

Legal and Policy Principles Relevant to the Canadian Context

California Senate Bill No. 1249 (the “**California Bill**”) is state law that makes it unlawful for a manufacturer to import for profit or sell any cosmetic in California if the cosmetic (either in its finished form or any ingredient) was developed or manufactured using animal testing that was conducted or contracted by the manufacturer, or its suppliers, on or after January 1, 2020. The California Bill includes several exemptions to the general prohibition as well as a grace period of 180 days for the sale of a non-compliant cosmetic.

The California Bill recognizes several principles which provide clarity and legal certainty to the prohibition. Notably, the California Bill avoids capturing non-manufacturing importers or retailers from the scope of the prohibition, allows for the review and retention of testing data conducted to satisfy federal, state or foreign regulatory requirements, and exempts any testing that is required pursuant to the Federal *Food, Drug and Cosmetic Act*.

Certain principles recognized in the California Bill are relevant in the Canadian context to Senate Bill S-214, *An Act to amend the Food and Drugs Act (cruelty-free cosmetics)* (“**S-214**”).

1. Defined Responsibility and Cosmetic Scope: The prohibition is limited to manufacturers whose name appears on the label of the cosmetic, and to cosmetic products only.

- a. By narrowing the target of the prohibition to the manufacturer whose name appears on the label of the cosmetic product, the California Bill acknowledges the realities of a global supply chain and prevents attributing liability to those entities that have no involvement the production of a cosmetic product (e.g. distributors, retailers). Furthermore, the clearly defined responsibility provides certainty and clarity with respect to the application of the prohibition.

- A clarification of responsibility should be implemented in S-214 as the bill does not make clear who is legally responsible for compliance. Clarity and certainty are fundamentally important legal principles. As currently drafted, the prohibition in S-214 encompasses all “persons” which could inadvertently include others in the supply chain (e.g. retailers, distributors, direct sellers). In the *Cosmetic Regulations*, it is the “manufacturer” who is responsible for submitting evidence of safety, and the “manufacturer” or “importer” who is responsible for notifying the regulator of the sale of a cosmetic in Canada. By specifying it is responsibility of the “manufacturer” and “importer” to comply with requirements, S-214 would better align with the California Bill, and provide needed clarity.

- b. The California Bill restricts the application of the prohibition to the sale of cosmetics (as defined therein) and the testing to finished form cosmetics and its ingredients (as defined therein). The prohibition does not include drugs or foods, or their ingredients, which aligns with the purpose of the California Bill, to restrict animal testing for cosmetics only.
- S-214 contains a provision that provides authority to extend the prohibitions beyond cosmetics, to drugs and natural health products (NHPs) and their ingredients. Under the Canadian *Food & Drugs Act*, natural health products are included under the statutory definition of “drugs”. The scope of S-214 is only with respect to cosmetics, as such, the prohibition is overbroad. Furthermore, the potential to expand the scope of S-214 creates uncertainty, and given the global supply chain for ingredients with mixed use (e.g. pharmaceutical drugs, OTC drugs, foods, consumer products) could have a dampening effect on innovation and reduce access to innovative food, drug and consumer products in Canada. S-214 should be limited to cosmetics as defined in the *Food and Drugs Act*, and ingredients as defined in the *Cosmetic Regulations*.

2. Clear standard for acceptability of alternative test methods: The availability of alternative test methods for use by manufacturers is defined in relation to existing California law.

- a. The Legislative Counsel’s Digest provides that existing law in California acknowledges that appropriate alternative test methods must be scientifically validated and recommended by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) or other specified agencies. This provides a measure of clarity to manufacturers regarding the application of exemptions to the prohibition where there is no “nonanimal alternative method accepted” for a relevant endpoint by federal or state regulatory authorities.
- The exemption in S-214 makes reference to only to the lack of an “alternative test method”, with no mention of the requirement for alternative test methods to be scientifically validated or approved for use by any agency or regulatory body such as Health Canada. In the absence of clear standards, the application of this exemption is unclear. S-214 should require the Minister of Health to establish a list of acceptable non-animal alternative test methods, and/or a reference list of recognized international institutions (e.g. ICCVAM) that recommend alternative test methods, to provide certainty to manufacturers and importers with respect to compliance.

- 3. Recognition of foreign legal requirements:** The prohibition provides clear exemptions to the prohibition where animal tests were conducted to comply with a requirement of a foreign regulatory authority.
- a. Exemptions in the California Bill allow a manufacturer or supplier to conduct or contract an animal test on a cosmetic or ingredient of a cosmetic to meet foreign regulatory requirements. As such, a cosmetic or an ingredient will not be precluded from use in California simply because animal testing was conducted as required by law in another jurisdiction.
 - Cosmetics and ingredients may be subject to animal testing conducted in other jurisdictions to meet the legal requirements of those jurisdictions. S-214 could prohibit the sale of cosmetics or the use of ingredients that have been tested on animals to meet regulatory requirements internationally. Animal tests required for cosmetics or ingredients in foreign jurisdictions should not bar those cosmetics or cosmetic ingredients from being available in Canada.
- 4. Recognition of the authority of state regulators:** Exemptions to the prohibition recognise the authority of state regulators to require animal tests to protect human health.
- a. The general exemption in the California Bill allows a manufacturer or supplier to conduct or contract an animal test on a cosmetic or ingredient of a cosmetic where the test is required by a state regulatory authority and other specified criteria are met. As such, a cosmetic or an ingredient will not be precluded from use in California solely as a result of animal testing that was conducted to meet the requirements of state regulators.
 - S-214 could prohibit the sale of cosmetic or the use of ingredients that have been tested on animals to meet provincial regulatory requirements. The authority of provincial regulators to require animal tests to protect human health and safety is not recognized. Animal tests required for cosmetics or ingredients by provincial regulators should not prevent those cosmetics or cosmetic ingredients from then being sold or used in Canada.
- 5. Recognition of the authority of federal regulators:** Exemptions to the prohibition recognise the authority of federal regulators to require animal tests and allows for the use of data from animal tests conducted to meet the requirements of the Federal *Food, Drug and Cosmetic Act*.

- a. The California Bill is state law, and contains express exemptions to exclude animal testing required under federal authority from the prohibition. In addition, there is no limit on the reliance on animal testing data on any product or ingredient generated to meet the requirements of Chapter V of the Federal *Food, Drug and Cosmetic Act* (which regulates drugs and devices). The California Bill recognizes that animal test results obtained to meet the requirements of federal law or for non-cosmetic purposes, can provide important data that manufacturers should be able to review, maintain and rely upon as the data already exists. The exemptions provided in the California Bill do not preclude the sale of a cosmetic for which a federally required animal test was used to substantiate safety of the product or ingredients. For example, where animal testing is required for a drug ingredient, that ingredient could still find use in cosmetic products, and that evidence could be used to substantiate safe use.
- S-214 could prohibit the sale of a cosmetic where the cosmetic or any of its ingredients were subject to animal tests, even where those animal tests were required by federal regulators to protect human health and safety. Furthermore, S-214 significantly limits the regulator's discretion to allow animal testing to protect human health and safety. The requirement for public consultation limits the ability of the regulator to act quickly in matters of health and safety. Cosmetics and ingredients may be subject to animal testing conducted to satisfy regulatory requirements in Canada under other regulatory frameworks (e.g. *Canadian Environmental Protection Act*, Workplace Health and Safety legislation), or to substantiate use for a variety of purposes or products (e.g. pharmaceuticals, NHPs, foods, cleaning products, disinfectants, other consumer goods). S-214 should recognize that there are circumstances where federal regulators may still require animal testing and that manufacturers should be able to review, maintain and rely upon this data where it exists.

6. Ability to sell-through non-compliant product: Cosmetic inventory in violation of the prohibition can to be sold for a period of 180 days.

- a. The California Bill will allow the sale of violating cosmetics for a grace period of 180 days.
- A similar grace period should be incorporated into S-214, as there is no public safety issue associated with the sell-through of stock of cosmetics that are in violation of the prohibition.