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MEMORANDUM

To: Darren Praznik, President & CEO, Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA)

Re: Contextual Legal Analysis of Senate Public Bill S-214 (10 December 2015)

Date: April 13, 2016

I. INTRODUCTION

You have asked us to provide a contextual legal analysis of the proposed Senate Public Bill S-214, *An Act to amend the Food and Drugs Act (cruelty-free cosmetics)* (referred to herein as the "proposed amendment(s)")[1]. Specifically, you have asked us to review the proposed amendments and provide an analysis of potential issues relating to the interpretation, operation and implementation of the proposed amendments in the context of the cosmetic industry in Canada.

II. BRIEF ANSWER

The proposed amendments present foreseeable legal issues with respect to certainty, clarity and enforceability of the law by regulators. The proposed amendments require one to establish the purpose (i.e. intent) at the time animal testing is conducted. In the context of the global supply chain for ingredients used in cosmetics, the mixed-use of ingredients and the product regulatory framework in Canada, the proposed amendments would have unintended effects, including (a) prohibiting all animal testing on substances in Canada, including substances for use in drugs (non-prescription and prescription), natural health products ("NHPs"), medical devices, foods, consumer products, chemical products and pest control products (collectively referred to herein as "other regulated consumer products") for human or animal use, if those substances could be used in cosmetics, and (b) preventing any new cosmetics or new cosmetic substances from being able to be introduced in Canada.

III. BACKGROUND

Legislative Intent

Based on a plain reading of the text, the legislative intent of the proposed amendments is to prevent animal testing from being conducted or relied upon in Canada, where the animal testing is conducted solely to establish the safety or efficacy of a cosmetic product. The limitation of the scope to "any cosmetic" and ingredients "of a cosmetic" suggests the proposed amendments are not intended to prohibit animal testing in Canada of all substances or reliance on animal testing where such testing is necessary to substantiate the safety of other regulated consumer products. Furthermore, the inclusion of an exemption to the prohibition on the reliance on animal testing, suggests the legislative intent is to limit, not ban, reliance on animal testing in relation to cosmetic products.

[1] Bill S-214, *An Act to amend the Food and Drugs Act (cruelty-free cosmetics)*, 1st Sess, 42nd Parl, 2015 (first reading 10 December 2015).

Regulatory Framework in Canada

The regulatory framework in Canada classifies products in a variety of categories based on legal definitions and policy objectives. These categories include, but are not limited to, cosmetics, drugs (non-prescription and prescription), NHPs, medical devices, foods, consumer products, chemical products and pest control products (collectively referred to herein as "regulated products").

By virtue of a variety of legislation, including the *Food and Drugs Act* (and regulations promulgated thereunder, including the *Cosmetic Regulations*, *Food and Drug Regulations, Natural Health Products Regulations* and *Medical Devices Regulations*), the *Canada Consumer Product Safety Act ("CCPSA")* (and regulations promulgated thereunder including the *Consumer Chemicals and Containers Regulations, 2001*), and the *Pest Control Products Act*, manufacturers[2] are legally required to establish the safety of regulated products for sale in Canada.

It is possible to assess the safety of certain regulated products by considering and examining the relevant toxicological endpoints of their ingredients, and the likely local and systemic consumer exposure to the product. Although all relevant existing data (including past results of animal testing) are generally evaluated before new animal testing is required, new safety testing using animal testing may be warranted when there is no alternative method to obtain the data, the existing information is not adequate to support the safety of an ingredient, or new potential safety issues arise. For some toxicological endpoints (e.g. carcinogenicity, reproductive toxicity or neurotoxicity) there may be no alternative non-animal methods for testing. As such, when there are no alternative methods, authorities such as Health Canada, may still require manufacturers of regulated products, including cosmetics, to determine the likelihood of toxicity of ingredients using animal testing.

Development and Manufacturing of Mixed-Use Ingredients

When a new substance is developed or manufactured, it can potentially be used in a variety of regulated products. Most substances used in cosmetics (e.g. preservatives, colourants, emulsifiers, solvents, skin conditioning agents, antioxidants) have mixed uses. These same substances could be used in <u>any</u> regulated product for human or animal use (e.g. pet grooming products or veterinary use products).

The mixed use of ingredients presents a significant issue in terms of identification of purpose and evidence of such purpose. When a new substance is being developed, it is not possible to distinguish between substances that are being developed for the "purpose of developing or manufacturing <u>a cosmetic</u>" or for the purpose of developing or manufacturing other regulated consumer products. Because of the real-world mixed purpose of these ingredients, linking the legal status of an ingredient to the purpose for which it was developed or manufactured is unfeasible.

IV. ISSUES

1) Identification of Purpose

Identifying the purpose for which an ingredient is subjected to animal testing is not feasible where there exists other potential purposes for animal testing conducted on a substance. Other purposes could include substantiation of safety for use in other regulated consumer products, or compliance with legislation of other jurisdictions (e.g. China or Japan). Testing might be carried out with these other purposes in mind, but in developing a new substance any company is unlikely to completely disregard other potential uses or other global markets. It is not feasible to determine at what point the prospect of future use of the ingredient in cosmetics transforms into a "purpose" or intent such that the ingredient was tested for the "purpose of developing or manufacturing a cosmetic", or if such a determination could ever be made.

[2] The term "manufacturer" is used herein to represent the person responsible for the sale of a product in Canada, including potentially the brand owner, fabricator, importer or a seller of the product in Canada.

2) Global Supply Chain

Within the supply chain, there are many entities with global operations who are involved in the development and manufacturing of ingredients and cosmetics. Data sets on ingredients may circulate, to be sold or resold between companies, crossing geographical borders and regulatory frameworks. In this context, the intent of multiple corporate entities would be relevant in determining the purpose of the development/manufacturing of an ingredient, including the brand owner, fabricator of the product, the lab conducing the testing, the entity initially mandating the testing, or an entity to which the data is subsequently licensed or transferred. Confirming the intent of all of these entities in the supply chain is not feasible. Furthermore, where an identical substance is manufactured by two different entities for use as an ingredient in cosmetics, and one entity has tested the ingredient on animals, while the other has not - is the ingredient then prohibited for use in cosmetics regardless of which manufacturer the ingredient is purchased from?

3) Potential for Circumvention

The potential for circumvention of the proposed amendments is significant. In light of the mixed use of substances, animal testing could continue in Canada with the intent of an ingredient being used in other regulated consumer products or in the fabrication of a cosmetic for export to other jurisdictions[3]. Ingredients that were not initially developed or manufactured with the cosmetics market in mind, could be tested on animals but as the initial purpose was not for use in cosmetics, regulators could not prevent these same ingredients from subsequently being used freely in cosmetic products sold in Canada once their safety has been established using animal testing.

Alternatively, interpreting the proposed amendments to ban use of any ingredient that has been tested on animals from ever being used in a cosmetic, would create significant legal and business issues. A Canadian manufacturer cannot confirm that no entity elsewhere in the world (e.g. supplier, university) has ever tested the ingredient on an animal for a cosmetic purpose. This interpretation is even more problematic as a result of jurisdictions which may require animal testing - if a supplier is required to conduct animal testing in order to market the ingredient for use in cosmetics in another jurisdiction, is that ingredient then prohibited for use in any cosmetics in Canada?

4) Administration and Enforcement of Regulatory Framework

A prohibition that is based on purpose or intent, from an evidentiary point of view presents major challenges for regulators who are tasked with the day-to-day administration of the legal framework. A legal framework that requires regulators to ascertain the subjective intent of potentially a number of entities, in different legal jurisdictions, spanning many years, would present significant challenges within the administrative process currently in place for cosmetics in Canada. Reliance on attestations or self-declarations by the entity submitting the notification for the cosmetic in Canada (i.e. post-market registration), would be administratively reasonable, but enforcement of same would be unworkable in practice as this would be based on subjective intent. While it is possible for a court to deal with questions of fact and proof, it is unreasonable to expect a regulator within an administrative framework to engage in such an exercise.

5) Jurisdictional Differences in Product Regulation

The proposed amendments do not address the differences in the definitions of “cosmetic” that exist between jurisdictions around the world and how that could affect the purpose of testing in relation to interpretation in Canada. A product that is regulated in one jurisdiction as a cosmetic, may be regulated as a drug in another, or vice versa. For example, the intent of the development or manufacture of a product may be related to a drug in a foreign jurisdiction, but ultimately this product could be regulated as a

[3] Section 37 of the *Food and Drugs Act* exempts from the Act cosmetic products “not manufactured for consumption in Canada and not sold for consumption in Canada”. See also Health Canada, Health Products and Food Branch Inspectorate, “Import and Export Policy for Health Products Under the *Food and Dugs Act* and its *Regulations*”, POL-0060 (Ottawa: Health Canada, 2010).

cosmetic in Canada. This would create a situation where the same product would not be able to be sold in Canada if animal testing was required in a foreign jurisdiction as a result of the product being classified as a drug in that jurisdiction. This would limit Canadians' access to products, without a corresponding benefit in reducing any animal testing.

6) Veterinary or Animal-Use Products

The definition of "cosmetic" in the *Food and Drugs Act* includes cosmetics for both human and animal use and as such, the proposed amendments are not limited to human-use products. The proposed amendments would therefore prohibit the testing or sale of cosmetics for animal use (e.g. animal grooming products), as by their nature, these products must be tested on animals to establish safety or efficacy for animal-use. Furthermore, testing of cosmetics or ingredients that could be used in both human-use and animal-use regulated products (e.g. veterinary drugs), results in the same mixed-use concerns identified above.

7) Unintended Effects on Canadians and Canadian Industry

Uncertainty regarding compliance with the proposed amendments due the various issues raised above, could result in businesses involved in the regulated product supply chain (including ingredient suppliers, research and development, manufacturing) and manufacturers of cosmetic products avoiding the Canadian marketplace. This would result in new or improved cosmetic products not being brought to market in Canada, negatively affecting Canadian consumers. In some cases, the unavailability of new or improved cosmetics in the Canadian marketplace will lead Canadians to purchase these products from other jurisdictions (e.g. online, by mail or by telephone) under personal importation policies, which will negatively affect Canadian businesses. In both instances, the negative effects on Canadians will have no corresponding benefit in saving animal lives.

Within the global supply chain, companies can choose among many countries to conduct research and development and manufacture regulated products. Where there is uncertainty regarding legal requirements and compliance as a result of the unintended effects of the proposed amendments, businesses may choose to conduct business in other jurisdictions – including research and development and manufacture of other regulated consumer products (e.g. drugs, consumer chemicals) that are not within the scope of the proposed amendments. This would impose an undue economic hardship on Canadian businesses and further contribute to the loss of research and development, as well as skilled manufacturing jobs in Canada.

V. ANALYSIS OF PROPOSED AMENDMENTS

Bill S-214 Proposed Amendment
"cosmetic animal testing" means the topical application or internal administration of any cosmetic or ingredient of any cosmetic to a live non-human vertebrate to evaluate its safety or efficacy for the purpose of developing or manufacturing a cosmetic. (*emphasis added*)
16 (d) [No person shall sell any cosmetic that] was developed or manufactured using cosmetic animal testing conducted after the coming into force of this paragraph. (*emphasis added*)

The proposed amendment includes a prohibition on selling a cosmetic that was "developed or manufactured using cosmetic animal testing". When read in conjunction with the definition of "cosmetic animal testing", the prohibition is problematic from a legal and practical perspective. The prohibition relates broadly to an "ingredient of any cosmetic" and requires that one establish the purpose (i.e. intent) of the animal testing at the time animal testing is conducted.

As provided in detail in section IV, the proposed amendments present significant legal issues. Several of the issues identified in parts 1) through 5) above, have been recently judicially considered in the context of

EU legislation. In the published opinion, the Advocate General determined that an interpretation of the EU regulation that required reference to the specific purpose or intention at the moment animal testing is conducted would not be enforceable.[4] As such, the issues identified in section IV, represent foreseeable legal issues with respect to the implementation and enforcement of the proposed amendments in Canada.

Bill S-214 Proposed Amendment
16.1 No person shall conduct or cause cosmetic animal testing to be conducted in Canada. (*emphasis added*)

By virtue of the inclusion of the defined term "cosmetic animal testing", the proposed amendment is linked to the purpose or intent of the animal testing. In light of the mixed use of substances, and the evidentiary issues identified in section IV above, the proposed amendment would effectively prohibit all animal testing on substances in Canada, if those substances could also be used in cosmetics. As the scope of the proposed amendments is intended to be limited to cosmetics, this prohibition is overbroad.

Bill S-214 Proposed Amendment
18.1 No evidence derived from animal testing conducted after the coming into force of this section may be submitted or used to establish the safety of a cosmetic or an ingredient of a cosmetic under this Act or the regulations.
18.2 (1) Paragraph 16(d) and sections 16.1 and 18.1 do not apply to animal testing authorized by the Minister, in prescribed form and manner, when there is no alternative method to evaluate substantiated specific human health problems associated with a cosmetic or ingredient of a cosmetic that is in wide use and cannot be replaced by another cosmetic or ingredient of a cosmetic capable of performing a similar function. (*emphasis added*)
(2) The Minister shall, after having given notice in the prescribed form and manner, conduct public consultations before issuing an authorization under subsection (1).

The exemption within the proposed amendments limits the ability of the Minister to exempt new substances for use in cosmetics in Canada such that it is unlikely that any new substance for use in cosmetics would be able to be introduced in Canada until alternative non-animal methods are available to test all relevant toxicological endpoints.

The exemption requires three conditions to be met: (1) there is no alternative method to evaluate substantiated specific human health problems associated with a cosmetic/ingredient, (2) the cosmetic/ingredient is in wide use, and (3) the cosmetic/ingredient cannot be replaced by another cosmetic/ingredient capable of performing a similar function.

For some toxicological endpoints (e.g. carcinogenicity, reproductive toxicity or neurotoxicity) there may be no alternative non-animal methods for testing. These toxicological endpoints form part of internationally recognized safety assessments for cosmetic ingredients.[5] Unless Health Canada can confirm that these endpoints will no longer be necessary for cosmetic safety assessments in Canada, then it is certain that new substances being introduced in Canada for use in cosmetics may need to be tested on animals in order to address these endpoints.

With respect to the first condition, it is not possible for a human health problem to be "substantiated" without that substance first being tested. No new cosmetic/ingredient could have "substantiated specific human health problems associated" with its use, before being tested or introduced into the marketplace. Furthermore, it is not possible to study chronic exposure in humans as it relates to certain endpoints.

[4] *European Federation for Cosmetic Ingredients v Secretary of State for Business, Innovation and Skills*, C-592/14 (ECJ) at para 49 (CURIA).
[5] Daisuke Araki et al, "2011-05 ICCR Principles of Cosmetic Product Safety Assessment" (2011) International Cooperation on Cosmetic Regulation, online: <http://www.iccrnet.org/files/7714/0475/3767/2011-05_ICCR_Principles_of_Cosmetic_Product_Safety_Assessment.pdf>.

Even assuming the first condition could be resolved, with respect to the second condition, any new substance being introduced into the marketplace may not be in "wide use" prior to it being available for use in Canada. As such, this condition would prohibit new cosmetics, or new ingredients for use in cosmetics, from being able to meet the criteria for this exemption.

Lastly, even if the two previous conditions could be met, the vast majority of cosmetics or ingredients are variants with the same uses, capable of performing the same functions. With respect to cosmetics (e.g. moisturizers, shampoos, body wash and mascara), there are thousands of similar products in the marketplace that are technically "capable" of performing a similar function. Similarly for ingredients, there are hundreds of ingredients that have the same function or purpose in a cosmetic product. By way of example, there are currently over 200 cosmetic ingredients with the reported function of "preservative" in the wINCI Database.[6] As such, technically some of these existing ingredients may be "capable" of performing a similar function within a cosmetic product as a newly introduced ingredient. However, this condition would preclude any new cosmetic or new ingredients for use in cosmetics from being able to meet the criteria for this exemption.

The combined effect of the proposed amendments would prevent any new cosmetics or new cosmetic substances from being able to be introduced in Canada. The unavailability of new or improved cosmetics in the Canadian marketplace will negatively impact Canadians and Canadian businesses, with no corresponding benefit in saving animal lives.

[6] *International Cosmetic Ingredient Dictionary & Handbook*, 14th ed, online: <http://webdictionary.personalcarecouncil.org/jsp/Home.jsp> (accessed April 6, 2016).