

DANONE POLICY ON ANIMAL RESEARCH



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Danone Policy on Animal Research

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SECTION A – CONTEXT AND OBJECTIVES

Danone is committed to the highest scientific and ethical standards in its innovation and scientific research activities to develop products and obtain scientific knowledge on the impact of food, nutrition, and health, and to ensure effective and safe medical and health solutions.

As a principle, Danone strives not to rely from animal testing in its development and research activities. Insofar non-animal alternatives for obtaining the results sought are available, we favour approaches based on animal-free methods.

Animal research may be necessary upon requirement of scientific authorities for regulatory approvals, special foods with medical purposes, for safety and suitability purpose of certain foods for vulnerable populations, and for specific research in the field of health, diagnoses, prevention or treatment of certain diseases. In such cases, Danone research is carried out in respect of international animal welfare, ethical, and quality standards and a strict framework:

- External experts and independent ethical committee review the approach and any study to be undertaken;
- All animal protocols comply with mandatory guidelines to take into consideration animal welfare and guidelines recommended by authorities and NGOs (WHO, OIE, ILSI, etc.);
- Danone applies the strict existing standards for the protection and care of animals used for scientific purposes, based on the European Union guidelines and compliant to local regulations, and aim to exceed the standard requirements for all animal research we are involved in;

Danone extends these standards as referential to all collaborations in countries outside Europe.

SECTION B – SCOPE

This policy concerns:

1. Animal research refers to the use of non-human animals and animal tissues in experiments for any scientific purpose.
2. The Danone Policy on Animal Research applies to all animal research conducted by, for or in collaboration with Danone and research supported by Danone by means of grants or educational grants involving animals or animal tissues.
3. The Danone Policy on Animal Research applies to all Danone affiliated companies and Danone R&I Centres.

SECTION C – POLICY

Research and experiments involving animals must be approved following a strict internal process that evaluates the absolute necessity to rely on animal research model such as in the following cases:

- For the development of novel ingredients, medical devices, therapeutic approaches, or nutritional solutions for vulnerable consumers with (or at risk of) a medical condition, babies, and young children;
- To demonstrate safety of novel ingredients or nutritional solutions;
- When regulatory bodies demand animal data for authorization to commercialize products to demonstrate safety or efficacy;
- As part of the scientific and mechanistic understanding of diseases and health conditions;
- When no alternatives are available, standardization is required, longer term follow up is not feasible, and/or in cases where ethical considerations prevent the use of human subjects;
- To validate alternative models for replacement, reduction, and refinement, and convince authorities for the feasibility, relevance, and validity of “3R” models.

Danone does not perform animal research:

- For the development of conventional food products like waters, milk, creamers, and consumer products not aimed at a specific health condition, unless explicitly required by local law;
- For comparison of Danone products against competitor products.

SECTION D –GOVERNANCE AND DOCUMENTATION

At project design stage the need for animal research models is evaluated and alternative approaches are assessed. In case animal research cannot be avoided, the research proposal is reviewed and challenged by the internal Danone Animal Welfare & Quality Committee on need, type and number of animals involved, quality, and 3R (Replace, Reduce, Refine) principles, and advice is provided to the Danone Animal Research & 3R Steerco.

Evaluation by an external ethical committee is requested before submission to the appropriate local competent authority, in compliance to Directive 2010/63/EU on the protection of animals used for scientific purposes, as well as local laws and regulations. All steps in this process, from project submission to study conducted, must be documented and archived in line with the Danone quality system.

In case animal research is required:

- Danone and/or the Partner conducting the study involving animals or animal tissues must obtain the certification, accreditation, or qualified inspection report from a well-recognized institution such as AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care International) or equivalent national recognized competent authority;
- Qualification and training of Danone employees and/or the Partner employees involved in the care, welfare, and /or use of animals, as well as the regulatory requirements related to the design of protocols, must be documented and archived;
- Danone and/or Partner employees involved in the use of animals or animal-derived material, need to keep up to date on 3R-developments on an annual basis;
- All required actions are taken toward our ethical responsibility for animal welfare including housing, nutrition, humane animal care and handling, and refinement thereof;
- Animal procedures are documented in standard operating procedures to ensure quality and best practice;
- Justification of the animal models used, and number of animals involved, is evaluated by both internal Animal Welfare and Quality & Compliance Committee, and by external Animal Ethics and Welfare bodies;
- Evidence must be kept that contract research organizations, external collaborators, or animal suppliers strictly follow Danone Policy and appropriate laws and regulations.

SECTION E – ALTERNATIVES

Danone actively seeks alternative methods to limit the use of animal. To this end, we apply the internationally recognized “3R” principle (Replace animal testing, Reduce the number of animals being used, and Refine the procedures).

To foster progress in 3R research, Danone takes part in several concrete initiatives that include participation in research-projects in which alternative methods are developed and validated. In addition, Danone plays a key role in the ILSI Europe multi-stakeholder task force: “Alternatives to Animal Testing in Food Safety, Nutrition and Efficacy Studies”.

Details on Danone 3R activities are reported annually.

SECTION F – COMMUNICATION AND PUBLICATION

Scientific publications or general communication regarding animal research performed by, for, or in collaboration with Danone must be reviewed prior to publication by the Danone review committees to ensure compliance with Danone policies and quality standards for reporting of animal research for which Danone refers to the ARRIVE guiding principles. Furthermore, we comply to the amendment of Directive 2010/63/EU by Regulation (EU) 2019/1010 to incorporate ambitious goals for reporting and transparency on animal use.