



Environmental, Health and Safety Report

3M's Approach to Use of Animals in Research (August 2014)

3M is obligated to ensure that its products are safe and effective. At present, this requires the judicious use of laboratory animals in research and development of some products. Approximately eighty five percent of animals used in research by 3M are for mandated studies, which are necessary to comply with national and international laws and regulations. Non-USDA regulated species (mice and rats) are the most commonly used species in 3M animal studies. For many years, 3M has cultivated a culture where efforts to **reduce, refine, and replace** the use of animals in research and testing are encouraged wherever possible. Examples of steps 3M has taken to support these efforts are as follows:

- **Non-animal or alternative models or methods** to effectively meet research objectives and/or limit animal studies are used when possible, and include but are not limited to the following examples:
 - **The meat industry is used as a source of teeth** to evaluate the effectiveness of potential new techniques intended for use in dentistry.
 - Test articles thought to have the potential to cause severe irritation or corrosivity are screened using *in vitro* models such as the Bovine Corneal Opacity and Permeability (**BCOP**) or **Corrositex™ Assays**. 3M continues to increase the use of such tests methods when appropriate, and has developed capabilities to conduct these types of assays internally.
 - **In vitro models**, including cultured human skin and lung tissue are used to assess potential irritation, absorption, dermal sensitization, acute toxicity, and inhalation effects. 3M has increased its capacity to conduct these studies internally as well as at Contract Research Organizations.
 - **Computational toxicology** is frequently used, as an alternative to animal testing, to predict toxicological endpoints. In 2012, it is estimated that computer modeling was utilized to assess more than 150 compounds for more than 600 endpoints. 3M has developed a robust process for conducting computational toxicity assessments using a variety of public and commercially available (Q)SAR and Read-Across software programs, as well as an internal database to store and access these results.
 - Where appropriate, a **validated alternative dermal sensitization testing method**, the murine local lymph node assay (LLNA), which utilizes mice as opposed to guinea pigs is used to characterize sensitization potential of test materials.
 - **Liver cells and microsomes** from rats have been used to assess metabolism of industrial chemicals and **gene array studies** are being utilized to develop a library of gene expression to enhance our mechanistic understanding of the chemicals and materials we investigate.

A **risk assessment** process is routinely conducted on new materials to ensure applicable test data are not already available and duplicate testing does not occur. In addition, **chemical characterization** is used as a means to define chemical equivalency, justify bridging of existing data to similar test materials; and thus, eliminate the need for some additional animal testing. Furthermore, animal testing is not used as a means of quality control evaluation. Rather, quality and consistence of products/materials are ensured through other means, including conformance with established specifications and chemical analysis. **These techniques are used routinely across all of 3M's business, resulting in very significant savings in total animals used.**

- **3M is continually exploring scientifically valid alternatives to animal use.**
 - 3M continues to build partnerships with contract research organizations to assist in method development and validation of alternative methods. We work to maintain alignment with the principles of Toxicity Testing in the 21st Century.
 - 3M has continued to invest in equipment and personnel training in order to conduct alternative testing internally. Our internal capabilities have expanded and will continue to grow as we invest in new laboratory space and equipment.
 - In 2012, 3M funded a M.S. student whose thesis was focused on alternative methods for sensitization testing.

In addition to continually striving to reduce overall animal numbers, refine current methods, and replace animals in testing, **3M works to maintain the highest standards for animal welfare in testing.** For example:

- **Research Animal Sourcing:** 3M does not use random-sourced companion animals in any research. **Only purpose-bred animals are used.**
- **United States Department of Agriculture (USDA) and Animal Welfare Act (AWA; 7 USC §2131):**
 - 3M's internal research facility is routinely inspected by the USDA and operates in compliance with the AWA.
- **Association for Assessment and Accreditation of Laboratory Animal care (AAALAC):**
 - **Since 1966, 3M has voluntarily participated and has been fully accredited** by AAALAC, a private, non-profit organization that promotes humane animal care and use in science. The most recent AAALAC site visit was held in May of 2012. Continued full accreditation was granted. The site visitors were very complimentary of the facility and animal care and use program.
- **3M Institutional Animal Care and Use Committee (IACUC) Oversight:**
 - The 3M IACUC **consists of scientific and nonscientific members, a doctor of veterinary medicine, and nonaffiliated member/ethicist.**

- The 3M IACUC **ensures animal testing conducted within 3M is necessary, and minimizes the number of animals used.** The committee uses a formal process to review all study protocols prior to implementation, and requires justification for the use of animals. On a yearly basis, the Principal Investigator for each protocol is required to document animal use during the previous year, indicate if and how the use of animals was reduced, and discuss non-animal methodology or approaches that were considered.
- The 3M IACUC maintains **continuous oversight and involvement** in the testing process, by randomly monitoring studies conducted under approved protocols.
- The 3M IACUC **promotes relevant education.**
 - For example, all 3M IACUC members are expected to attend an **IACUC 101/201 training seminar.** This seminar is sponsored by the US Department of Health and Human Services Office of Laboratory Animal Welfare (OLAW), and supported by numerous other organizations, including the United States Department of Agriculture (USDA) and AAALAC.
 - In addition, **new IACUC member and new principal investigator training** are routinely conducted.
 - **Staff development** sessions on various topics, (e.g., animal allergies, changes to the *Guide for Care and Use of Laboratory Animals*, ethics of animal use, and choosing the correct experimental model) are held three to four times per year.
- An effort is made to **maximize the benefit of each animal use.** For example, tissues from euthanized animals are often harvested and utilized for research purposes.
- In 2010, an **Animal Adoption** process was instituted, making it possible for research animals to be adopted where appropriate and desired.
- Furthermore, in 2011 and 2012, multiple animals no longer being used for research purposes were surrendered to animal adoption agencies and sanctuaries. These organizations were reviewed by 3M, and approved as organizations that fully meet 3M's standards of care. All of these animals have been placed in adoptive homes. 3M has highlighted this among peer groups as a 'best practice' end of study alternative.

➤ **Vendor Management**

- **All Contract Research Organizations (CROs) that may be used to conduct 3M-sponsored animal testing, worldwide, are subjected to a rigorous, formal review** process to determine compliance with the 3M Animal Welfare in Testing and Research Policy. This policy, among other things, requires all CROs act in accordance with the principles set forth in the Animal Welfare Act (7 USC §2131), and in a manner consistent with the National Research Council *Guide for the Care and Use of Laboratory Animals*. This includes social and physical well-being. Only CROs formally approved may be used to conduct studies involving animals.

- **All CROs currently used by 3M have been evaluated and approved** through the established formal review process.
- **Not all CROs are approved.** Reasons for disapproval include factors such as poor environmental controls and inadequate monitoring of animal health.
- **Each approved CRO is required to complete an annual review,** detailing any changes to their facility or animal use program.
- **3M has dedicated resources to audit its approved CROs,** both in the United States and internationally, and utilizes a prioritization scheme based heavily upon AAALAC accreditation to determine auditing priority.

In the years ahead, 3M will continue to uphold its obligation to ensure that its products are effective and safe while striving to reduce, refine, and replace the use of animals in research and testing and maintaining the highest standards for animal welfare.