Merck KGaA, Darmstadt, Germany Animal Science and Welfare Policy

Excerpt for public use

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1. Objective

This policy provides the framework for Animal Science and Welfare (ASW) related activities at Merck KGaA Darmstadt, Germany. These activities shall be performed in compliance with our Code of Conduct, our applicable internal standards, applicable local/national legal requirements as well as local established ethical, scientific, quality, and regulatory standards.

This policy addresses Merck KGaA Darmstadt, Germany's responsibility and core commitments for the use, care and welfare of animals in the frame of animal use activities conducted by us or on our behalf (e.g. at external vendors).

Our Group Animal Science and Welfare long term aspiration is:

All animal utilization replaced with non-animal alternatives.



Our commitment to animal science and welfare excellence is expressed in the following guiding principles:

As long as we need to use animals, we apply the highest ethical and animal welfare standards related to quality, housing, husbandry and veterinary care to all animals in our reach.

Replace animal testing whenever possible by alternative methods.

Stepwise reduction of animals used by effective projects to reduce, refine and replace (3R) animal use and political engagement to phase-out of animal utilization.

Implementation of refinement processes for all work using animals at our own vivariums or on our behalf to improve the quality of animal life and to reduce burden to the absolute minimum.

2. Scope

This Merck KGaA Darmstadt, Germany Group Animal Science and Welfare Policy is unique and mandatory within the entire Group. It applies to all organizational units and legal entities of the Group for the direct implementation.

3. Mission

It is our mission to ensure that all work using animals is made with high quality and under **state-of-the-art housing and husbandry conditions**. The highest publicly agreed standard in our reach is the ETS123^{*}.

All vivariums owned by Merck KGaA Darmstadt, Germany globally shall comply with the following standards:

• All our vivariums shall work in compliance with both, ETS123^{*} Appendix A and the ILAR guide[#], ensuring adherence to highest standards.



• Use only Animal Using Vendors (AUV) that are compliant with national laws and our ASW criteria.

All non-Merck KGaA Darmstadt, Germany businesses utilizing, housing or breeding living animals or using living animals in projects (incl. production) on behalf of us shall comply with the following standards:

- ETS123, Appendix A standards for all work using animals inside the EU.
- ETS123, Appendix A standards for all work using vertebrates other than mice or rats outside the EU.
- ILAR or ETS123, Appendix A standards for all mice, rats and non-vertebrates inside and outside the EU.
- No single housing of vertebrates except for hamsters, male mice, and male rabbits.

Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates is of the greatest concern to Merck KGaA Darmstadt, Germany and shall thereby avoided at most.

Processes implemented to minimize burden for all work using living animals at Merck KGaA Darmstadt, Germany or on our behalf:

- Release by independent multidisciplinary Animal Usage Review boards (MAUR) or Institutional Animal Care and Use Committee (IACUC) respectively for all animal work at Merck KGaA Darmstadt, Germany and on our behalf.
- Humane endpoints defined and monitored.
- Criteria defined for analgesia, anesthesia and euthanasia.
- Qualified and independent veterinary care and ASW oversight.
- Incident reporting processes.
- Definition and monitoring of animal burden.
- Environmental enrichment and enrichment plan.
- Social/Group/Pair housing plus clear definitions for exceptional single housing.
- Consequent training of staff.



Significant reduction of animals used:

- Effective 4Rs (Reduction, Refinement, Replacement and Responsibility) program with objectives and KPIs.
- Significant number of dedicated research projects aiming to reduce or replace animal utilization and create value for Merck KGaA Darmstadt, Germany with objective setting and KPIs.

*European Convention for the Protection of Vertebrate Animals, used for experimental and other scientific purposes (ETS NO. 123), Guidelines for Accommodation and Care of Animals

[#]GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS, Eighth Edition; Committee for the Update of the Guide for the Care and Use of Laboratory Animals; Institute for Laboratory Animal Research; National Research Council, ISBN: 0-309-15401-4

