

QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

FOOD ADDITIVES

What substances are considered to be food additives?

Food additives include any substance added to food or used in the production, processing, treatment, packaging, transportation or storage of food. Examples include natural or artificial flavorings to improve or enhance a food's taste, as well as other chemical additives to alter the food's appearance or texture, delay spoiling, and/or prevent the growth of harmful bacteria.

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

Responsibility for the regulation of food additives lies with the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).¹ FFDCA requires that manufacturers and packagers of processed foods demonstrate the safety (i.e., "reasonable certainty of no harm") of all chemical additives and/or other materials that come into contact with food prior to marketing.

What animal tests are carried out on food additives?

FDA guidance for the toxicological assessment of food ingredients (also referred to as the Redbook)² prescribes often extensive toxicological testing based on "concern levels" as determined by chemical structure and cumulative human exposure. Commonly required study types³ include the following:

- ▶▶ Acute systemic toxicity in rodents
- ▶▶ Repeated dose (1, 3 and/or 24 month) oral toxicity studies in rodents and/or dogs
- ▶▶ Genetic toxicity *in vitro* and/or in rodents
- ▶▶ Carcinogenicity (including possible *in utero* exposure phase) in rats and/or mice
- ▶▶ Reproductive toxicity in at least 2 generations of rodents
- ▶▶ Developmental toxicity in rats and/or rabbits
- ▶▶ Neurotoxicity in rodents
- ▶▶ Immunotoxicity in rodents
- ▶▶ Toxicokinetics in rodents
- ▶▶ Human clinical and/or epidemiology

Exceptions to the above testing requirements are provided under a 1958 amendment to the FFDCA for two broad groups of substances:

- ▶▶ Substances that FDA or the U.S. Department of Agriculture had determined safe for use in food prior to 1958
- ▶▶ Ingredients "generally recognized as safe" based on a long history of use and/or published scientific evidence.⁴

¹ <http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm>

² <http://www.cfsan.fda.gov/~redbook/red-toca.html>

³ http://www.hsus.org/animals_in_research/animal_testing/toxicity_testing_overview.html

⁴ <http://www.cfsan.fda.gov/~dms/opa-noti.html>

How many animals may be used in the testing of food additives?

Some of the tests above consume hundreds or thousands 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.⁵ However, according to European statistics for 2005, the testing of food additives consumed approximately 3.7% of all animals used in toxicological and other safety evaluations that year.⁶

Are animal tests accurate predictors of risks to people from food additives?

Not necessarily. Animal tests may under- or over-estimate human health hazards. For example, studies of acute lethality and birth defects in rats have been shown to be poor predictors of such effects 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.⁷

What are some practical alternatives to animal testing?

A number of *in vitro* and other alternative methods germane to food additive safety assessment have been endorsed as scientifically valid by the European Centre for the Validation of Alternative Methods and its counterparts worldwide.⁸ These include rapid non-animal genetic toxicity tests, animal reduction measures for acute systemic toxicity, and a cell-based screening test for toxicity to the developing embryo.⁹ In addition, an independent scientific expert group¹⁰ 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).

What is the Humane Society doing to help animals used in food additives 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.¹¹ 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.

⁵ <http://www.nal.usda.gov/awic/legislat/awa.htm>

⁶ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf

⁷ http://www.hsus.org/animals_in_research/animal_testing/limitations-of-animal-methods.html

⁸ http://ecvam.jrc.it/f_home.cfm?voce=m&idvoce=3

⁹ http://www.hsus.org/animals_in_research/animal_testing/alternatives.html

¹⁰ <http://www.hesiglobal.org/Committees/TechnicalCommittees/ACSA>

¹¹ http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html



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](https://www.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](https://www.hslf.org)