

## QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

# NANOMATERIALS

### **What are nanomaterials?**

Nanomaterials are substances that have been designer engineered at scales of less than 100 nanometers to achieve size-dependent properties and functions (1 nm = 1 billionth of a meter). Some nanomaterials are new-to-the-world creations (e.g., carbon nanotubes, quantum dots and fullerenes), while others are just smaller versions of existing materials (e.g., nanoscale gold and silver).

### **Are nanomaterials already being used in commercial products?**

Yes. A few of the many examples include a dental adhesive from 3M, Behr NanoGuard mildew-resistant paint, Eddie Bauer NanoCare khakis, General Motors' Hummer H2, Henkel's Nanit-Activ toothpaste, Petrol Ofisi gasoline, Proctor & Gamble Olay sunscreens, and Wyeth's Rapamune immunosuppressant.<sup>1</sup>

### **Why test nanomaterials?**

It is not known whether nanoscale materials present an inherently greater hazard to human health and/or the environment than larger-sized materials.

### **How are nanomaterials regulated in the U.S.?**

Current U.S. legislation governing cosmetics, chemicals, pesticides and other products does not contain specific provisions regarding nanomaterials; however, nano-forms of substances still fall within the scope of existing regulatory frameworks, which require the assessment of potential health and/or ecological hazards. The difficulty, however, is that most existing toxicity testing methods are generally considered to be inadequate for the evaluation of substances in nano-form.<sup>2</sup> Thus, U.S. agencies are moving to prepare technical guidance to support the implementation of existing regulatory requirements in relation to nanomaterials. Examples include:

- ▶▶ The Environmental Protection Agency's Nanoscale Materials Stewardship Program<sup>3</sup> and White Paper<sup>4</sup>
- ▶▶ The Food and Drug Administration Nanotechnology Task Force<sup>5</sup>
- ▶▶ The White House Office of Science and Technology Policy report on Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials<sup>6</sup>
- ▶▶ And numerous other initiatives by individual agencies, as well as and collaborative research programs coordinated under the auspices of the National Nanotechnology Initiative.<sup>7</sup>

<sup>1</sup> <http://www.nanotechproject.org/inventories/consumer>

<sup>2</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihp/docs/scenihp\\_o\\_003b.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o_003b.pdf)

<sup>3</sup> <http://www.epa.gov/oppt/nano/#stewardship>

<sup>4</sup> <http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>

<sup>5</sup> <http://www.fda.gov/nanotechnology/taskforce/report2007.pdf>

<sup>6</sup> [http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf)

<sup>7</sup> <http://www.nano.gov>

### **Are animal tests accurate predictors of human health hazards?**

Not necessarily. Serious limitations of animal tests for substances in bulk-form have already been well established.<sup>8</sup> In addition, influential scientific advisory bodies have questioned whether conventional tests can reliably be applied to nanomaterials. For example, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has noted that: "In view of the specific characteristics demonstrated for nanoparticles and nanoparticle formulations, the assays usually performed for determining toxicity of products may not be sufficient to detect all possible adverse effects of nanoparticles."<sup>9</sup>

### **What are some practical alternatives to animal testing?**

Although no validated nano-specific test methods of any kind are available at this time, rapid, non-animal *in vitro* tests are widely regarded as a critical cornerstone in nanosafety testing. For example, the SCENIHR has reported that: "*In vitro* testing has provided mechanistic data on particle toxicology in general and many *in vitro* assays demonstrate convincing differences between low and high toxicity particles; it is therefore considered appropriate that *in vitro* testing is used in situations involving nanoparticles."<sup>10</sup>

### **What is the Humane Society doing to help animals used in testing?**

The Humane Society of the United States and Humane Society Legislative Fund are actively working to end animal testing—permanently. We are working to promote greater reliance on available non-animal testing methods, and are actively supporting the vision of "twenty-first century toxicology" articulated by the U.S. National Research Council, which would see animal tests that are decades old, costly, slow and of dubious relevance to people replaced by ultra-modern, efficient and human-relevant non-animal methods.<sup>11</sup> We are calling for a "big biology" project to meet this challenge, akin to the Human Genome Project of the 1990s, and are forging an international, multi-stakeholder consortium make this landmark vision a reality as quickly as possible.



*The Humane Society of the United States is the nation's largest animal protection organization—backed by more than 10.5 million Americans. For over 50 years, HSUS has worked to reduce suffering and to create meaningful change for animals in laboratories through public education, scientific outreach, legislative advocacy, and strategic partnerships.*

*Online at [HSUS.org/research](http://HSUS.org/research)*

*The Humane Society Legislative Fund is a social welfare organization incorporated as a separate lobbying affiliate of the HSUS. HSLF works to pass animal protection laws at the state and federal level, to educate the public about animal protection issues, and to support humane candidates for office.*

*Online at [HSLF.org](http://HSLF.org)*

<sup>8</sup> [http://www.hsus.org/animals\\_in\\_research/animal\\_testing/limitations-of-animal-methods.html](http://www.hsus.org/animals_in_research/animal_testing/limitations-of-animal-methods.html)

<sup>9</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/scenihr\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm)

<sup>10</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf)

<sup>11</sup> [http://www.hsus.org/animals\\_in\\_research/animal\\_testing/hsus-projects/human\\_toxicology\\_initiative.html](http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html)