



July 7, 2015

Senator David Vitter  
U.S. Senate  
516 Hart Senate Office Building  
Washington, DC 20510

Senator Tom Udall  
U.S. Senate  
531 Hart Senate Office Building  
Washington, DC 20510

Dear Senators Vitter and Udall:

On behalf of The Humane Society of the United States and the Humane Society Legislative Fund, we are writing to express our support for S. 697, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, a bill promoting the use of best available science for regulating chemicals while providing for animal protection. Our support is grounded upon several animal protection provisions that are unprecedented in federal legislation in requiring the use of accepted non-animal-based testing methods (see addendum).

Toxicity testing is a particularly cruel use of animals, often involving poisoning until death or some disease state is achieved. It is important to note that 95% of animals that are used in research, including chemical testing, are not protected by legislation in the U.S. (mice, rats, and birds are specifically excluded from provisions of the Animal Welfare Act). This is in dramatic contrast to the situation in the world's largest economy, the European Union, where all vertebrates (and some non-vertebrates) are protected in all scientific uses. European Commission's Directive 2010/63<sup>1</sup> requires that non-animal methods are preferred, and every procedure using animals must be submitted for approval by the government. In addition, the EU's toxic chemicals legislation stipulates reduction of animal testing as an overarching principle, and requires use of all approaches not involving animals first, with animal testing only as a last resort.

When it comes to human and environmental health, our current animal testing-based approach is fundamentally flawed, and we are in position to do a radically better job. Since the original TSCA was put into force in 1976, EPA has asked for safety data on only 200 of the tens of

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<sup>1</sup> [http://ec.europa.eu/environment/chemicals/lab\\_animals/legislation\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm)

thousands of chemicals to which we are exposed, and has regulated only a handful of those. This is due to several failures of our current regulatory approach, not least of which is the heavy reliance on animal testing. For example, to generate screening data for a single chemical it currently takes three years and \$6 million,<sup>2</sup> and the results are often highly variable, difficult to interpret (leading to years of argument and dispute) and not easily applied to regulatory action (leading the Agency to ask for more and more data, nearly all of which is inconclusive).

Because of the failure of this testing approach, EPA commissioned the National Academies of Sciences to come up with a better way: the NAS outlined an approach that capitalizes on our vast knowledge of chemistry and biology and modern technology to design highly reliable tests that measure chemical effects on critical biological pathways.<sup>3</sup> This revelation has resulted in an emerging consensus among scientists and regulators around the world, including the EPA, that this forward-looking approach is the best regulatory framework for the future.<sup>4</sup> It turns out this new scientific approach also involves a move away from using animal testing. To ensure the best available science is applied to protecting human and environmental health, it is critically important to make sure that any future U.S. legislation embraces this new approach to the greatest extent practicable.

We endorse S. 697 though, because it incorporates 21<sup>st</sup>-century science into its testing and risk-assessment framework and marks a dramatic advance for the nation in animal protection values. We continue, however, to be concerned with any language in the legislation to preempt states' rights on health and safety issues and urge you to support efforts in final negotiation to find the right balance on that issue.

Sincerely,



Wayne Pacelle  
President and CEO  
Humane Society of the United States



Michael Markarian  
President  
Humane Society Legislative Fund

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<sup>2</sup> Schmidt, C. 2009. *J Natl Cancer Inst.* 101 (13): 910-912.

<sup>3</sup> NRC (National Research Council). *Toxicity Testing in the Twenty-first Century: A Vision and a Strategy.* Committee on Toxicity and Assessment of Environmental Agents, National Research Council. ISBN: 0-309-10989-2, 146 pages (2007).

<sup>4</sup> The U.S. Environmental Protection Agency. 2009. *Strategic Plan for Evaluating the Toxicity of Chemicals.* Office of the Science Advisor, Science Policy Council. <http://tinyurl.com/http-epa-strategic-plan>

## **ADDENDUM:**

The following amendments to the Toxic Substances Control Act proposed under S.697 are critical for protecting animals used in testing, and for promoting the use of best available science for regulating chemicals:

### **Section 4: Policies, Procedures and Guidance (adds a new TSCA Section 3A)**

This section sets up the overall guiding principles for the bill, and here critically includes a directive to EPA to consider all existing and non-animal sources of information before requesting vertebrate testing. This section of the bill also requires EPA to review its guidance for adequacy, and creates a Science Advisory Committee on Chemicals to advise on all technical aspects of the bill and includes animal protection.

### **Section 5: Testing of Chemical Substances of Mixtures (amends TSCA Section 4)**

This section describes the conditions under which EPA can ask for information, how it can ask, and how that information should be generated. This section is fundamental to the animal reduction measures in the bill: it requires EPA to “explain the basis for any decision that requires the use of vertebrate animals” when asking for new information, and includes a section devoted to reducing vertebrate testing and developing and implementing alternatives, the development of a strategic plan and funding. This section also requires EPA to consider related information in other jurisdictions to avoid duplicative testing, and lists a number of situations in which animal testing can be waived. It also requires the consideration of all existing and non-animal sources of information prior to carrying out vertebrate testing for any voluntary data submissions.

### **Section 6: Prioritization screening (adds a new TSCA Section 4a)**

In this section EPA is directed to bin existing chemicals into low and high priority chemicals. This has the effect of focusing resources and any animal testing on high priority chemicals.