THE HUMANE SOCIETY OF THE UNITED STATES

HUMANE SOCIETY LEGISLATIVE FUND

QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

CHEMICALS

What kinds of chemicals are candidates for animal testing?

As many as 80,000 chemicals are currently in commercial use in the United States, with an additional 700 or more new chemicals being introduced each year.[1] Most are plastics and related polymers, while a smaller proportion include cleansers, paints, adhesives, lubricants, fuels, industrial solvents and additives, and a variety of short-lived by-products of chemical reactions. Some are kept tightly contained in closed systems and never released into the environment, while others may be marketed in high volumes and/or used as ingredients in products to which human beings and the environment may be exposed (e.g., cosmetics and household cleaning products, plastic packaging, and gasoline).

Who regulates chemicals in the U.S. and under what laws?

A number of federal laws have been enacted to control the trade in chemicals in the United States and to manage chemical pollution of the environment. However, the statute that deals most directly with the safety assessment and testing of chemicals in the Toxic Substances Control Act of 1976 (TSCA), which is administered by the Office of Pollution Prevention and Toxics at the Environmental Protection Agency (EPA).

What specifically does the law state with respect to animal testing?

TSCA authorizes EPA to assess chemicals before they enter commerce (new chemicals) and review those chemicals already in commerce (existing chemicals).[2] Specifically:

- Before a *new chemical* may be marketed in the U.S., TSCA requires that a premanufacture notice be filed with EPA, providing information on the chemical's identity, intended uses and production volume, anticipated exposure and emission levels, as well as any toxicity data in the company's possession. EPA uses the information in premanufacture notices, together with structure-activity relationship modeling, to determine whether there is a need to impose restrictions on the release and/or marketing of a chemical in order to ensure there is "no unreasonable risk of injury to health or the environment." This step generally does not involve any new animal testing.
- For *existing chemicals*, TSCA provides the authority to compel companies to submit "all existing data concerning the environmental and health effects of [a chemical] or mixture." EPA is further empowered to compel companies to undertake new (animal) testing when the agency finds that a chemical may present an "unreasonable risk of injury to health or the environment" or is or will be produced in "substantial quantities" and there is or may be "significant or substantial human exposure to the chemical" or it "enters or may reasonably be anticipated to enter the environment in substantial quantities."[2]

[1] http://www.gao.gov/new.items/d05458.pdf
[2] http://epw.senate.gov/tsca.pdf

Are there other ways that chemicals may be subject to animal testing?

Yes. In addition to its legal powers under TSCA, EPA, in partnership with the chemical industry and environmentalists, has spearheaded a number of voluntary programs to gather available and/or new toxicity data, including the following:

- High Production Volume (HPV) Chemical Challenge and Extended HPV Programs[3-4]
- Voluntary Children's Chemical Evaluation Program (VCCEP)[5]
- Nanoscale Materials Stewardship Program[6]
- Chemical Assessment and Management Program (ChAMP)[7]

The agency is also in the process of implementing its Endocrine Disruptor Screening Program, which may lead to extensive new animal testing chemicals used as ingredients in pesticide formulations, as well as those found in rivers, lakes and drinking water.[8]

What animal tests are carried out on chemicals?

The HPV and ChAMP programs call for submission of data for the following common animal tests[9]:

- Rodent acute lethality
- Fish acute lethality
- Rodent 28-day repeated dose toxicity
- Genetic mutations
- Toxicity to reproduction[10]
- Toxicity to development[10]

VCCEP information requirements are similar to those above, but are more extensive, and divided among three levels of testing, which may or may not all be required. Additional animal testing that may be required in the higher tiers includes reproductive toxicity in two generations of rodents, toxicity to the nervous and/or immune systems, and testing for cancer-causing potential.

Under the Nanoscale Materials Stewardship Program, EPA has requested submission of "all relevant information that is known or reasonably ascertainable," including data concerning human health and environmental effects, but has not yet called for specific animal tests to be conducted.

A discussion of tests for endocrine disrupting effects is provided in a separate HSUS fact sheet.[11]

How many animals may be used in chemical toxicity testing?

Some of the tests above consume dozens or hundreds of animals per study. Unfortunately, laboratory-bred rats and mice and non-mammalian species are not covered under the U.S. Animal Welfare Act standards for animals used in experiments, and as such, statistics concerning their use are not recorded or made publicly available.[12] However, according to European statistics for 2005, the testing of chemicals and environmental contaminants consumed approximately 18 percent of all

[3] http://www.epa.gov/chemrtk
[4] http://www.americanchemistry.com/s_acc/sec_acc_rcol.asp?CID=199&DID=530
[5] http://www.epa.gov/oppt/vccep
[6] http://www.epa.gov/oppt/nano/stewardship.htm
[7] http://www.epa.gov/champ
[8] http://www.epa.gov/scipoly/oscpendo/index.htm
[9] http://www.hsus.org/animals_in_research/animal_testing/toxicity_testing_overview.html
[10] A combination reproductive/developmental toxicity or 28-day repeated dose/reproductive/developmental toxicity screening study may be conducted in place of separate animal tests for these endpoints.
[11] http://www.hsus.org/web-files/PDF/ARI/endocrine.pdf
[12] http://www.nal.usda.gov/awic/legislat/awa.htm

animals used in toxicological and other safety evaluations that year.[13] Proposed new testing under EPA's HPV Challenge program alone could consume upwards of 160,000 animals, and many more will be consumed as the Extended HPV program, ChAMP, and the Endocrine Disruptor Screening Program are implemented.[14]

Are animal tests accurate predictors of chemical risks to people?

Not necessarily. Animal tests may under- or over-estimate the human health and/or ecological hazards of chemicals. For example, studies of acute lethality and birth defects in rats have been shown to be poor predictors of similar test results in mice and rabbits—let alone the real-world health risks for people. The same is true for rodent cancer studies and other types of animal tests. For example, both rat and rabbit tests failed to predict the developmental hazards of PCBs, industrial solvents, and many drugs, while cancer tests in rats and mice failed to detect the hazards of asbestos, benzene, cigarette smoke, and many other substances—delaying consumer and worker protection measures by decades in some cases.[15]

What are some practical alternatives to animal testing?

A number of *in vitro* and other alternative methods germane to chemical safety assessment have been endorsed as scientifically valid by the European Centre for the Validation of Alternative Methods and its counterparts worldwide.[16] These include rapid non-animal genetic mutation tests, animal reduction measures for acute lethality studies in rodents and fish, and a cell-based screening test for toxicity to the developing embryo.[17]

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.[18] 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 to help make this landmark vision a reality as quickly as possible.

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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

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

[13] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf
[14] Physicians Committee for Responsible Medicine, personal communication.
[15] http://www.hsus.org/animals_in_research/animal_testing/limitations-of-animal-methods.html
[16] http://ecvam.jrc.it/f_home.cfm?voce=m&idvoce=3
[17] http://www.hsus.org/animals_in_research/animal_testing/alternatives.html
[18] http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html