

QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

PESTICIDES

What kinds of substances are considered pesticides?

A pesticide is any substance or mixture of substances used to repel, mitigate, prevent or destroy living organisms regarded as “pests.” Examples include weed-killers (herbicides), bug sprays and flea collars (insecticides), rat poison (rodenticides), bird poison (avicides), fumigants (nematocides), “germ-killing” soaps and cleaning products (antimicrobials), and even natural biochemicals and genetically engineered toxins.

Why are pesticides subject to animal testing?

Most pesticides are designer poisons—tailor-made to be toxic to living creatures. Many are applied to foods we eat, to residential lawns and gardens, to our pets and to our own bodies. In addition, residues from agricultural and other outdoor pesticide applications can linger in soil and groundwater, sometimes building up in plants and wildlife. Given their inherent toxicity and the potential for significant human and environmental exposure, pesticides are subject to stringent testing (mainly in animals) to determine the nature and severity of harmful effects, as well as the levels of exposure at which such effects do not occur.

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

The U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs is responsible for registering and licensing pesticides for use in the United States. EPA’s statutory authority is primarily rooted in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)¹ and the Federal Food, Drug and Cosmetic Act (FFDCA);² however, provisions in the Endangered Species Act³ and the Food Quality Protection Act⁴ also impact EPA’s pesticide regulatory activities.

FIFRA authorizes EPA to evaluate and register pesticides for particular uses and to enact regulations specifying testing that must be carried out to judge whether a pesticide may pose an “unreasonable risk to human health or the environment.” These requirements are specified within Title 40, Part 158 of the U.S. Code of Federal Regulations.⁵ FFDCA further requires EPA to determine with “reasonable certainty” that no harm will come to infants, children or other sensitive individuals from pesticide residues on food before granting a license for agricultural use.

Does EPA specifically require that pesticides be tested on animals?

Yes. EPA regulations list several dozen animal tests that may be required, depending on the nature of a substance and the intended use pattern of the pesticide product. Most animals are used in the testing of the toxic component in a pesticide formulation (active ingredient); however, EPA also

¹ http://www.access.gpo.gov/uscode/title7/chapter6_.html

² <http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm>

³ http://www.law.cornell.edu/uscode/html/uscode16/usc_sup_01_16_10_35.html

⁴ <http://www.fda.gov/opacom/laws/foodqual/fqpatoc.htm>

⁵ http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr158_04.html

prescribes animal testing of other pesticide ingredients (e.g., stabilizers, propellants, etc.), as well as all finished formulations (which may contain different combinations of active and other ingredients). Generally speaking, the greater the anticipated human exposure, the more animal testing is required. For example, in the case of pesticide chemicals intended for use in agriculture or food production, EPA regulations call for dozens of separate toxicity tests⁶ to evaluate potential human health and ecological effects, including the following:

- ▶▶ Acute systemic toxicity in rodents/rabbits via oral, inhalation *and* skin routes
- ▶▶ Eye and skin irritation *in vitro* and/or in rabbits
- ▶▶ Skin sensitization in mice and/or guinea pigs
- ▶▶ 3-4 week repeated dose toxicity via the skin in rabbits or rodents
- ▶▶ 3 month repeated oral dose toxicity in rats *and* dogs
- ▶▶ 2 year oral repeated dose toxicity in rodents (and sometimes 1-year studies in dogs)
- ▶▶ Lifetime carcinogenicity in rats *and* mice
- ▶▶ Genetic toxicity of at least 2 varieties *in vitro* and/or in rodents
- ▶▶ Reproductive toxicity in at least 2 generations of rodents
- ▶▶ Developmental toxicity in rabbits *and* rodents
- ▶▶ Toxicokinetics in rodents
- ▶▶ Acute toxicity to fish of two or more species
- ▶▶ Partial or full life-cycle toxicity to fish of two or more species
- ▶▶ Acute and/or dietary toxicity to birds of two or more species
- ▶▶ Reproductive toxicity to birds
- ▶▶ ... and many more.

EPA generally accepts reduced data sets for natural vs. synthetic chemicals and for other lower toxicity substances.

Testing requirements for finished formulations consist of acute lethality studies via oral, skin and inhalation routes, as well as skin and eye irritation and skin sensitization testing (collectively known as the acute toxicity “six-pack”).⁵ EPA has also developed a separate methodology for determining the data needed for lower toxicity pesticide chemicals.⁷

How many animals are used in pesticide testing?

Some of the tests above consume hundreds or thousands of animals per study. It is estimated that at least 12,000 animals are consumed in the testing of a single food-use active ingredient, while hundreds or thousands more are used to test other individual ingredients and formulations. 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.⁸ However, according to European statistics for 2005, the testing of pesticides consumed approximately 10 percent of all animals used in toxicological and other safety evaluations that year.⁹

Are animal tests accurate predictors of pesticide risks to people?

Not necessarily. Animal tests may under- or over-estimate the human health and/or ecological hazards of pesticides. 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.

⁶ http://www.hsus.org/animals_in_research/animal_testing/toxicity_testing_overview.html

⁷ http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf

⁸ <http://www.nal.usda.gov/awic/legislat/awa.htm>

⁹ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf

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.¹⁰

What are some practical alternatives to animal testing?

A number of *in vitro* and other alternative methods germane to pesticide safety assessment have been endorsed as scientifically valid by the European Centre for the Validation of Alternative Methods and its counterparts worldwide.¹¹ 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.¹² In addition, an independent scientific expert group¹³ has recommended the deletion of certain longstanding testing requirements (e.g., 1-year dog studies and mouse carcinogenicity studies, which would save more than 400 animals per food additive), and the significant scaling back of other standard tests (e.g., evaluating reproductive toxicity using one, rather than two, generations of offspring, which would save an additional 1,200 or more animals per test).

Are there other developments that could impact pesticide testing on animals?

In 2007, EPA issued a final rule amending its testing requirements for synthetic pesticide chemicals.¹⁴ The only positive change from an animal welfare perspective is EPA's move away from routine 1-year dog studies, which will spare approximately 32 dogs per active ingredient. At the same time, however, EPA has dramatically increased its animal testing requirements in other areas, which will lead to the death of many tens of thousands of rabbits, birds, rats and other animals in the coming years, as new pesticides are brought on the market and existing products are subject to new or repeat animal testing according to conventional agency requirements and test guidelines.¹⁵

EPA is also in the process of implementing a Congressionally mandated program to screen pesticide chemicals to determine whether they may “have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as [EPA] may designate.”¹⁶ Nearly 20 new and revised testing methods are being developed and validated in the U.S. and internationally for the purpose of screening for “endocrine disrupting” substances, several of which consume hundreds or thousands of animals at a time.

Another development with the potential to further increase animal testing is the emerging use of ultra-small “nanomaterials” in pesticide products.¹⁷ The unique nature of these substances raises a host of complex toxicological questions, which some environmental organizations and other stakeholders have claimed can only be answered through long-term animal testing.

What is the Humane Society doing to help animals used in pesticide 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-

¹⁰ http://www.hsus.org/animals_in_research/animal_testing/limitations-of-animal-methods.html

¹¹ http://ecvam.jrc.it/f_home.cfm?voce=m&idvoce=3

¹² http://www.hsus.org/animals_in_research/animal_testing/alternatives.html

¹³ <http://www.hesiglobal.org/Committees/TechnicalCommittees/ACSA>

¹⁴ <http://edocket.access.gpo.gov/2007/pdf/E7-20826.pdf>

¹⁵ http://www.epa.gov/oppsrrd1/registration_review/index.htm

¹⁶ <http://www.hsus.org/web-files/PDF/ARI/endocrine.pdf>

¹⁷ <http://www.hsus.org/web-files/PDF/ARI/nano.pdf>

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.



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

¹⁸ http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html