

Cosmetic Animal Testing Act

		Explanatory Notes
	An Act to amend the Food and Drugs Act (<i>cosmetic animal testing</i>)	
	Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:	
	SHORT TITLE	
Short title	1. This Act may be cited as the <i>Cosmetic Animal Testing Act</i> .	
R.S., ch. F-27	FOOD AND DRUGS ACT	
	2. The <i>Food and Drugs Act</i> is amended by adding the following after section 18:	
Definitions	18.1 (1) The following definitions apply in this section, <i>animal testing</i> means the topical application or internal administration of any substance to a live non-human vertebrate to evaluate its safety or efficacy; <i>manufacturer</i> has the same meaning as defined in section 2(1) of the <i>Cosmetic Regulations</i>. <i>ingredient</i> has the same meaning as defined in section 2(1) of the <i>Cosmetic Regulations</i>.	“<i>animal testing</i>” same definition as proposed under Bill S-214. “<i>manufacturer</i>” and “<i>ingredient</i>” same definitions as <i>Cosmetic Regulations</i>. <i>manufacturer</i> means a person, a partnership or an unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trade-mark, design, trade name or other name or mark owned or controlled by it; <i>ingredient</i> means any substance that is one of the components of a cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the cosmetic but that are not present in the final product as a result of the chemical process;

WORKING DRAFT NOV 15/18

Prohibition – testing	(2) Subject to subsection (5) no person shall conduct or cause animal testing to be conducted in Canada for the purpose of establishing the safety or efficacy of a cosmetic for human use, or its ingredients, under the provisions of this Act or regulations.	<i>Prohibition on conducting animal testing in Canada on cosmetics to meet the legal requirements to market a cosmetic product in Canada under the Food and Drugs Act and Cosmetic Regulations. Prohibition applies to all persons.</i>
Prohibition – sale	(3) Subject to subsections (4) and (5) no manufacturer or importer shall sell a cosmetic for human use, where for the purpose of satisfying the provisions of this Act or regulations, the manufacturer or importer relies on evidence from animal testing.	<i>Prohibition on sale where manufacturer or importer relies on evidence from animal testing (safety & efficacy included in definition of animal testing). Manufacturers and importers are not permitted to rely on animal testing to meet the legal requirements to market a cosmetic product in Canada under the Food and Drugs Act and Cosmetic Regulations (e.g. Food and Drugs Act s. 16, Cosmetic Regulations ss. 21 and 29). Manufacturer and importer are responsible for compliance (consistent with Cosmetic Regulations) so as not to inadvertently capture non-importer retailers.</i>
Exemption – reliance on guidance	(4) Subsection (3) does not apply to reliance on guidance, and without limiting the generality of the foregoing, any limits, levels of use, thresholds or approvals, established in accordance with the laws of Canada, or the laws of a province, even where it is based in whole or in part on evidence from animal testing.	<i>Permits reliance on limits which may be based on data from animal testing, e.g. Cosmetic Ingredient Hotlist. Intended to apply to any limits, including those established for environmental purposes or workplace health and safety.</i>
Exemption – food, drug, device	(5) This section does not apply to animal testing of any substance regulated as a [food,] drug or device.	<i>Exempts animal testing conducted on substances regulated under the FDA which are not cosmetics. Note: As FDA applies to foods, consider whether foods should be excluded for clarity as section only intended to apply to cosmetics.</i>
Existing evidence	(6) For greater certainty, a manufacturer or importer may review, assess or retain evidence from animal testing with respect to a cosmetic for human use and its ingredients, only if the animal testing was conducted in response to a requirement of a federal, provincial, or foreign regulatory authority and such use is in compliance with subsection (3).	<i>Clarifies that it is permitted to consider evidence of animal testing, only if testing conducted to meet regulatory requirement. [Note: this section is for greater certainty, it does <u>not</u> affect the clear prohibition on reliance in subsection (3).]</i>

WORKING DRAFT NOV 15/18

Power to authorize	(7) The Minister may issue an authorization, with or without conditions, that exempts any person from the application, in whole or in part of this section where (a) there is no non-animal alternative test method acceptable to the Minister to evaluate a substantiated specific human health problem associated with a cosmetic or an ingredient that is in wide use and cannot be replaced by another cosmetic or ingredient capable of performing a similar function; or	<i>Provides the Minister the ability to exempt animal testing under limited circumstances, consistent with exemption as currently provided in Bill S-214.</i>
	(b) the Minister determines that it is necessary to address a serious or imminent risk of injury to health or for the protection of human health or safety of the public.	<i>Provides the Minister with the ability to exempt animal testing, consistent with Ministerial powers to take action necessary to protect health and safety.</i>
Notice - authorization	(8) The Minister shall notify the general public of any decision by the Minister to issue an authorization under subsection (7).	<i>Requires the Minister to provide notice when authorizations to exempt animal testing are issued.</i>
Prior testing	(9) This section does not apply to animal testing conducted prior to the coming into force of this section.	<i>Clarifies that animal testing conducted prior to the coming into force of this section is exempted. Intended to allow reliance on historical data already generated prior to the coming into force of this section.</i>
Violation – notice	(10) Despite subsection (3), a cosmetic found to be in violation of this section may be sold for a period of 180 days after the day on which notice of the violation is delivered or sent to the manufacturer or importer by any method that provides proof of delivery.	<i>Provides ability to sell-through cosmetic inventory found to be in violation of this section for a period of time.</i>
Coming in force	This Act comes into force on the day that is 2 years after the date of enactment of this Act.	<i>Proposed 2 year timeline for coming into force. [Note: current S-214: 4 years]</i>

EXPLANATORY NOTES

Food and Drugs Act

Relevant definitions from the *Food and Drugs Act*:

cosmetic includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes;

device means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

- (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
- (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
- (c) diagnosing pregnancy in human beings or animals,
- (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
- (e) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal;

drug includes any substance or mixture of substances manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept;

food includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;