

# Government-Required Animal Testing: Overview

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Government regulations in most countries require some animal-based toxicity testing as a condition for the importation or sale of pesticides, industrial chemicals, drugs and vaccines, genetically manipulated foods, and some consumer products. Depending on the substance in question, its likely toxicity, and the degree of anticipated human or environmental exposure, as many as 50 separate animal-poisoning studies may be required.(1)

## Animal Numbers and Suffering

Statistics published by government authorities and research-oversight bodies in North America and Europe reveal that the vast majority of the cruelest and most painful animal experiments are conducted to satisfy government-mandated testing requirements. In these tests, animals such as birds, dogs, fish, guinea pigs, mice, rabbits, rats, and even monkeys are forced to swallow or inhale massive doses of a test substance—which can cause severe abdominal pain, paralysis, swelling and ulceration of the skin and/or eyes, convulsions and seizures, and bleeding from the nose, mouth, and genitals—before they are poisoned to death or killed by the experimenter.(2)

In 2000, regulatory testing accounted for 81 percent of Canadian experiments known to “cause pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals” (Figure 1).(3) Although at least one research-oversight body acknowledges that such invasive procedures are “highly questionable or unacceptable, irrespective of the significance of the anticipated results,” these tests are still permitted—even required—by government regulators around the world.(4) In fact, lethal-poisoning (“acute”) studies accounted for one-third of all toxicity tests carried out in U.K. labs in 2002.(5) Other common tests involve dosing an animal daily with a test chemical for one month (“subacute”), three months (“subchronic”), or for most of the animal’s life (“chronic”) to determine what kind of harmful health effects result. Comparable U.S. statistics are not currently available because the species most commonly used in toxicity testing (birds, mice, and rats) are specifically exempt from even the minimal protections of the federal Animal Welfare Act, so experimenters are not even required to report the number and species of animals used.(6)

## Scientific Validity

In addition to the horrendous cruelty, there is another problem with animal testing: No animal test in use today has ever been properly scientifically validated according to internationally agreed-upon criteria, a fact that calls into question the reliability, accuracy, and relevance of animal-test results as predictors of possible human-health or environmental hazards. The following examples illustrate this unreliability:

- One international study examined the results of rat and mouse “lethal dose” tests for 50 chemicals and found that these tests were able to predict toxicity in humans with, at best, only 65 percent accuracy.(7)
- During the Draize eye- and skin-irritation test, rabbits are immobilized in full-body restraints while a substance is dripped or smeared into their eyes or onto their shaved skin. One study found that the Draize test “grossly over predicted the effects that could be seen in the human eye,” and another concluded that the test “does not reflect the eye irritation hazard for man.”(8) The human four-hour patch skin test has proved to provide chemical skin-irritation data that are “inherently superior to that given by a surrogate model, such as the rabbit.”(9)
- With respect to the standard rat test for toxicity to the developing nervous system, the U.S. Environmental Protection Agency’s (EPA) Scientific Advisory Panel concluded that the tests “must be further refined to develop more sensitive endpoints which are relevant to significant outcomes in humans.”(10)

So despite a longstanding bias on the part of toxicologists and regulators who claim that animal tests are intrinsically more relevant than in vitro and other non-animal methods, the reality is that the results of nonvalidated animal tests are always questionable and are subject to vastly differing interpretations and often-successful legal challenges. Dr. Joshua Lederberg, Nobel laureate in medicine, wrote in Chemical and Engineering News that “it is simply not possible with all the animals in the world to go through new chemicals in the blind way that we have at the present time, and reach credible conclusions about the hazards to human health.”(11) The solution lies in the development and use of scientifically validated non-animal test methods.

## The Way Forward

PETA is actively pressuring world governments, both individually and through international consortia such as the Organization for Economic Cooperation and Development and the International Conference on Harmonization, to take steps to reduce their reliance on animal testing by becoming more involved in the development and use of sophisticated non-animal test methods.

Examples of non-animal test methods that have been scientifically validated and/or accepted by one or more world governments include the following:

- EPIKIN® and EpiDerm®, models made up of cultures of human skin cells, which have been validated and accepted around the world as total replacements for rabbit skin-corrosion studies(12)
- The cell-based "3T3 neutral red uptake phototoxicity test," which has become a widely accepted alternative to the use of guinea pigs and mice to assess sunlight-induced skin irritation(13)
- The "embryonic stem cell test for embryotoxicity," which uses cells obtained from mice to detect chemicals that have the potential to cause the malformation of developing embryos(14)
- The use of human skin tissue to measure the rate at which chemicals are absorbed through the skin(15)

Where non-animal replacements are not yet available or fully validated, PETA lobbies companies and government agencies to provide funding for research and development and works closely with organizations that specialize in test-method validation, such as the European Centre for the Validation of Alternative Methods and the Institute for In Vitro Sciences, to bring new non-animal test methods into the mainstream.

In 2001, PETA and other animal-protection organizations persuaded the U.S. Congress to require the EPA to allocate \$4 million for "research, development and validation of non-animal, alternative chemical screening and prioritization methods." The congressional committee also expressed concern that "the agency has paid little attention and provided fewer resources to the development of alternative test methods" that minimize the number of animals used while ensuring that human health and the environment are protected.(16) This funding directive means that the EPA can no longer ignore the plight of the millions of animals it condemns to death in chemical-poisoning tests.

#### What You Can Do

Contact the EPA, the U.S. Food and Drug Administration, and Health Canada to ask them to take the following steps:

- Amend relevant U.S. and Canadian legislative requirements and test guidelines by omitting animal-based tests for skin corrosion, skin irritation, skin absorption, phototoxicity, and pyrogenicity and replacing them with scientifically validated and/or internationally accepted non-animal test methods that are currently available and ready for use.
- Devote more resources to the development and validation of non-animal test methods, such as developmental and reproductive toxicity, toxicity to the nervous and immune systems, and more general short- and long-term toxicity.

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