

**REPORT ON LEGISLATION
BY THE ANIMAL LAW COMMITTEE**

S.1113

Sen. Feinstein

AN ACT to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics.

Personal Care Products Safety Act

I. SUMMARY OF PROPOSED LEGISLATION

The Personal Care Products Safety Act (PCPSA or the Act)¹ would amend Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 361 *et seq.*) to require cosmetics companies to register their facilities with the Food and Drug Administration (FDA) and to submit to the FDA cosmetic ingredient statements that include the amounts of its products' ingredients. The Federal Food, Drug, and Cosmetic Act defines a cosmetic as something "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance...[or] intended for use as a component of any such articles; except that such term shall not include soap."²

Currently, manufacturers and processors of cosmetic companies and formulations may voluntarily register with the FDA and there is no mandatory FDA review of cosmetic ingredients, with the exception of color additives. Under the PCPSA, manufacturers and processors of cosmetic products and formulations distributed in the United States would be required to pay a facility registration fee based on their annual gross sales of cosmetics, to file cosmetic ingredient statements, and to allow the FDA to inspect their cosmetic safety records. If the FDA determines that a cosmetic has a reasonable probability of causing serious adverse health consequences, it would be able to prohibit the cosmetic's distribution by suspending the cosmetic ingredient statement. If other cosmetics from the same facility may be affected, the FDA would be able to prohibit distribution of multiple or all products from the facility by suspending the facility's registration. Cosmetic companies would be required to report to the FDA any serious adverse health event associated with their cosmetics.

¹ S. 1014, Personal Care Products Safety Act, summary, 114th Congress, <https://www.congress.gov/bill/114th-congress/senate-bill/1014>.

² 21 U.S.C. § 321.

The FDA would be required to review the safety of at least five cosmetic ingredients each year, and it would be authorized to establish conditions for safe use of an ingredient, including a limit on the amount of the ingredient or a requirement for a warning label. A cosmetic would be banned from sales if it contains an ingredient that is not safe, not safe under the recommended conditions of use, or not safe in the amount present in the cosmetic. In addition, the Act would require the FDA to develop and implement cosmetic manufacturing standards that are consistent with existing national and international standards and recall a cosmetic that is likely to cause serious adverse health consequences.

Section 108 of the PCPSA would add a new section 616 to the Federal Food, Drug, and Cosmetics Act that seeks to minimize the use of animal testing for cosmetics, including by requiring the FDA to issue guidance on the acceptability of scientifically reliable and relevant alternatives to animal testing and by providing online resources about such alternatives.

II. THE ANIMAL LAW COMMITTEE URGES REVISIONS TO SECTION 108 OF THE BILL

The results of a 2004 survey suggest that the average adult uses nine personal care products each day, with 126 unique chemical ingredients, and that some such consumers are exposed to probable or possible carcinogens through their use of personal care products.³ Women use more cosmetics and face greater risks than men.⁴ The purpose of the PCPSA is to promote the safety of cosmetics consumers and workers, such as hair salon employees, who work with cosmetic products.⁵ If enacted, it would be the most significant change to the Federal Food, Drug, and Cosmetic Act in over 70 years.

Numerous health organizations, such as the March of Dimes, American Cancer Society Cancer Action Network, and National Women's Health Network, support the PCPSA. And many cosmetics industry groups and manufacturers also support the PCPSA, such as Unilever, Johnson & Johnson, L'Oreal, and the Personal Care Products Council. Yet the PCPSA has been criticized by animal advocacy organizations due to its failure to prohibit animal testing.⁶

Although the purpose of the PCPSA is commendable and there is a demonstrated need for increased regulations to ensure cosmetic safety, the Animal Law Committee opposes the

³ Environmental Working Group, *Exposures add up – Survey results* (June 15, 2016), <http://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results>. (All websites last visited Dec. 26, 2016.)

⁴ *Id.*

⁵ Statement of Senator Susan M. Collins, United States Senate Committee on Health, Education, Labor and Pensions, Full Committee Hearing, Exploring Current Practices in Cosmetic Development and Safety (Sept. 22, 2016), <http://www.help.senate.gov/imo/media/doc/Collins9.pdf>.

⁶ E.g., The National Anti-Vivisection Society, http://act.navs.org/site/MessageViewer?em_id=1881.0&dlv_id=5851#.WGHSc6IrLdQ; the American Anti-Vivisection Society, <http://aavs.org/news/activate-animals-march-2016>; Physicians Committee for Responsible Medicine, *Physicians Committee Scientists Oppose Personal Care Products Safety Act*

Unless Explicit Ban on Animal Testing is Included, <http://www.pcrm.org/sites/default/files/S1014-cosmetics-bill-statement.pdf>.

PCPSA unless Section 108 is replaced with a ban on animal testing. We believe that a ban is necessary on the grounds that, without a ban on animal testing, the PCPSA could result in more testing on animals. Further, available safety testing methods that do not use animals or that greatly reduce the use of animals tend to be more accurate⁷ and less expensive;⁸ such methods should be required, not encouraged. Finally, we note that animal testing is prohibited in the European Union and other jurisdictions.

The Animal Law Committee has supported legislation to restrict animal testing and animal experimentation, including the Humane Cosmetics Act (H.R.2858, 114th Congress).⁹ We urge the sponsors to revise the PCPSA to incorporate the Humane Cosmetics Act's prohibition on animal testing.

A. Without a ban on animal testing, the PCPSA could result in more testing on animals.

The PCPSA would require that each cosmetic company make a written determination as to a product's safety prior to distributing the product for sale.¹⁰ The PCPSA provides for two methods for making such a determination: either a reference to an official statement of a medical or scientific body as to each cosmetic ingredient's safety or "appropriate safety testing of the ingredient."¹¹ We are concerned that the second option for safety testing could increase cosmetics companies' use of animal testing despite the fact that Section 108 of the PCPSA requires the FDA to "encourage" alternatives to animal testing.

Cosmetic animal testing is not currently required by the FDA for any cosmetic product or ingredient.¹² According to the Personal Care Products Council, a national trade association of

⁷ E.g., Thomas Hartung, *Food for Thought ... on Animal Tests*, ALTEX 4 (2008) (correlation between humans and laboratory animals is about 60% depending on the animal; even a substance found to be safe in monkeys caused multiple organ failure in human subjects within hours), http://www.altex.ch/resources/altex_2008_1_3_9_FFT_HartungE.pdf.

⁸ E.g., Jim Moran & Paul A. Locke, *Beauty and the Beasts: The U.S. Should Ban Testing Cosmetics on Animals*, SCIENTIFIC AMERICAN (May 28, 2014), <https://www.scientificamerican.com/article/beauty-and-the-beasts-the-u-s-should-ban-testing-cosmetics-on-animals> ("[M]any multinational companies have embraced these alternative test methods, reducing and in some cases eliminating their dependence on animal testing. As a result, they cut costs and save time; animal testing is expensive, slow and, because animals are not people, not always predictive."); Thomas Hartung, *From Alternative Methods to a New Regulatory Toxicology*, ALTEX PROCEEDINGS 24 (Jan. 2013), http://altweb.jhsph.edu/altex/proceedings/2_1/Hartung1.pdf ("Another problem is that testing in animals is far too expensive and laborious: To determine whether a substance is carcinogenic, for example, takes four years and costs about one million dollars.")

⁹ New York City Bar Association Animal Law Committee reports, *Report on the Humane Cosmetics Act* (Nov. 2014), <http://www2.nycbar.org/pdf/report/uploads/20072807-ReportonHumaneCosmeticsAct.pdf>; and *Report in Support of Legislation to Prohibit Vivisection at NYS Colleges and Universities* (Apr. 2016), <http://www2.nycbar.org/pdf/report/uploads/20073071-ReportonVivisectionBillANIMALS4252016.pdf>.

¹⁰ PCPSA § 609(a)(1).

¹¹ PCPSA § 609(b)(1)(A).

¹² FDA, *Cosmetics Safety Q&A: Animal Testing*, ("The Federal Food, Drug, and Cosmetic Act does not specifically require the use of animals in testing cosmetics for safety, nor does it subject cosmetics to FDA premarket approval"), <http://www.fda.gov/cosmetics/resources/forconsumers/consumers/ucm167216.htm>.

over 600 personal care products manufacturers, cosmetic companies have largely ceased testing finished products on animals except when required by government regulations or when testing a new ingredient where there is no viable alternative.¹³ But according to animal advocacy groups, testing of new cosmetic ingredients still results in the deaths of thousands of animals a year.¹⁴ The Council has advocated for testing methods that do not use animals and in fact has provided grant funds to research alternative testing methods, but it claims that the FDA has not yet accepted some such alternative methods.¹⁵ Yet federal government agencies have approved the use of numerous safety tests to replace traditional animal testing methods, including skin and eye irritation tests,¹⁶ and are continuing to approve new methods through the work of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).¹⁷

B. Available safety testing methods that do not use animals tend to be more accurate and less expensive; such methods should be required, not encouraged.

Each year, thousands of animals, including rabbits, guinea pigs, rats and mice, are subjected to cosmetics testing in the United States.¹⁸ Animals subjected to these tests commonly experience significant pain over a protracted period of time and rarely receive pain relief.¹⁹

¹³ Statement by John Hurson, Executive Vice President, Government Affairs, Personal Care Products Council on the Humane Cosmetics Act (H.R. 2858) (July 1, 2015), <http://www.personalcarecouncil.org/newsroom/20150701>.

¹⁴ E.g., Humane Society of the United States (HSUS), *Cosmetic Tests that Use Animals*, http://www.humanesociety.org/issues/cosmetic_testing/tips/common_cosmetics_tests_animals.html#.U11QvaKn9D0.

¹⁵ *Id.*

¹⁶ U.S. Dept. of Health & Human Svcs., *Alternative Methods Accepted by U.S. Agencies*, <https://ntp.niehs.nih.gov/pubhealth/evalatm/accept-methods/index.html>; see also AltTox.org, *Table Of Validated & Accepted Alternative Methods* (last updated June 23, 2016), <http://alttox.org/mapp/table-of-validated-and-accepted-alternative-methods>.

¹⁷ The ICCVAM was formally established in 2000 by the ICCVAM Authorization Act (42 U.S.C. § 2851-3) to:

establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

¹⁸ HSUS, *Cosmetic Tests that Use Animals*, http://www.humanesociety.org/issues/cosmetic_testing/tips/common_cosmetics_tests_animals.html. A precise number of animals used in cosmetic testing is unknown because there are no laws requiring disclosure of the number of animals a company uses in animal testing. Christina Russo, *Think Your Lipstick Is Cruelty-Free? Think Again*, THEODO.COM (Apr. 23, 2015), <https://www.thedodo.com/lipstick-cruelty-free-testing-1106829870.html>.

¹⁹ Animal Legal Defense Fund, *Animal Testing and the Law*, <http://aldf.org/wp-content/uploads/2013/08/animal-testing-and-the-law.pdf> (“Animals in labs are routinely mutilated and subjected to physical and psychological torment—often they are restrained and cut open without painkillers.”); E.g., S. Parasuraman, *Toxicological Screening*, J. OF PHARMACOLOGY & PHARMACOTHERAPEUTICS 76 (Apr. – June 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127354/> (For example, subchronic toxicity studies are carried out over 90 days; repeated dose toxicity studies are conducted for a period of 28 days; and the ocular Draize test is usually conducted for 14 days.)

Animals are commonly killed at the completion of the test,²⁰ by methods including asphyxiation, neck breaking, and decapitation.²¹ In the acute oral toxicity variation of the LD50 test, for example, a cosmetic product or ingredient is administered to rats or mice and used to determine what amount of a particular substance, when ingested, will cause half of animals to die within fourteen days of exposure.²² The substance is forcefully administered down the rat's throat in a feeding tube, and commonly causes the animal to suffer from extreme and prolonged pain through convulsions, bleeding from the mouth, seizures, and paralysis.²³ Another example is the Draize eye test, in which a cosmetic product or ingredient is administered into rabbits' eyes and left untreated over a seven-day period or longer without anesthesia, resulting in bleeding, ulceration and blindness.²⁴ The rabbits' eyes are often held open with clips at the lid, and the rabbits may break their necks or backs struggling to escape from the pain.²⁵

Additionally, cosmetic animal testing has failed to demonstrate true product safety due to its inherent unreliability and inaccuracy. Animal tests to show a cosmetic's toxicity "have never been validated by a regulatory body," and thus "represent an outdated science of techniques that are not adequate to predict human safety."²⁶ Specifically, animal test results do not always predict human effects,²⁷ since animals and humans have "differences in absorption, distribution, metabolism, and excretion of chemicals."²⁸ For example, the Draize eye test has been criticized because a rabbit eye's cornea is structured differently than that of a human.²⁹ Rabbits also produce fewer tears than humans, which means chemicals linger longer and cause greater

²⁰ HSUS, *Cosmetic Tests that Use Animals*, http://www.humanesociety.org/issues/cosmetic_testing/tips/common_cosmetics_tests_animals.html.

²¹ E.g., University of Minnesota, Research Animal Resources, Acceptable Methods for Euthanasia of Animals, <http://www.ahc.umn.edu/rar/euthanasia.html>; University of California Riverside, Office of Research and Development, Guidelines for Euthanasia, <https://research.ucr.edu/ocv/laboratory-animal-guide/euthanasia.aspx>.

²² E.g., Erik Walum, *Acute Oral Toxicity*, ENVIRONMENTAL HEALTH PERSPECTIVES 497 (Apr. 1998), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533392/pdf/envhper00537-0100.pdf>.

²³ Humane Society of the United States (HSUS), Fact Sheet: Cosmetic Testing, http://www.humanesociety.org/issues/cosmetic_testing/qa/questions_answers.html; see also New England Anti-Vivisection Society (NEAVS), *Product Development and Drug Testing*, <http://www.neavs.org/research/testing>.

²⁴ *Id.* See also Johns Hopkins Bloomberg School of Public Health, Center For Alternatives To Animal Testing, FAQs, <http://altweb.jhsph.edu/resources/faqs.html>.

²⁵ NEAVS, *supra* note 23. See also Katie C. Galanes, Detailed Discussion of Animal Testing in Commercial Products, Michigan State University College of Law (2010), <http://www.animallaw.info/articles/ddusanimaltesting.htm>.

²⁶ Press Release, HSUS, Federal Bill to End Cosmetics Testing on Animals Introduced in Congress (Mar. 5, 2014) http://www.humanesociety.org/news/press_releases/2014/02/federal_bill_to_end_cosmetics_testing_introduced_in_Congress.html.

²⁷ Jim Moran & Paul A. Locke, *Beauty and the Beasts: The U.S. Should Ban Testing Cosmetics on Animals*, SCIENTIFIC AMERICAN (May 28, 2014), <https://www.scientificamerican.com/article/beauty-and-the-beasts-the-u-s-should-ban-testing-cosmetics-on-animals>.

²⁸ Vicki Katrinak, *Blinded for Beauty: Rabbits Used in Product Testing*, AV MAGAZINE 6 (Winter 2007), http://aavs.org/cms/assets/uploads/2015/06/aavs_av-magazine_2007-winter_rabbits.pdf.

²⁹ *Id.*

irritation than in a human eye.³⁰ Similarly, the Draize skin test has been criticized because animals have very different skin than that of humans.³¹ Further, scientists' subjective observations during the tests and the differences of reactions from animal to animal make it very difficult to routinely reproduce the Draize score for a product.³²

Non-animal methods of product safety testing of cosmetics provide a superior alternative to animal tests.³³ These non-animal methods include computational or in silico models,³⁴ which “are based on human biology and are more predictive of human reactions than animal tests”³⁵ as well as vitro models which use tissue and cells.³⁶ The FDA publicly supports the use and development of alternatives to animal testing, and has stated that it “will continue to be a strong advocate of methodologies for the refinement, reduction, and replacement of animal tests with alternative methodologies that do not employ the use of animals.”³⁷

C. Animal testing is prohibited in the European Union and other jurisdictions.

Section 610(a) of the PCPSA requires the FDA to review national and international standards for cosmetic good manufacturing practice and promulgate regulations that are consistent with such standards to the extent the FDA determines it is practicable and appropriate. Although Section 610(a) is commendable, it does not go far enough, given that numerous jurisdictions already ban animal testing for cosmetics.

The European Union prohibits animal testing of finished cosmetic products³⁸ and of ingredients in cosmetics products.³⁹ New Zealand “bans the use of animals to test finished cosmetic products or ingredients that are intended for use exclusively in cosmetics.”⁴⁰ Israel bans

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ Katrinak, *supra* note 28.

³⁴ See National Antivivisection Society (NAVS), *The Use of Animals in Product Testing*,

<http://www.navs.org/what-we-do/keep-you-informed/science-corner/areas-of-science-that-use-animals/animals-in-testing/#.WGG506IrLdQ>; see generally Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, *FAQs*, <http://altweb.jhsph.edu/resources/faqs.html#3>.

³⁵ Press Release, HSUS, Federal Bill to End Cosmetics Testing on Animals Introduced in Congress (Mar. 5, 2014), http://www.humanesociety.org/news/press_releases/2014/02/federal_bill_to_end_cosmetics_testing_introduced_in_Congress.html.

³⁶ Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, *supra* note 34.

³⁷ *Id.*

³⁸ Regulation (EC) No 1223/2009 (Nov. 30, 2009), § 41.

³⁹ *Id.* at § 43.

⁴⁰ New Zealand Animal Welfare Amendment Act (No 2) 2015 § 84(A), <http://www.legislation.govt.nz/act/public/2015/0049/latest/DLM6432504.html>.

cosmetic animal testing and the import and marketing of cosmetic products tested on animals.⁴¹ India also bans cosmetic animal testing and the import of cosmetic products tested on animals.⁴² Four Brazilian states ban cosmetic animal testing.⁴³ South Korea has a ban.⁴⁴ In 2016, the Australian Government committed to introduce a ban on animal testing of cosmetic products.⁴⁵ And several other countries and states have enacted or are considering bans on animal testing of cosmetics.

D. An animal testing ban in the United States would encourage China and other countries to also adopt animal testing bans in order to more easily access the lucrative United States cosmetics market.

The European Union has the largest global cosmetics market, valued at €77 billion (\$89.82 billion) in 2015, followed by the United States with a value of €64 billion (\$74.65 billion) and China with €41 billion (\$47.82 billion).⁴⁶

Currently, American cosmetic companies must comply with divergent regulations to sell products in both the European and Chinese markets. In September 2016, the High Court of Justice of the European Union addressed the conflict between Chinese laws and the European Union prohibition against animal testing. The Court ruled that the ban includes cosmetics that contain ingredients tested on animals outside the European Union for purposes of marketing the products in a third country if the animal testing data is used to prove the product's safety.⁴⁷ Under this ruling, an American company could not, therefore, rely upon data collected through animal testing that complied with Chinese regulations to sell its product in the lucrative European market.⁴⁸

⁴¹ Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, *Import Ban on Animal-Tested Products Goes into Effect in Israel*, http://altweb.jhsph.edu/news/2012/Israel_bans_testing.html.

⁴² Vishwa Mohan, *India bans import of cosmetics tested on animals*, THE TIMES OF INDIA (Oct. 14, 2014), <http://timesofindia.indiatimes.com/india/India-bans-import-of-cosmetics-tested-on-animals/articleshow/44814398.cms>.

⁴³ Humane Society International, *Brazilian State of Pará Bans Animal Testing for Cosmetics* (May 17, 2016), http://www.hsi.org/news/press_releases/2016/05/brazilian-state-of-para-bans-animal-testing-for-cosmetics-051716.html?referrer=https://www.google.com.

⁴⁴ *S. Korea to Penalize Animal-Tested Cosmetics*, THE KOREA TIMES (Nov. 28, 2016), http://www.koreatimes.co.kr/www/news/nation/2016/11/116_219046.html.

⁴⁵ Australian Government, Department of Health, *Ban on Cosmetic Testing on Animals*, <http://www.health.gov.au/internet/main/publishing.nsf/Content/ban-cosmetic-testing-animals>.

⁴⁶ Cosmetics Europe, *Cosmetics and Personal Care Industry Overview: Economic Overview*, <https://www.cosmeticseurope.eu/cosmetics-industry/>

⁴⁷ Judgment of 21 September 2016, High Court of Justice of the European Union, *European Federation for Cosmetic Ingredients*, C-592/14, ECLI:EU:C:2016:703, paragraph 46, <http://curia.europa.eu/juris/document/document.jsf?text=&docid=183602&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=283312>.

⁴⁸ Humane Society International, *CFDA adjusts requirements for imported regular cosmetics in Shanghai Free Trade Area* (Jan. 20, 2017), http://www.hsi.org/news/press_releases/2017/01/cfda-cosmetics-requirements-adjusted-012017.html.

The China Food and Drug Administration (CFDA) has recently released regulations that indicate the country is shifting away from mandatory animal testing. In June 2014, the CFDA removed mandatory animal testing on domestically manufactured general cosmetics⁴⁹ and, in March 2017, the agency passed a temporary measure that allowed some imported general cosmetics to avoid animal testing.⁵⁰

A ban on animal testing in the United States would encourage China to continue its movement towards a reversal of its animal testing requirements. Although a testing ban in the PCPSA would not automatically preclude China from marketing any and all products in the United States, it would require Chinese manufacturers to test those products separately and in addition to those products tested on animals pursuant to Chinese law and intended for the Chinese market. This additional pressure on Chinese manufacturers would provide a significant incentive to China to reduce or eliminate its testing requirements rather than risk losing a combined market of approximately \$214.63 billion, including the first, second, fourth, fifth and seventh largest global markets — European Union, United States, Brazil, India and South Korea.⁵¹ Conversely, allowing animal testing in the United States would encourage China to retain its mandate and demand that U.S. companies bear the financial costs of complying with the conflicting regulations to access both the Chinese and European markets.

III. SUMMARY

For the reasons explained above, the Animal Law Committee opposes the PCPSA unless section 108 is revised to ban animal testing.

Animal Law Committee
Lori Barrett-Peterson, Chair

December 2017

⁴⁹ Humane Society International, *China's Cosmetics Animal Testing FAQ*, http://www.hsi.org/assets/pdfs/bcf_china_cosmetics.pdf

⁵⁰ Humane Society International, *CFDA adjusts requirements for imported regular cosmetics in Shanghai Free Trade Area* (Jan. 20, 2017), http://www.hsi.org/news/press_releases/2017/01/cfda-cosmetics-requirements-adjusted-012017.html.

⁵¹ Cosmetics Europe, *Cosmetics and Personal Care Industry Overview: Economic Overview*, <https://www.cosmeticseurope.eu/cosmetics-industry/>.