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Canada's Cosmetic Animal-Testing Ban: What It Means For China Testing, New Ingredients, USA

by Eileen Francis

Canada's prohibitions on cosmetic animal testing enter into force in December, largely in line with EU, California and other bans around the globe, but with some notable distinctions. "Now it's really time to increase the pressure in the US – action can't be far behind," says Brandi Halls, chief ethics officer at Lush Cosmetics, North America.

Beginning on 22 December, no cosmetic product will be permitted for sale in Canada unless its safety can be substantiated without the use of data derived from animal testing after that date.

Passed as part of the Budget Implementation Act (<u>C-47</u>) on 22 June, Canada's cosmetic animaltesting ban aligns closely with EU regulations and California law, among other prohibitions spreading around the globe.

"By implementing these changes, Canada is aligning with the global shift toward ethical cosmetic testing by joining other countries, including all European Union countries, Australia, the United Kingdom and South Korea, that have already taken measure to prohibit cosmetic animal testing," Health Canada says in a 27 June release.

Animal-welfare groups are celebrating the victory. According to Michael Bernard, deputy director of the Humane Society International (HIS) in Canada, "This legislation truly shows the great things that can happen when government, industry, the non-profit sector, and the public work together to create a better future."

Lush Cosmetics North America also welcomed the news, noting it has worked since 2013 in partnership with HSI and the Animal Alliance of Canada to achieve the Canadian ban. "Through campaigning in Lush shops, co-presenting to Parliament committee hearings, and engaging

more than 150,000 people to send message to the Canadian government, an overwhelming 87% of Canadians support this nationwide ban on animal testing for cosmetics," says Brandi Halls, chief ethics officer at Lush Cosmetics, North America, in the company's own release.

"Cosmetics Alliance is working with Health Canada on the creation of a Cdn. Government-issued GMP Certificate that would exempt Cdn. products exported to China from any Chinese regulatory requirement for testing on animals."

Advances in in vitro and in silico methods for safety assessment and regulatory measures already taken in the EU and other jurisdictions have significantly reduced animal testing for cosmetics purposes worldwide. Health Canada notes that such testing "was rarely conducted in Canada."

However, instances remain in this increasingly cruelty-free world where cosmetic products or ingredients could be tested on animals or considered for such testing.

China

China has relaxed its cosmetic animal-testing requirements in recent years, providing exemptions for non-special use ("ordinary") cosmetics, including most skin- and hair-care products, nail-care products, makeup, and perfumes.

However, the Personal Care Products Council and other stakeholders say securing exemptions can be challenging, and animal testing still is regularly required for special-use cosmetics – including SPF products, whitening products, deodorants, hair dyes, hair perming products, hair-growth products and other categories deemed higher-risk –as well as new ingredients. (Also see "PCPC Raises 'Grave Concerns' About China's Cosmetic Regs, Possible WHO Treaty Noncompliance" – HBW Insight, 18 Nov, 2022.)

Cruelty-free, vegan and sustainable beauty site Ethical Elephant provides a useful *graphic* depicting the animal-testing gauntlet that cosmetics companies must run in China.

Debate over whether a cosmetic product sold in the EU that undergoes mandatory animal testing in China is in violation of Article 18 of the Cosmetic Products Regulation rose all the way to the European Court of Justice. The EU's highest court determined in 2016 that companies cannot use safety data derived from third-country animal testing to substantiate product safety in accordance with the Cosmetic Products Regulation, but such testing does not in itself constitute

a violation of the EU's animal-testing ban. (Also see "*Landmark EU Ruling: Animal-Tested Cosmetic Ingredients Not Banned Per Se*" - HBW Insight, 21 Sep, 2016.)

The same principle is embodied in Canada's new law, in that reliance on third-country animal-testing data to comply with EU safety substantiation requirements is what triggers a violation, not the third-country animal testing per se.

"The Canadian legislation has no bearing on what happens in China," affirmed Susan Nieuwhof, public policy and communications at Cosmetics Alliance Canada, in a 19 July email. "If a Cdn-based manufacturer wishes to export their products to China and China needs animal test data, the Canadian manufacturer cannot test on animals in Canada as per the new legislation (there is no carve out for China). However, if China tests the imported cosmetics once they arrive in China on animals, that is their business. Canada can't control or dictate that."

That said, under Canada's new law "[n]o person shall make a claim on the label of or in an advertisement for a cosmetic that is likely to create an impression that the cosmetic was not tested on animals after the day on which this section comes into force unless the person has evidence that no such testing occurred after that day."

Ostensibly, that means that cruelty-free claims are off-limits in Canada for cosmetic products affected by animal testing in China or other foreign regimes. Per Bernard, "Canadian consumers can finally rest assured that the cosmetics they purchase have not come as a result of animal suffering – and that is something we can all feel good about."

Nieuwhof noted that Cosmetics Alliance Canada members, if they had their druthers, would not subject their products to animal testing in China or anywhere else in the world. "Cosmetics Alliance is working with Health Canada on the creation of a Cdn. Government-issued GMP Certificate that would exempt Cdn. products exported to China from any Chinese regulatory requirement for testing on animals," she said, referring to one of China's exemption criteria for ordinary cosmetic animal testing. (Also see "China's Cosmetic Animal-Testing Exemption 'Not Yet A Terribly Meaningful Solution' – PCPC" - HBW Insight, 22 Sep, 2020.)

New Ingredients

Canada's animal-testing ban dictates that "[n]o person shall sell a cosmetic unless the person can establish the safety of the cosmetic without relying on data derived from a test conducted on an animal [after 22 December 2023] that could cause pain, suffering or injury, whether physical or mental, to the animal."

There are some exceptions [see box].

Nieuwhof explained, "Finished products sold in Canada must not rely on animal test data to

support their safety (which isn't a problem because finished products don't need to be tested on animals), AND the ingredients used in that product must not have been testing on animals going forward – which may only be a problem for brand new ingredients with no history of safe use for which there are no non-animal alternative test method to prove the ingredients toxicological safety." (Also see "*EU Motivated Like Never Before To Advance Non-Animal Methods For Chemical Assessment*" - HBW Insight, 16 Jun, 2023.)

She added, "But this would be rare as very few ingredients are exclusive to cosmetics." She gave the example of a new cosmetic preservative that already has been shown to be safe via animal testing in drug or food products per regulatory requirements in the EU or abroad. Data from such testing would be permitted to support cosmetic product safety in Canada under the new law's exemptions.

Multinationals should be aware that California's Sherman Food, Drug and Cosmetic Act was amended in 2018 to ban the sale of cosmetics tainted by animal testing, and it forbids companies from using new non-cosmetic animal testing data to substantiate the safety of cosmetic products sold in California, the world's fifth largest economy. (Also see "California Passes Cruelty-Free Cosmetics Act: Now Friendlier To Industry, Still A Legal Minefield " - HBW Insight, 3 Sep, 2018.)

The Sherman Act parallels the US Food, Drug and Cosmetic Act, which was amended in late 2022 by the Modernization of Cosmetic Regulations Act (MoCRA), making cosmetics manufacturers' safety substantiation records much more accessible to regulatory officials. (Also see "Cosmetic Manufacturers Preparing For MoCRA Safety Substantiation Should Look To EU – Attorneys" - HBW Insight, 4 May, 2023.)

US

While around a dozen US states have

Exceptions to prohibition on new animal data to establish cosmetic product safety in Canada:

- the government of Canada has published the data in a scientific journal or on a government of Canada website;
- the data is publicly available and is derived from a test that was not sponsored by or conducted by or on behalf of a person who manufactures, imports or sells the cosmetic;
- the following conditions are met:
- 1. the data is derived from a test that was conducted on a substance in order to meet (a) a requirement under a provision of an Act of Parliament or any of its regulations that applied at the time that the test was conducted, except a requirement that relates only to cosmetics under a provision of this Act or the regulations, or (b) a requirement that does not relate to

passed legislation to end cosmetic animal testing, a federal ban has yet to materialize.

The proposed Humane Cosmetics Act has been introduced repeatedly on Capitol Hill without success. In the last (117th) US Congress, *the bill* – which would have banned the sale of cosmetics developed or manufactured using [new] cosmetic animal testing that was conducted or contracted for by any person in the cosmetic product's supply chain – garnered 19 cosponsors in the Senate and 187 in the House, but failed to advance out of committee.

Administration has advised cosmetics companies to do whatever testing is necessary to substantiate the safety of their products and ingredients prior to marketing. As alternative testing methods for key safety endpoints have yet to be developed, validated and regulatory-approved, the agency has not seemed keen on adapting its stance to renounce animal testing entirely.

cosmetics under the law that applied in a foreign state at the time that the test was conducted.

- 2. the substance is or has ben used in a product that is not a cosmetic and that is or has been legally sold in the country where the requirement in question applied, and
- 3. the test was necessary to meet the requirement in order to sell the product in that country.
- the data is derived from a test that was conducted before the day on which this section comes into force;
- the cosmetic was sold in Canada at any time before the day on which this section comes into force; or
- any prescribed circumstance applies.

Asked at a 2017 industry regulatory workshop whether the FDA was comfortable with cosmetics companies using unvalidated alternative methods to substantiate the safety of their products, Linda Katz, director of the agency's Office of Cosmetics and Colors, acknowledged, "We allow you the option to do whatever you feel is appropriate, provided that you can show us that what you've done is appropriate."

She added, "Remember though, if you're relying on something and there is a problem, someone's going to come and ask what you relied on to show that your product and your ingredient were safe. If you're relying on a method that's not validated, you may have a problem." (Also see "California's Cruelty-Free Cosmetics Act Makes New Ingredients Officially Endangered" - HBW Insight, 3 Sep, 2018.)

MoCRA provides that "[i]t is the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances."

In response the FDA <u>notes</u> on its website that animal testing is not a requirement for marketing a cosmetic product in the US. "It's important, however, that all data used to support the safety are derived from scientifically robust methods," the agency says.

Animal-welfare groups, LUSH Cosmetics and other advocates are hopeful that Canada's ban on cosmetic animal testing will spark new movement in the US to follow suit.

Lush says its support has resulted in more than \$2m of funding to end the use of animals in research. There are more than 20,000 cosmetic ingredients that have been established as safe, as well as a growing number of "proven, non-animal test methods that are scientifically superior, faster and cheaper than their cruel alternatives," according to the Fresh Homemade Cosmetics maker.

Health Canada is committed to continued work with the international scientific and regulatory community to develop, validate and implement effective alternatives to animal testing. "This includes providing continued leadership and contributions to the work of various committees and organizations, such as the Organisation for Economic Co-Operation and Development (OECD) and the International Cooperation on Alternative Test Methods," it says.

In a June report to the European Commission, the European Chemicals Agency notes that use of alternative methods for assessing chemical properties and risks under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation have increased dramatically in recent years. However, full replacement of in vivo studies with validated non-animal methods to assess chemical safety remains out of reach.

For complex toxicological endpoints, such as repeated dose toxicity, reproductive toxicity, carcinogenicity and long-term aquatic toxicity or bioaccumulation, mandatory information requirements under EU chemical regulations still rely on animal testing, ECHA says. (Also see "EU Motivated Like Never Before To Advance Non-Animal Methods For Chemical Assessment" - HBW Insight, 16 Jun, 2023.)