, including carcinogens used in cosmetics and personal care products. In cases where alternatives have been identified, no assessment of their safety has been undertaken.

To effectively address the challenge of toxic substances in cosmetic and personal care products, a significant shift in the risk management approach should require the identification and promotion of safe alternatives in order to facilitate the move away from toxic substances.

v) **Limited transparency on safety of cosmetics and personal care products**

There are several sources of information on cosmetic and personal care products available to consumers. These include Health Canada's website for advisories, notices and warnings regarding cosmetic and personal care products. Section 24 of the Cosmetic Regulations outlines labelling requirements for cosmetic products, particularly for restricted substances that are required to include directions for safe handling.

These sources of information are insufficient to fully protect the public. The burden is on consumers to understand potential impacts of ingredients and any violations to the Hotlist that

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[10] Ibid., page 2.

[11] See for example: Environment Canada and Health Canada. July 2008. Proposed Risk Management Approach for Naphthalene Chemical Abstracts Service Registry Number (CAS RN) 91-20-3. http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=B68532E6-1.

result in warnings, advisories or recalls, but only after the product may have been available for sale.

D. Examples of Specific Carcinogens on the Cosmetic Ingredient Hotlist

Below, we have selected two substances that are listed on the Hotlist. These substances are known, possible or suspected carcinogens. These substances are both listed as CEPA toxic based on carcinogenicity and are highlighted to provide examples of substances currently listed on the Hotlist and were chosen to demonstrate possible gaps with the Hotlist. These carcinogens are restricted rather than prohibited on the Hotlist, which means they may still be in some cosmetics and personal care products.

Hydroquinone

In selected assessments conducted under the CMP, there are indications that additional regulatory measures to address toxic substances in cosmetic products may be warranted. For example, according to the Risk Management Scope document for CMP Batch 1 substance, hydroquinone (1,4-Benzenediol), Chemical Abstract Service Registry Number (CAS RN):123-31-9, it was noted that:

> *Although prohibited for use in cosmetic products applied to the skin and mucous membranes, including skin-lightening products (Health Canada 2007a), there were 110 notifications of cosmetic products containing hydroquinone filed with Health Canada under the Cosmetic Regulations of the Food and Drugs Act, primarily in manicure preparations and hair dyes, at concentrations ranging up to 3%.*[12]

Hydroquinone is listed on the Hotlist with specific restrictions. From its final screening assessment, the critical effect for characterizing the health effects for this chemical is carcinogenicity. It is also a known skin irritant for humans. Imported products containing this chemical are generally intended for use as skin brighteners or lighteners and may be found in the Canadian market though apparently not in large retail stores. While this substance is restricted under the Hotlist, we question why this chemical is permitted in other cosmetic products in Canada.

Formaldehyde

Formaldehyde (CAS RN 50-00-0) is a CEPA toxic substance that is listed on Schedule 1 of CEPA. It is also listed on the Hotlist as a restricted substance. The listing for formaldehyde mentions that it can cause skin sensitivity. Formaldehyde is listed by IARC as a Group 1 known human carcinogen. Formaldehyde is permitted for use as a preservative in products. The

[12]Environment Canada and Health Canada. July 2008. Proposed Risk Management Approach for 1,4-Benzenediol (Hydroquinone) Chemical Abstract Service Registry Number (CAS RN) 123-31-9 Access at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=A7E16A4D-1.

rationale for listing this substance as a restricted substance on the Hotlist is difficult to determine based on the information presented on the Health Canada website.

Recently, Health Canada has identified a number of professional hair smoothing products available in the Canadian market that contained excessive levels of formaldehyde present in their formulations. This was determined only after Health Canada received health complaints after use of the products. Health Canada posted advisories in April 2011 about a number of products containing formaldehyde. The focus of the advisory is to stop the sale of products and warn professionals and consumers against the use of the products identified with concentration levels of formaldehyde exceeding the permitted levels. However, Health Canada has not disclosed to the public how many products containing excessive concentrations of formaldehyde were sold to the public, how the violations were addressed by the government, and how the remaining products were handled by retailers and manufacturers.[13]

E. CEPA Review and Review of the Cosmetic Regulations

Since CEPA remains Canada's main federal legislation on environmental and human health, evidence of its effectiveness is necessary. The government has an opportunity to strengthen or amend CEPA. Specifically, section 343(1) requires that:

> The administration of this Act shall, every five years after the coming into force of this Act, stand referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for that purpose.[14]

The last parliamentary review of CEPA was initiated in 2005 but was not completed. Another parliamentary review is long overdue. The findings of this petition will provide relevant information on the quality and effectiveness of government measures on toxic substances including carcinogens.

Health Canada initiated the review of the Cosmetic Regulations in early 2010 by issuing an electronic survey. As the public prepares to participate in this review, it would be prudent to also seek information on how effective the Hotlist has been in the prohibition and restriction of CEPA-toxic substances in cosmetic and personal care products.

This data along with the responses requested through the petition will provide relevant information to our organizations in preparation for the review of the Cosmetic Regulations. A better understanding of government implementation and industry (including importer) compliance in Canada with the Hotlist are essential pieces of information for the government as

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[13]Health Canada. April 2011. "About Health: Several Professional Hair Smoothing Solutions Contain Excess Levels of Formaldehyde". Accessed at http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2011/2011_56-eng.php . Dated July 12, 2011.

[14]*Canadian Environmental Protection Act*, 1999. Section 343. http://www.ec.gc.ca/lcpe-cepa/26A03BFA-C67E-4322-AFCA-2C40015E741C/lcpe-cepa99_0307_bil.pdf.

it currently relies on this administrative list to ensure the safety of personal care products and cosmetics in Canada.

As a result, responses to the following questions are requested from Health Canada, Environment Canada as well as other relevant departments identified by the Auditor General.

F. Questions

Regulatory and policy goals to reduce overall levels of carcinogens in cosmetics and personal care products in Canada

The following questions focus on regulatory and policy goals that target the presence of carcinogens in cosmetics and personal care products and aim to eliminate such substances in these products.

1) What is the government's policy or regulatory goals, if any, that **specifically** aim to reduce the levels of known and suspected human and animal carcinogens, in cosmetics and personal care products? Describe the details of the relevant policies.
2) For relevant policies, describe the progress made by government in achieving its goals and include quantitative and qualitative measures that have been applied by the federal government in achieving the goals of the policy. If there is no policy or commitment, explain why are there no such policies?

Cosmetic Ingredient Hotlist (Hotlist) under the Cosmetic Regulations to the *Food and Drug Act*

The following questions focus on the effectiveness of the Hotlist in prohibiting or restricting toxic substances in cosmetics and personal care products, with emphasis on known or probable carcinogens.

3) What is the decision making process for the addition of a chemical to the Hotlist? Please include information on the use of scientific databases and the role of all stakeholders, particularly environmental and health organizations, in the process.
4) What health endpoints (carcinogenicity, endocrine disruption, reproductive and developmental toxicity, respiratory irritant, sensitization, etc.) are reviewed for the addition of a chemical to the Hotlist?
5) How are substances listed on Schedule 1 of CEPA (Toxic Substances List) considered in the decision making process for addition to the Hotlist?
6) For those substances listed in Schedule 1 of CEPA that are not listed in the Cosmetic Ingredient Hotlist, please identify these substances by name and Chemical Abstract System Registry Number (CAS RN) and explain their absence from the Hotlist.

Compliance with notification requirements under the Cosmetic Ingredient Hotlist of the Cosmetic Regulations

Currently, Health Canada releases advisories or recall notices through various communication tools to indicate concerns with specific substances in cosmetic products. The following questions seek to clarify issues where manufacturers, importers or distributors do not meet the requirements of the Cosmetic Regulations, specifically the Cosmetic Ingredient Hotlist.

7) Since 2005, how many cosmetic notification forms were submitted to Health Canada by manufacturers, importers and distributors under the Cosmetic Regulations and the Hotlist? Please provide data on an annual basis.
8) Based on the response to #7, please provide data on an annual basis, the number of incidences where companies have failed to meet the guidelines for restricted or prohibited substances under the Hotlist. Include substance name and CAS RN.
9) Commencing in 2005, please identify the number of incidences, if any, where manufacturers, importers or distributors failed to submit cosmetic notification forms to Health Canada for personal care and cosmetic products entering the Canadian market.
10) Based on #9, what were the penalties and measures taken by government to ensure that those manufacturers, importers or distributors that have failed to submit notification forms under the Cosmetic Regulations, meet the requirements of the Cosmetic Regulations and the Hotlist?
11) Based on the response to #8, please provide details on subsequent measures taken by government to address infractions regarding Hotlist substances. Please identify where bans, recalls, product advisories, precautions, and communications with consumer groups have been taken.
12) Based on recalls or advisories issued for cosmetic products that exceed the restriction or prohibition requirements of the Hotlist, please explain the obligations and limits, if any, placed on manufacturers to remove the products from the market, their disposal or destruction in a safe manner.
13) Are exports permitted to other countries of products that do not comply with the Hotlist? If so, explain by providing specific examples.
14) Does the government undertake random third party validation of the activities of manufacturers of cosmetics and personal care products with respect to substances listed for restriction or prohibition?

Public reporting

Management of toxic substances identified under CEPA rely on the use of various federal laws such as the *Pest Control Products Act, Canada Consumer Products Safety Act, Canada Consumer Product Safety Act, Fisheries Act,* and *Food and Drug Act* to work together to protect the environment and human health. In addition, activities such as monitoring and biomonitoring provide the government with information to make decisions during the assessment and management processes with implementation activities summarized in the CEPA Annual Report. However, there is a need to enhance public reporting on

implementation activities, including the effectiveness of managing toxic substances in cosmetics and personal care products.

15) Excluding the posting of specific advisories, recalls or warnings, does the government prepare and release reports to the public that provide overall results on non-compliance and government actions related to the Cosmetic Notification Forms submitted by manufacturers, importers and distributors as required under the Cosmetic Regulations? If so, how often are they released and what information is provided in these reports?
16) If the information is not released publicly, please explain why this information is not available and explain any future plans for releasing the information to the public.

Strengthening the Cosmetic Ingredient Hotlist

The utility of the Hotlist as an administrative list could be strengthened by converting the Hotlist from an administrative tool to a regulatory requirement under the Cosmetic Regulations.

17) Does the government plan to make the Hotlist a regulatory requirement? If yes, please advise as to the timeframe for doing so. Please explain why this is the case.

Responses from the relevant government departments on the above matters also would be appreciated.

Thank you for your consideration.

Yours truly,

CANADIAN ENVIRONMENTAL LAW ASSOCIATION

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