

# Animal Care & Use FAQs

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## Why are animals used for research by Elanco?

*Advanced scientific testing methods have reduced the need for research animals. However, some product testing on a small number of animals is still needed to ensure safety and efficacy for all animals, humans and the environment. This research is important in helping us to understand how to best prevent and treat disease in all animals. The data is also required by regulatory bodies and allows us to keep our products registered and available for sale.*

At Elanco, we are committed to developing innovative products that enhance the health of farm animals and pets, contributing to animal wellbeing and benefiting animals, people, and society as a whole.

While advancements in scientific methods have reduced and sometimes replaced the need for animal research, some animal work remains necessary.

Our research animals play a crucial role in developing new treatments, improving existing ones, and ensuring ongoing product registration. Testing on the target species—the animals intended to benefit from our products—is essential for obtaining the most accurate data. We must provide data from specific animal species, including farm animals like sheep, cattle, pigs, and poultry, as well as companion animals such as dogs and cats, to regulatory authorities for product approval and registration.

Strict regulatory requirements, both in Australia and globally, mandate data collection from animal studies to ensure the safety, effectiveness, and environmental friendliness of new animal health and veterinary products.

For example, authorities like the Australian Veterinary Pesticide Medicines Authority (AVPMA) require data on drug action, toxicology, efficacy, safety and chemistry for all species, along with residue data for farm animals, when registering new products.

Specific data for Australian conditions, such as flea and tick treatments for companion animals, tick and fly data for cattle, and fly and lice data for sheep are also necessary. This requires trials to be conducted in Australia using Australian companion animals and livestock.

Similar regulatory requirements exist in other countries, where animal-based data is crucial before these products can be sold. This stringent process ensures that the veterinary medicines and animal health products used by pet owners and farmers are safe, effective, and perform as intended.



The valuable work of our animals ensures the health of your pets and farm animals by assisting in the development of essential animal health products for prevention and treatment of disease and ensuring our products can be registered and used by all those who care for animals.

## Where did animal testing begin?

*History explains how animal studies became legislative requirements. Public health disasters have led to the regulatory requirement for animal testing.*

Specific public health disasters played a role in the creation of regulatory requirements for animal testing. Situations such as the sulfanilamide elixir disaster in the 1930s and the thalidomide disaster in the early 1960s<sup>1,2,3,4,5</sup> resulted in large scale human tragedies because they were used on humans before they were shown to be safe.

Public demand to prevent similar human health disasters have led to mandatory animal testing which is now required by regulatory authorities worldwide to ensure the quality, efficacy and safety of the medicines and therapies we develop. Equivalent regulations exist to prevent similar disasters in veterinary medicine.

Regulations for animal health products require data from the species for which the product will be used and include the requirement for testing information on the dose to be used, information ensuring it has shown to be safe and effective, and if used in food producing animals, data to ensure no residue remains in the animal (e.g. meat), or its products (e.g. eggs, milk) that could then be eaten by humans.

### References

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## Which animals are used by Elanco in Australia?

*Our research is done on the animals the product is designed to help, so we can ensure it works on these animals and is safe. At Elanco these animals include farm animals such as sheep, cattle, pigs and poultry, and companion animals including dogs and cats. Our trials also include the use of client owned pets and livestock animals on privately owned farms. We use the smallest number of research animals possible, and only carry out the research when absolutely necessary, and when there are no alternative testing methods available.*

Conducting research on the species intended to benefit from our products (the target species) is key to obtaining the best data. We are required to provide data from the specific animal species targeted by our products, including both farm animals (such as sheep, cattle, pigs and poultry) and companion animals (including dogs and cats) to the regulatory authorities so that our products can be approved and registered.

Because we test on the animals our products are designed to help, our studies also validate the efficacy and safety of the product for that specific species. This approach directly benefits the intended species, as it guarantees tailored solutions that meet their unique health needs and contribute to their well-being.

Our animals are cared for by veterinarians, veterinary nurses, qualified animal attendants and technicians who have extensive knowledge and experience in each species.

We also conduct field studies using client owned pets and animals on privately owned farms. The trials are conducted with oversight from Elanco AEC, researchers and veterinarians, and require informed owner consent

Our approach to animal use is strictly governed by principles of necessity and justification. Animals are used in research only when absolutely necessary, when there are no viable alternatives available, and in the fewest numbers required to meet regulatory guidelines and provide reliable results.

## What role does the Elanco Animal Ethics Committee play?

*The Elanco Animal Ethics Committee (AEC) makes sure any research in animals meets the ethical standards of the Australian Code. They assess whether animal research is necessary by considering the balance between animal health knowledge and the welfare of the animals, or whether the testing can be performed with non-animal alternatives.*

The Elanco Animal Ethics Committee (AEC) comprises members from various backgrounds, including veterinary, animal welfare, and more. Where animal testing is the only viable option, Elanco researchers undertake a rigorous process to demonstrate justification and ethical use to satisfy the AEC for approval to conduct a trial using animals.

The AEC applies the guiding principles of animal research, the 3Rs - Replacement, Reduction and Refinement (see more below) to any proposed research and evaluates the balance of animal welfare with outcomes for animal health knowledge before granting or denying approval for the research to go ahead.

The AEC also provides ethical advice on standards of animal care, welfare, and housing, and conducts regular inspections of facilities and animals to ensure these standards are maintained.

Elanco's AEC ensures regular training for researchers and committee members is undertaken to ensure current best practice is always followed. This training covers ethical, social, and scientific issues related to animal use and is facilitated through ComPass, an online training module developed by the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART). This ensures that everyone involved stays updated and informed about ethical considerations in animal research.

Researchers must follow relevant legislation, ethics guidelines, policies, and procedures established by Elanco and the AEC. You can download Elanco's AEC Terms of Reference [here](#).

## What are the 3Rs and how does Elanco adhere to these principals?

*The 3Rs form the fundamental framework for the ethical, humane, and responsible care and use of animals in research and refer to Replacement, Reduction, and Refinement principles. All animal research work undertaken by all employees at Elanco strictly adheres to these principals, which include:*

*Replacement: alternatives to animals are used wherever possible, including a variety of scientific testing methods.*

*Reduction: the number of research animals are strictly reduced to as smaller number as possible.*

*Refinements: testing procedures are refined to ensure animals are cared for with respect and any negative impacts are minimised.*

The 3Rs form a fundamental framework for the ethical, humane, and are established as global good practice in responsible care and use of animals in research. The "Rs" refer to Replacement, Reduction, and Refinement principles. All animal research work undertaken by all employees at Elanco strictly adheres to these principals, which include:

**Replacement:** We are committed to prioritising the use of non-animal scientific testing methods wherever possible. This includes utilising alternative testing methods such as cell culture, tissue culture systems, isolated cell component testing, computational modelling and advanced data analysis. This approach minimises the number of animals used in our research.

**Reduction:** We always reduce the number of animals used in each study to the absolute minimum required to achieve accurate results and research objectives. We strictly adhere to guidelines that ensure we meet regulatory requirements for minimum numbers so that our results are accurate and valid. This approach also reduces the need to duplicate studies and prevents further use of more animals for the same research aims.

**Refinement:** We refine our procedures and programs to minimise negative impacts and maximise positive experiences for our animals. Our animal care program includes focused animal socialisation and enrichment programs. These programs are subject to continuous review and improvement and include focused individual animal reassessment. Close monitoring and regular feedback from animal care staff help guide adjustments inside a flexibly

delivered program to ensure individual animals' physiological, social, and behavioural needs are met. Ongoing facility re-design and renovation also forms part of our commitment towards continuous improvement. Staff utilise Elanco's global behaviourists to help guide changes in facility design and animal care programs. Researchers work towards modifications of project designs and techniques wherever possible, through practical innovation and collaboration, to reduce or eliminate impact on our animals.

## How does Elanco ensure animals are appropriately cared for?

*Elanco's main aim when conducting animal research is to ensure all animals are treated with respect and good care. The humane and ethical use of animals by researchers is supported by veterinarians and animal welfare officers who oversee the studies. They make sure that all regulatory requirements are followed, and that all animals are cared for in social and enriched environments that promote wellbeing.*

At Elanco, we take our responsibility for animal care very seriously. Every animal in our care is treated with respect and compassion by our dedicated team. We ensure that all researchers working with animals are supported by veterinarians, which also meets the requirements of the Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition (2013).

Our facilities have dedicated animal welfare officers and veterinarians overseeing our programs, our animals and our facilities. Our animal care is provided by trained personnel with qualifications and experience in animal care, veterinary nursing, and farm management. We train all involved in the care, welfare, and use of animals to perform exemplary care, be aware of expected ethical standards, and demonstrate compassion, respect and humane treatment towards the animals in their care.

Field studies involving client owned animals, or animals on privately owned farms, are also subject to the same ethical and welfare standards, with informed owner consent and oversight from Elanco AEC, researchers and veterinarians.

All employees follow Elanco's Animal Welfare Policy which is guided by the 'Five Domains', a scientifically based framework that is highly regarded by welfare experts as a comprehensive means of evaluating the welfare of animals. We recognise, support, and apply the 'Five Domains' of animal welfare which include:

1. Nutrition: access to adequate, balanced, varied and clean food and water.
2. Environment: comfort through temperature, substrate, space, air, odour, noise, and predictability.
3. Health: good health is promoted through the absence of disease, injury, and impairment with a sufficient fitness level.
4. Behaviour: varied, novel, and engaging environmental challenges are provided through sensory inputs, exploration, foraging, bonding, playing and retreating.
5. Mental state: the mental wellbeing of animals is prioritised with predominantly positive mental states promoted, such as pleasure, comfort, or vitality while negative states such as fear, frustration, hunger, pain or boredom are reduced.

Our research involving animals undergoes thorough ethical consideration and review in accordance with the Australian Code for the Care and Use of Animals for Scientific Purposes,

the Animal Research Act 1985 (NSW), and the Animal Research Regulation 2021 (NSW). Additionally, all research activities at Elanco are conducted in accordance with the Australian Code for the Responsible Conduct of Research 2018.

## What laws are there in Australia to protect the animals you use?

*Respect for animals is an individual responsibility of everyone at Elanco, and all strictly adhere to the following laws for animal care and use in Australia to ensure the highest level of care and respect for all animals:*

*Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013  
(updated 2021)*

*Animal Research Act 1985 (NSW)*

*Animal Research Regulation 2021 (NSW)*

In Australia, animal care and use is governed by the:

- Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013 (updated 2021)
- Animal Research Act 1985 (NSW)
- Animal Research Regulation 2021 (NSW)

Our use of animals in research is also based on various local and global regulatory compliance, guidelines and best practices, which include the:

- NSW Department of Primary Industries and Regional Development and Animal Research Review Panel Guidelines
- European Convention for the Protection of Vertebrate Animals used for Scientific Purposes (European Directive 2010/63)
- American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals

Globally, our internal and partner sites follow:

- Guide for the Care and Use of Laboratory Animals
- Guide for the Care and Use of Agricultural Animals in Research and Teaching
- Any other applicable local/state/country regulations and other species-specific guidelines that ensure best practices around animal care and use.

At Elanco, we use these guidelines and standards as the framework for our Global Animal Welfare Compliance programs, which enables us to continually drive higher standards of animal care.

Additionally, we require all of our contract research organisations (CROs) and suppliers to apply our Core Concepts for Animal Welfare. A periodic evaluation program, in which trained specialists in animal welfare perform assessments, is in place to monitor and assist our partners with adhering to these concepts.

We encourage our CROs globally to obtain and maintain AAALAC\* accreditation or use the AAALAC principles described in the Guide for the Care and Use of Laboratory Animals and the

Guide for the Care and Use of Agricultural Animals in Research and Teaching. These guidelines are internationally recognised standards for appropriate animal care and use, with additional resources found on the AAALAC website that provide best practice guidance information.

The Elanco logo is a blue rectangular box with the word "Elanco" written in white, italicized, sans-serif font.

Elanco Australasia is proudly AAALAC accredited.

*\*AAALAC International enhances the welfare of animals used in science and education by accrediting organizations that meet high standards of humane and responsible animal care and use. AAALAC's voluntary accreditation process requires research programs to demonstrate that they meet the minimum standards required by law and are also going the extra step to achieve excellence in animal care and use.*