
ANIMAL TESTING

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DANONE

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ANIMAL TESTING: WHEN NO ALTERNATIVE RESEARCH MODELS ARE AVAILABLE

This document informs about Danone's current practices on animal testing and the significant initiatives deployed by the company to reduce, refine and replace animal testing.

International bodies such as the World Organization for Animal Health (OIE) have defined animal welfare standards, including specific recommendations for animal testing. There are also strict rules for animal testing, which are spelled out in a Directive for the protection of animals used for scientific purposes first adopted by the European Union in 1986 and revised in 2010. At Danone, we are fully committed to follow these stringent rules, and are also committed to developing methods and tools to Replace, Reduce and Refine animal research—the internationally recognized "Triple R".

At Danone, animal testing is conducted in order to ensure the safety and efficacy of new products. In some cases, these tests are used to understand the mechanism of action of our innovations or are part of the safety assessments required by national regulatory authorities for pre-market approvals. In the case of specialized nutrition for vulnerable populations, animal testing is still sometimes necessary to advance fundamental knowledge. All tests are carried out in respect of international animal welfare standards and when no alternative research models are available.

02 OUR GUIDING PRINCIPLES WHEN CARRYING OUT TESTS ON ANIMALS

We always challenge the need to do animal testing and, where possible, use available approaches based on alternative methods. We consult external experts and ethical committee review, to ensure we choose the right approach.

Where no other options are available, we carry out animal testing but only within a very strict framework. All animal tests comply with mandatory guidelines to take into consideration animal welfare and protocols recommended by authorities and NGOs (WHO, OIE, ILSI, etc.). We apply the strict existing standards for the protection and care of animals used for scientific purposes, based on the European Union, USA or Canada regulations. We are also extending these standards as referential to all collaborations in other countries.

Each research project must comply with:

1. Applicable legal, ethical, scientific and quality standards. All study proposals that involve laboratory animals are presented to an external independent and licensed Ethics Review Committee.
2. A reference methodology: we use the Translational Research Approach, which integrates available *in vitro*¹, *in vivo*¹ and clinical research into a framework recommended by international governmental and non-governmental organizations and authorities (WHO, ILSI, FDA, European Commission). This methodology aims to avoid unnecessary animal testing.

¹ *In vitro* means outside of a living body, as opposed to *in vivo*.

03 OUR INITIATIVES TO REDUCE, REFINE AND REPLACE ANIMAL TESTING

We actively seek alternative methods to limit the use of animal testing. To this end, we apply the internationally recognized "Triple R" (Replace animal testing, Reduce the number of animals being used in the tests, and Refine the testing process, or 3R).

To foster progress in Triple R research, Danone takes part in a number of concrete initiatives that include on-going collaboration with 3R centers in the UK and the Netherlands and with the John Hopkins Center for Alternatives to Animal Testing (CAAT) in the US. In addition, Danone has played a key role in the recent creation of a new task force at ILSI Europe (Alternatives to Animal Testing in Food Safety, Nutrition and Efficacy Studies).

Our numerous initiatives to foster Replacement models include:

- Active participation in the Netherlands in "SLIM", a multi-stakeholder project (2010-2014) under a public-private consortium focusing on the development and legal approval of alternative methods. This project led to the development of a robust and sensitive *in vitro* assay to test the safety of cow's milk hydrolysates (important for infants with cow's milk allergy).
- Development with TNO in the Netherlands since the early 90s of "TIM systems" which simulate the gastrointestinal tract from stomach to small intestine. More recently, Danone Nutricia Research also set up a joint project on the use of these models with the University of Clermont-Ferrand in France. In addition, Danone Nutricia Research has developed one *in vitro* gastrointestinal model to simulate the upper tract for internal use. These models are widely used in our research on food, reducing the need for animal testing.

Routine use of *in vitro* gut fermentation models in research projects. Danone Nutricia Research has also developed a model to simulate colonic fermentation for internal use. These simulator models are replacing animal models.