

Humane Cosmetics Act

The Humane Society of the United States, Humane Society Legislative Fund, and the Personal Care Products Council support the expeditious, bipartisan passage of the Humane Cosmetics Act. Enactment of this legislation is critically important to ensure a uniform standard for animal welfare, while continuing to support the development of safe and innovative cosmetics and personal care products.

The Humane Cosmetics Act will: 1) prohibit new animal testing of cosmetics and their components; and 2) prohibit the sale in the United States of cosmetics that have undergone cosmetic animal testing one year after the date of enactment of the bill.

Important provisions related to new testing:

- **Foreign Regulatory Requirements:** While US law cannot change the laws of other countries, for example animal testing required by and conducted in China, the bill specifically prohibits companies from using any data generated by such tests to substantiate the safety of a cosmetic sold in the United States.
- **Non-cosmetic animal testing:** Most cosmetic manufacturers do not presently test cosmetic ingredients on animals to satisfy cosmetic safety needs, but in some cases, ingredients may be tested for non-cosmetic purposes, such as for chemical management programs (e.g., EU REACH), pharmaceutical regulations, etc. The bill would not prohibit the use of such ingredients in cosmetic products, however, cosmetic manufacturers would be allowed to rely on the data from non-cosmetic testing only under certain specified conditions:
 - There is a specific requirement from a federal, state or regulatory authority to conduct the test;
 - No non-animal method is available for the relevant safety endpoint;
 - Evidence of the non-cosmetic purpose of the test is documented; and
 - There is a history of use of the ingredient outside of cosmetics at least 1 year prior to the reliance.

FDA may ask to see documentation demonstrating compliance to these requirements, and the bill would provide FDA with streamlined authority to access such records.

Additional provisions to address emerging science and transparency:

- **FDA strategic plan:** The bill requires FDA to develop a strategic plan to promote the development and implementation of alternative test methods and strategies to replace vertebrate animal testing for assessing the safety of cosmetics. This is intended to facilitate additional engagement by FDA on non-animal methods (similar to what happened in EPA with TSCA reform), and we hope will bring greater awareness of new methods to all centers and staff at FDA.
- **Report to Congress:** Every 2 years, the Secretary must submit a report to Congress and make it available on the FDA website. The report must include (1) updates on the FDA strategic plan implementation, (2) the number of times the Secretary requested new animal test data for ingredients of concern including the ingredients involved, and the animal tests performed, and (3) the number of times manufacturers relied upon data developed for non-cosmetic purposes in the records reviewed by FDA in that period.

Annual meetings: The bill requires the Secretary to hold annual public meetings including scientific and academic experts, animal and consumer advocacy groups, and the regulated industry on the advancement of alternative test methods and strategies to replace animal testing for assessing the safety of cosmetics.

Provisions regarding existing FDA requirements or authority:

- **Over-the-Counter Drugs (OTCs):** In the US, many products like sunscreens, anti-dandruff shampoos or antiperspirants are regulated as OTCs. The bill exempts this class of ingredients/products, as the FDA has specific monographs for safety substantiation and efficacy of these ingredients.

- **Ingredients of concern:** There is a limited exemption for testing specifically requested by FDA in the event that any potential safety issues arise in the future, and this is similar to an exemption that is possible under the EU cosmetic animal test ban. Specifically, the Secretary must publish a written finding that:
 - There is no non-animal alternative method or strategy for the relevant safety endpoint;
 - The cosmetic ingredient or non-functional constituent poses a risk of causing serious adverse health consequences or death;
 - The cosmetic ingredient is in wide use and cannot be replaced by another; and
 - There is no previously generated animal data available for review that can replace the new animal testing requested/conducted.

- **Preemption:**
 - The bill preempts state laws regulating cosmetic animal testing – there are currently three (CA, IL, NV). A uniform standard for all 50 states has the most positive impact for animal welfare by eliminating or reducing new animal testing without creating barriers to marketing products under different regulatory environments in different states.

- **Consumer Transparency with Cruelty-free Labeling:**
 - This provision provides consumers additional clarity and transparency. Manufacturers would not be allowed to use the term “cruelty free” or other similar words or logos indicating the cosmetic was not tested on animals if:
 - New animal testing was conducted by or contracted for by the cosmetic product manufacturer or another person in the supply chain at the direction or request of the cosmetic product manufacturer. This includes testing without regard to the jurisdiction.
 - The manufacturer relies on the new animal test data produced for non-cosmetic purposes.
 - The cosmetic product manufacturer may include a claim if—
 - testing is for non-cosmetic purposes and the cosmetic manufacturer did not rely upon evidence; or
 - in the case of animal testing conducted outside the manufacturer’s control but the manufacturer relied on the new animal data, the manufacturer’s label must include a disclosure describing the circumstances surrounding the use of the exemption including a reference to the specific federal, state, or foreign requirement under which the animal testing was conducted or a reference to a publicly available internet website of the manufacturer that provides the disclosure.