CCTFA

CANADIAN COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION

ASSOCIATION CANADIENNE DES COSMÉTIQUES, PRODUITS DE TOILETTE ET PARFUMS

SUBMISSION
to the
STANDING COMMITTEE ON GENERAL GOVERNMENT

of the
LEGISLATIVE ASSEMBLY OF ONTARIO

on
BILL 167
AN ACT TO PROMOTE REDUCTIONS IN THE USE AND CREATION OF TOXIC SUBSTANCES AND TO AMEND OTHER ACTS

May 13, 2009

by

The Canadian Cosmetic, Toiletry and Fragrance Association

The Canadian Cosmetic, Toiletry and Fragrance Association would like to thank the Minister and Members of the Committee for the opportunity to present our thoughts on Bill 167.

Who is the CCTFA?

The Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA) is the voice of the personal care products industry in Canada. Founded in 1928, the CCTFA represents over 160 member companies who manufacture, distribute, import, export, and retail personal care products, as well as companies who provide products and service to the industry.

The CCTFA and our member companies have always worked to ensure the safety of our products and the health of our consumers, and are also very active in ensuring the safety of our products and the ingredients they contain from an environmental perspective. In addition to the work done within our member companies to meet these objectives, we also have been supportive of regulatory efforts that are based on sound science and risk assessment, and are efficient and effective in improving health and the environment.

Value of the Personal Care Products Industry

In Canada, the personal care products industry represent $5.4 billion in retail sales annually in addition to the added value of products manufactured in Canada and exported abroad. In Canada, Ontario represents the largest segment of these retail sales as well as being home to the largest portion of the manufacturing/exporting and support services components of the industry.

International Market Place

The market place in which we operate can best be described as truly international in scope. The reality for our products, as is also the case with most consumer products, is that they are produced and packaged in quantities in one location sufficient to supply national and international markets. Economies of scale are an important consideration. This applies not only to companies that import product into Canada, but also to our member companies who manufacture products in Canada (and Ontario) which are subsequently sold domestically as well as exported to international markets.

Differing or contradictory regulatory requirements for ingredients, labelling or packaging can make it either difficult or cost-prohibitive to either supply smaller markets or to manufacture in certain jurisdictions. Consequently, like most consumer product industries, we strongly encourage the alignment of regulatory requirements between jurisdictions to facilitate the international marketing of products, especially for those products produced in Canada (and Ontario) that are exported abroad.

With just over 30 million people, Canada is itself a "small" market for most personal care and other consumer products. Creating overlapping provincial regulations even further segregates our market and makes it difficult for manufactures and retailers to supply the market. Customizing products just for the Ontario market, including ingredients and labels, would be unrealistic from a production and economic perspective.

Regulation of Products at the Federal Level

For this important reason, we have always been supportive of the regulation of finished consumer products at the Federal rather than Provincial level and have also encouraged national regulators to

align their respective regulatory regimes. That is why we have been most supportive of the current International Coordination of Cosmetic Regulation (ICCR) process that is now underway between regulators from the European Union and the national regulators of Canada, Japan and the United States. This process is ensuring that regulations being developed to address emerging issues such as nanotechnology are consistent and aligned across these important trading partners and so do not become artificial barriers to the free flow of goods. Such international regulatory approaches have already lead to the adoption by most jurisdictions of the International Nomenclature for Cosmetic Ingredients (INCI) which is now used throughout the world and provides common names by which consumers and their health care providers can identify ingredients no matter where the product is manufactured.

Current Regulation of Personal Care Products

It is also important to understand that personal care products and their ingredients today are, in fact, extensively regulated for both human health and the environment by the Federal Government, and that Federal regulators are actively engaged with their counterparts in other important jurisdiction such as the European Union to draw upon the best science and risk assessments available. In fact, Canadian regulation is so highly respected that many foreign jurisdictions (including, for example, countries in South America such as Brazil, Argentina and Panama and countries in Asia such as China, Korea and Taiwan) require Canadian exporters to certify that the products they are exporting meet Canadian Government standards and regulations.

For personal care products and their ingredients, these products and the ingredients in them are regulated today by the following Federal legislation and regulations:

1. ***Food & Drug Act*** under three sets of regulations:
    a) Cosmetic Regulations for general cosmetic products (ie: skin and hair care products, make-up, deodorants, bath and shaving products and perfumes)
    b) Drug Regulations for products that have a therapeutic application (ie: sunscreens, acne products, anti-dandruff products, antiseptic skin cleansers, medicated skin care, and diaper rash products) and so must have a Drug Identification Number (DIN); and
    c) Natural Health Products Regulations for products with a therapeutic application using a applicable "natural" active ingredient (ie sunscreens, medicated skin care, toothpastes, acne products, anti-dandruff, antiseptic skin cleanser, and diaper rash products) and so must have a Natural Heath Product Number (NPN). Note: Whether it is categorized as a Drug or NHP product depends on the nature of the "active" ingredient.
2. ***Consumer Packaging and Labelling Act*** and regulations that include specific ingredient labelling and warning requirements, as well as govern claims that can be made about the product.
3. ***Competition Act*** which prohibits false and misleading representation or deceptive packaging.
4. **Canadian Environmental Protection Act** and regulations which govern ingredient safety including providing authority for the Chemicals Management Plan.

Two charts describing this regulatory structure are attached to the presentation.

Current Regulations: Right to Safe Products

As *Bill 167* indicates a concern for toxic substances in consumer products, it is very important to note that the Cosmetic Regulations clearly requires that:

"No person shall sell any cosmetic in Canada that has in or on it any substance that may cause injury to the health of the user when the cosmetic is used according to the directions on the label or accompanying the cosmetic, or for such purpose and by such methods of use as are customary or usual therefore;"

It is therefore illegal to sell personal care products in Canada that can cause injury to the health of the consumer when used as intended. This is, as we would call it, a "right to safe products" regulatory regime.

To fulfill these requirements, Health Canada maintains a "Hot List" of restricted or prohibited ingredients and regularly updates this list based on the newest sound science and risk assessments from around the world. Additionally, and this is a unique Canadian feature which is particularly beneficial from a public health perspective, Health Canada also requires the filing with them of a list of the ingredients and concentrations for all cosmetic products. This valuable data base allows Health Canada to quickly assess the presence and scope of any ingredient and, if ever necessary, to immediately take action should they have knowledge of a threat to consumer safety. Canada is one of the few jurisdictions to have this valuable regulatory tool.

Key Principles of Regulation

From a public policy perspective, there are two significant aspects to Canada's and other national regulatory regimes that are deserving of public confidence.

Firstly, decisions are based upon sound science and risk assessment. This does not exclude the precautionary principle, but it does mean that evidence used in making assessments MUST be able to stand the principles of the scientific method and scrutiny, and that assessments and regulatory decisions take into account the critical factors of both hazard and exposure.

And secondly, these processes provide for a sound and science based decision making process with the arbitrators not having vested interests, whether it be industry or NGO's, but rather public officials with a specific and defined mandate of protecting the public health and/or the environment. Any stakeholder can provide information for consideration if they believe it to be relevant. These are processes that allow for vigorous scientific discussion, but ultimately base decisions on facts, sound science and appropriate risk assessments. Although individual stakeholder groups may not always agree with or like the outcome, it is likely the most appropriate and effective way in which to make such decisions and maintain the long-term credibility and effectiveness of the process.

Canada's Chemicals Management Plan (CMP)

These same regulatory principles have also been applied to Canada's Chemicals Management Plan (CMP) in which our country is among the world's leaders in accessing substances for human health and environmental safety. This process is applicable to many of the ingredients used in personal care products and we, like many other stakeholders, are actively involved in this process which has many opportunities for the participation of interested parties including NGO's.

Another important feature of this plan is that it provides for a variety of tools for the appropriate management of "risk" which can include, but are not limited to, a reduction in use or the elimination of a substance. Again, this recognizes that "risk" is really the product of "hazard" and "exposure", and so allows for the management of many substances that provide benefits or have little or no risk in certain forms and amounts, while posing dangers or risks in other forms and doses. Thus "risks" can be reduced or eliminated, while "benefits" maintained. Additionally, it also considers that alternative substances may result in a similar or even greater "risk" which can often be the case. This approach, which is similar to that being used in other jurisdiction such as the European Union, is ensuring that efforts are targeted to the appropriate risks and so will likely be the most effective in accomplishing the goals of enhancing the protection of human health and the environment.

We would hope that this Committee and the Government will take into account these already existing significant regulatory efforts in considering *Bill 167* and when the accompanying regulations are being written.

Specific Comments on *Bill 167*

More specifically, we would make the following specific requests for consideration during the committee process:

1. **Sec. 64 - Proposed Amendment to Sec. 49 (1)** – This proposed amendment would create a regulatory power
   "prohibiting or regulating the manufacturing, sale or distribution of,
   (i)a toxic substance, a substance of concern or any other substance prescribed by the regulation, or
   (ii) anything that contains a toxic substance, a substance of concern or any other substance prescribed by the regulations;"

   As this power will create a parallel and possibly unaligned provincial regulatory regime with that already well established by the Federal Government and applying across Canada, we would urged that this provision not be included in the Act; or if it is, that consumer products and their ingredients already regulated under the Federal Food & Drug Act and Canada Environmental Protection Act be specifically exempted.

2. **Definition of "Substance of Concern"** – The proposed definition of a "substance of Concern", meaning a "substance prescribed by the regulations as a substance of concern for the purposes of this Act", is in fact no definition at all and so totally arbitrary. Good legislative drafting practices, as well as the need for certainty, requires at least some minimum description as to what is the basis for a "concern". Not providing at least a minimal definition will be interpreted by those governed by the law, including business considering investment in Ontario, as a significant and unquantifiable risk.

3. **Sec. 29 (6) – Absolute Liability** – This provisions establishes absolute liability and requires a penalty be imposed even if, "(a) the person took all reasonable steps to prevent the contravention; or (b) at the time of the contravention, the person had an honest and reasonable belief in a mistaken set of facts that, if true, would have rendered the contravention innocent."

   Absolute liability offenses have traditionally been used only for minor offences under statues like the Highway Traffic Act, and certainly not for offences with such a potential penalty as they are, by their nature, considered a denial of "natural justice". Additionally, with absolutely no possible defense, even for situations of an honest mistake, past experience has shown that this will only serve to force

potential offenders to hide their transgression or avoid seeking guidance or assistance from Government officials for fear of penalty. This, we would suggest, would be counter productive and not good public policy.

For these reasons, we would urge this provision be amended to remove "Absolute liability" and at least provide for a defense of "due diligence" as is used in the Canadian Environmental Protection Act.

4. **Authorization of Use of Suggested Alternative Substances** – As the Government's stated intention is to encourage "green" alternatives to existing substances, formal authorization by the Government of Ontario for the use of these suggested alternative substances in the Province would provide certainty to manufacturers and consumers. It would also provide a "formal" recognition for these alternatives to other jurisdictions that would encourage their use elsewhere and assist in the export of Ontario technology and products.

   Such a regulatory power would require the Minister to create a schedule listing specific substances to be reduced, as well as the suggested alternative substances acceptable to the Minister. The Minister would then certify that the suggested alternatives are approved for use by Health and Environment Canada, do not have the same or greater risks than the substances they are replacing, and perform as ingredients as portrayed.

   This pro-active addition to Bill would engage the Government as an active partner in developing better alternatives to existing substances and in the building of Ontario's "Green Economy".

Thank you for your time, attention and consideration of our presentation.

With best regards,

Darren Praznik
President & CEO
Phone: 905-890-5161
Email: dpraznik@cctfa.ca

CCTFA

www.cctfa.ca

Personal Care Product Regulation in Canada

A Simplified Flowchart

Is this a personal care/beauty product that falls into one of the following categories?

- Acne Therapy
- Antiperspirants
- Antidandruff
- Fluoride Anti-Caries (toothpaste)
- Medicated skin care
- Antiseptic skin cleansers
- Sunburn Protectants
  - •Secondary Sunscreen (make-up, lotion or other product making an SPF claim)

NO → **COSMETIC**

Cosmetic Regulations apply. Cosmetic Notification Form to be submitted to Health Canada within 10 days of first sale. See reverse for details.

YES ↓

Is the active ingredient considered "natural"? [refer to active ingredient classification chart available from Health Canada's Natural Health Products (NHP) website]

NO → **DRUG**

Food and Drug Regulations apply. Must obtain pre-market approval (DIN) from the Therapeutic Products Directorate at Health Canada. See reverse for details.

YES ↓

NHP

Natural Health Product Regulations apply. Must obtain pre-market approval (NPN) from the NHP Directorate at Health Canada. See reverse for details.

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Personal Care Product Regulatory Requirements at a Glance

FOOD AND DRUGS ACT	COSMETIC	DRUG	NATURAL HEALTH PRODUCT (NHP)
Regulatory Framework	Cosmetic Regulations	Food and Drug Regulations	NHP Regulations
Government Department	Cosmetics Program, Healthy Environments & Consumer Safety Branch	Therapeutic Products Directorate, Health Products & Food Branch	Natural Health Products Directorate, Health Products & Food Branch
Website	http://www.hc-sc.gc.ca/cps-spc/person/cosmet/index-eng.php	http://www.hc-sc.gc.ca/dhp-mps/index-eng.php	http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php
Approval/Notification	Notification within 10 days of first sale (Cosmetic Notification Form).	Pre-market authorization required (DIN).	Pre-market authorization required (NPN).
Ingredients	Hotlist of restricted and prohibited ingredients. INCI nomenclature mandatory (as of Nov 2006).	Active ingredient must be listed on package. Approved colourant list.	Active and NMIs must be listed on package. Approved NMI list.
Other Mandatory Label Information	Product identity, Net quantity, Name and address of manufacturer, Ingredient listing.	Proper name, DIN, Medicinal ingredient and quantity, Name and address of manufacturer, Lot number, Net contents, Directions for use, Applicable warnings, Expiration date.	Brand name, NPN, Dosage form, Net contents, Name and address of product license holder/importer, Medicinal ingredients and quantity, Recommended use & dose, Route of administration, Applicable warnings, Lot number, Expiration date, Source material of each medicinal ingredient, Non-medicinal ingredient list.
Claims	*Guidelines for Cosmetic Advertising & Labelling Claims*	Joint TPD/NHPD Product Monographs	Joint TPD/NHPD Product Monographs and *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*
Advertising	Pre-clearance available for broadcast advertising.	Pre-clearance required for broadcast and print advertising.	Pre-clearance required for broadcast and print advertising.
Language	All mandatory label information must be in both official languages. However, all label content must be fully bilingual for Quebec market.	All mandatory label information must be in both official languages. However, all label content must be fully bilingual for Quebec market.	All mandatory label information must be in both official languages. However, all label content must be fully bilingual for Quebec market.
Packaging Requirements	Mouthwashes must be child-resistant.	Security packaging not specific to personal care products.	Security packaging required on all NHPs.
Enforcement	Product Safety Inspectors (regional)	HPFB Inspectorate (regional)	HPFB Inspectorate (regional)
Facilities	No licensing required. Direct ship permissible.	Establishment License required. Imported product must be inspected in Canadian facility.	Site License required. Direct ship permissible.
GMP Certification	No	Yes	Yes
Cost Recovery Fees	No	Yes	Fees under development.
ENVIRONMENTAL ISSUES	Canadian Environmental Protection Act (CEPA) applies to all personal care products. The Chemical Management Plan (CMP) under CEPA was initiated in 2006. VOC regulations under development will restrict VOC content for certain product categories (i.e. aerosols). Packaging waste/recycling regulations apply in some provinces (i.e. Ontario, Quebec).		12/08