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Fact Sheet: Animals Used in Testing

The Use of Animals in Product Testing

Toxicity tests to estimate the safety of products and chemicals were developed in the early 20th century. These include experiments that subjectively measure the irritation of chemicals in the eyes or on the skin of rabbits (the infamous Draize test), and lethal dose (LD50) experiments that determine toxicity by the dosage of a chemical that kills half of the animals forced to consume, breathe or be injected with that chemical. These primitive animal test methods are, regrettably, still in use today.

Many scientists continue to rely on animal experiments, and regulatory agencies still mandate data collected from animal experiments, in large part because that is what tradition and current laws dictate. Toxicologists often mention feeling more comfortable basing their judgments on methods with historical context and data than on data from new and emerging methods. However, this maintaining of the *status quo* ignores the failure of animal tests to predict what is safe or effective in people while failing to recognize the advances made in non-animal testing methodologies. As a consequence, the lives of millions of our fellow creatures continue to be sacrificed, and our own safety compromised.

What Products Are Tested and Regulated?

Many items purchased and used by consumers every day, such as household cleansers, cosmetics, drugs and pesticides, are subjected to government regulations requiring that they be "safe" for humans, animals and the environment. Manufacturers are responsible for submitting safety test data to agencies, and this often involves conducting toxicity tests on the products and/or their ingredients before they enter the marketplace. Regulatory agencies determine whether the data are sufficient for labeling and marketing the product. The toxicity testing for many types of products still involves testing on animals.

Described in Table 1 below are some of the U.S. regulatory agencies that have regulations requiring data to support product labeling and safety, largely based on animal toxicity test data, before certain types of products can be put on the market.

Table 1. U.S. regulatory agencies and some of the products/substances under their purview subject to safety assessments based on animal toxicity tests.

U.S. Regulatory Agency[1]	Substances Regulated[1]
Food and Drug Administration (FDA)	drugs, food additives, medical devices, tobacco products, vaccines and biologics, veterinary drugs
Environmental Protection Agency (EPA)	chemicals, including industrial chemicals and ingredients, pesticides, endocrine disruptors, anti-microbial cleansers, environmental effluents
Consumer Product Safety Commission (CPSC)	consumer and household products that contain chemicals
Department of Transportation (DOT)	chemicals in transport
Occupational Safety and Health Administration (OSHA)	chemicals in the workplace

[1] Major agencies and products/substances listed; not comprehensive.

Other U.S. agencies may conduct a substantial amount of toxicity testing on animals as research to support their own missions or as part of an agreement with a regulatory agency.

Why Products are Tested

Products are tested on animals for three reasons: safety (this includes correct product labeling), efficacy and liability. Many products are tested for *safety* to meet legal requirements to identify potential hazards to humans, animals and the environment. Even non-regulated products, such as cosmetics, are commonly animal-tested for safety for the purpose of *liability*. (Companies do not want to market a product that could result in legal claims.) Drugs intended for human or animal use are additionally tested for *efficacy* (i.e., effectiveness in treating a condition or disease). This

testing typically involves animal models as well. For drugs, agency approval to conduct human testing in clinical trials typically requires a company to submit the results from animal study data and toxicity data.

Current Tests

The majority of animal toxicity tests are conducted using mice, rats and rabbits. Some tests required by the FDA or EPA also use dogs, primates and other species. Multiple toxicity tests are required to evaluate potential hazards for each product or chemical. The exact tests required can differ according to regulatory agency, product type and intended use/potential exposure.

Each test is based on a human health endpoint that is to be evaluated in the animal model. For example, human health endpoints evaluated in different types of toxicity tests include eye irritation, skin irritation, skin sensitization, carcinogenicity, genetic toxicity, neurotoxicity, reproductive toxicity and acute oral systemic toxicity.

Perhaps the most commonly known animal toxicity test is the Draize rabbit eye test, intended to predict whether a product or chemical would cause injury to the human eye. A reversible effect to the eye from a chemical is called *eye irritation* (or *ocular irritation*), and an irreversible effect that would result in permanent eye injury is called *eye corrosion* (or *ocular corrosion*). The Draize test involves placing a small volume of the substance into one eye of each rabbit in a small group of animals (typically three to six), and then recording specific effects observed in that eye over time (typically up to 21 days). The gross nature of this test and the likelihood of pain to the animals have evoked widespread public outcry against it. Scientifically, the test has been poorly reproducible, and not always predictive of the human response. The results are subjective and variable due to human scoring of the rabbit eye injuries, variations in the test method and other factors. Progress toward replacing this animal test with alternative non-animal test methods has been slow, disorganized and subject to political influences. However, a number of *in vitro* ocular test methods are now available, each with specific limitations, but the strategic testing lab can usually find a combination to address most testing needs.

The Draize test for skin irritancy, which was first introduced in 1944, has been used to measure the inflammatory response produced when a test substance is applied to the shaved and abraded skin of a group of rabbits, and can cause intense pain, burning and itching. (Skin is abraded by firmly pressing adhesive tape onto the animal's body and quickly stripping it off, and is repeated until several layers of skin have been removed.) The good news is that the use of this testing method has been largely replaced with validated alternative methods. The Environmental Protection Agency's Office of Pesticide Programs, for example, relies on data from the Local Lymph Node Assay. Additionally, in 2015, several new *in vitro* methods were approved by the Organisation for Economic Cooperation and Development for *in vitro* skin sensitization testing. Combinations of the *in vitro* methods using integrated testing approaches will be needed to substitute for the animal tests.

Another traditional animal toxicity test is the LD50 test, which stands for the lethal dose of a given test substance in 50% of the test's animal population. The test, performed mainly on mice and rats, is commonly used to evaluate the human health endpoint of acute oral systemic toxicity where animal subjects are force-fed oral doses of the chemical being tested. This oral systemic test is used as a general indicator of the overall relative toxicity of a substance. Many scientists

claim that the oral LD50 test has little relevance to evaluating the human safety of a substance, and some agencies and international organizations have withdrawn their requirement for this type of test data. Progress toward replacing the LD50 test with alternative non-animal methods has been ongoing, but the test involves toxicity to the whole organism, and is therefore biologically complex (and difficult to replace with alternative methods).

Problems with Animal Tests

The toxicity tests that are currently accepted by regulatory agencies (most being animal tests) were developed decades ago and are based on what was considered to be the best science at that time. Many regulations were developed around these animal tests, and toxicologists in both industry and the regulatory agencies have become comfortable with using the animal data for decision-making purposes. This comfort and policy complexity has contributed to foot-dragging when it comes to efforts in replacing them.

In addition to the ethical concerns and growing public opposition to the pain and suffering inflicted on animals, alternatives to these animal-based toxicity tests are now being sought for additional reasons, not the least of which include:

Better tests are being developed: Tests in animals are not always predictive of human health effects. The best tests for human toxicity would be conducted using humans, which is unethical. However, science has greatly advanced since the development of the animal tests that are still in use today. Cell culture, molecular and computation methods (*in silico* methods) are now well-developed scientific tools. *In vitro* methods based on human cells and tissues are now being developed and evaluated for assessing toxicity. Toxicity testing, however, has not had the urgency and support of government funding programs that disease-based research has enjoyed, although this has improved over the past several years.

Progress has been slow, because scientists pursue work in areas where funding is available. However, as new human-based *in vitro* test methods become available for regulatory testing, and the results provide better protection of human health when implemented, additional funding should be allocated for the development, validation and implementation of more human-based testing methodologies.

Faster and cheaper tests are needed to benefit industry: Many chemicals used in products today have not been tested, so their safety is largely unknown, and new chemicals and products are entering the marketplace at an ever-increasing pace. In fact, it is estimated that there is a backlog of more than 80,000 chemicals for which potential toxicity is largely unknown. The animal tests are slow and expensive, and safety testing using existing methods cannot keep up with the demand. The *in vitro* and computational methods in use today already provide faster testing, and that will only improve with each generation of development.

New test methods may not be cheaper initially, but will be less expensive over the long term. And as *in vitro* toxicity tests advance, they show greater predictivity than the animal tests that are currently used.