

Animal Welfare Issue Brief

Importance to Elanco and our Stakeholders

The research, development and regulatory approval of animal health products requires testing in research animals to assure optimal outcomes for all animals. Upholding our ethical and scientific obligations in discovering innovative animal health solutions, Elanco applies and oversees the principles of good animal welfare from product research and development through support for the responsible use of animal health products and services for animals on farms and in homes.

At Elanco, we also believe animal welfare is integral to the sustainability of global communities. We are dedicated to safeguarding the welfare of farm animals, pets, and research animals worldwide. Our comprehensive approach to animal welfare takes a holistic view of animal care that extends beyond the role of our animal health products and services.

Elanco supports and aligns with the World Organization for Animal Health (WOAH) objective to achieve “a world where the welfare of animals is respected, promoted and advanced in ways that complement the pursuit of animal health, human well-being, socio-economic development and environmental sustainability.”

Our Action

Elanco’s approach, positions and business practices are based on sound science and our ethical obligation to ensure the quality, efficacy and safety of all the products and services we develop and deliver for animals. We diligently implement our animal welfare programs for research animals, as developed by our global animal welfare team. These animal welfare experts provide guidance, oversight and approval of all global animal research protocols and inspect animal research sites.

Elanco’s animal welfare standards meet or exceed local, national and international laws and regulations.

In Australia, we are an inaugural signatory to The Openness Agreement on Animal Research and Teaching, in alignment with our longstanding dedication to promoting awareness and understanding regarding the critical role research animals play. The agreement outlines four key commitments, aimed at enhancing public understanding of the purpose and methods behind animal use in research and teaching. Additionally, Elanco has indicated an intention to be a signatory when the U.S. program starts in 2025.

Animal Welfare Policy

Elanco's Animal Welfare Policy applies to all employees and contractors who undertake any activity on behalf of Elanco involving animals. It 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. This policy expands on the "Five Freedoms" model, enabling greater opportunities to improve animals' quality of life, including their mental state and positive experiences. We recognize, support and apply the "Five Domains" of animal welfare:

1. **Nutrition** – access to sufficient, balanced, varied and clean food and water
2. **Environment** – provide comfort through temperature, substrate, space, air, odor, noise and predictability
3. **Health** – enable good health through the absence of disease, injury, and impairment with an appropriate fitness level
4. **Behavior** – provide varied, novel, and engaging environmental challenges through sensory inputs, exploration, foraging, bonding, playing, retreating and others
5. **Mental state** – the mental well-being of the animal should benefit from predominantly positive states, such as pleasure, comfort, or vitality while reducing negative states such as fear, frustration, hunger, pain or boredom

Safeguarding the Welfare of our Research Animals

Respect for animals is an individual responsibility of everyone at Elanco. Our trained and dedicated employees passionately care for our research animals, including socialization training and provide enriched environments.

All clinical research and development programs worldwide implement strict protocols focused on quality, safety, animal welfare, environmental management and operational excellence. Our quality and safety programs include global policies, standard operating procedures, training and qualification of personnel. We inspect our Contract Research Organizations (CROs) and internal animal research sites, investigator sites, clinical study processes and documentation.

All animal studies receive oversight through a government authority of Elanco's Institutional Animal Care and Use Committee (IACUC). The IACUC is a global committee of experts that reviews and approves protocols to assess best practices and compliance. It includes volunteer members not affiliated with Elanco, as well as Elanco veterinarians, scientists, and other research professionals. All research and development animal studies receive an independent ethical review and approval prior to starting. The ethical review processes in each country aligns with the specific regulatory requirements of the local authority. For studies where there are no regulatory requirements for an ethical review, the review and approval is performed by the Global Elanco Ethics Committee (GEEC). Two of three Elanco-owned research facilities are accredited by the Association for Assessment, and Accreditation of Laboratory Animal Care (AAALAC), while the third facility has begun the process to become accredited.

We perform, at a minimum, annual internal animal welfare audits for all Elanco animal facilities and audit CRO facilities at least once every three years to ensure all Elanco animal studies are performed to the highest welfare standards. We are also subject to external audits by accreditation organizations and government regulators at both prescribed intervals and with no notice. Auditors look for assessment of animal physical and psychological health, as well as training, attitude and competence of the staff. Since our IPO in 2018, Elanco has had no major or critical findings at any Elanco-owned research locations. We only work with research partners that meet our high standards of animal welfare and ensure all animal studies are subjected to ethical oversight.

We remain committed to embracing the globally recognized '3Rs' of animal research and apply these principles to maximize animal welfare in all animal studies.

1. **Replacement:** We permit animal studies only when necessary. We look to replace animal studies with other approaches, where possible and practical.
2. **Reduction:** We use the fewest number of animals possible in studies.
3. **Refinement:** We eliminate or reduce pain and distress where possible.

Elanco has a dedicated 3Rs committee to assist our scientists in implementation, training and study design refinements that incorporate these principles.

Elanco's quarterly Golden Heart Awards recognize employees who show compassion and respect for the privilege to conduct animal research by consistently upholding the 3Rs philosophy. Our past awards recognized innovative solutions that reduced animal stress, increased enrichment to support animals' expression of natural behaviors, and reduced the number of animals needed by redesigning a study to complete two objectives simultaneously instead of one.

Elanco helps find forever homes for retired research animals from its three research facilities. Each facility has programs to find suitable adoptive homes for research animals upon completion of their work.

Management Process for Contract Research Organizations (CROs)

We believe leveraging internal research and development capabilities while partnering with CROs, academic institutions, and other partners is essential to delivering innovation in animal health.

CROs and Elanco sponsored studies are audited by trained and qualified personnel to ensure strict regulatory requirements and our standards are met. Audits include development, execution and follow-up phases to ensure operational and protocol compliance. All clinical research is appropriately monitored by Elanco scientific staff. Prior to contracting and as a part of due



diligence, CROs are vetted by our animal welfare, quality assurance, and legal teams, and undergo a third-party risk assessment, as appropriate.

Clinical trials are governed by strict protocols that are vetted and approved by independent bodies, based on local laws and regulations – to ensure appropriate animal welfare, quality and scientific standards.

Education Improves Animals' Lives

At Elanco, we support the stewards of animal care and work to drive practical innovation that advances animal welfare. Beyond the research and development of our products, Elanco also employs regional animal welfare experts who provide services to animal caretakers and owners to promote animal welfare practices and the responsible use of our animal health products. Our experts work alongside farmers, ranchers, veterinarians and pet owners to ensure the best possible care for each animal.

Advancing the Welfare of Pets

The well-being of pets inspires our research and development teams to work towards creating innovative and easy-to-administer medicines. Additionally, we advocate for the responsible use of our products to help enrich the lives of pets and their owners. Across the globe, our teams collaborate with veterinarians, animal trainers and educators to promote responsible pet ownership for people of all ages. We also serve as a resource to pet owners by providing free educational materials on relevant pet health and health issues through print and digital channels, including our websites, social media channels, radio and TV.

We are also committed to offering accessible, free opportunities to further veterinary professional and technical learning. Our teams around the world help veterinary practitioners expand their knowledge through a variety of online and offline seminars, lectures, symposiums, conferences and other educational events in partnership with key thought leaders and veterinary experts.

Through Elanco's Paws4Purpose™ program, we partner with more than 600 U.S. non-profit organizations that focus on pet adoption to provide pet health tools, resources and expertise. Specifically, Elanco supports shelters with resources to discuss vaccination strategies, infectious disease control and parasite prevention in shelter facilities. The program also provides product discounts to help make important veterinary care more accessible for rescue animals waiting to be adopted, fostered or re-homed. In addition, Elanco partners with Fear Free® and the Fear Free® Shelter Program, helping to improve the experiences of pets in shelters by educating employees and volunteers about animals' physical and emotional needs.

Empowering Farmworkers Through Customized and Role-Specific Training

Animal welfare and best on-farm management practices are interconnected. Our services providing on-farm animal welfare evaluations and consultations enable customers to refine protocols, enhance employee training and evolve the way they care for animals. In addition, these services help many customers receive third-party verification for their animal welfare programs and practices.

Additionally, our field teams work with customers to embed surveillance and benchmarking services in their operations. These include our feed cattle mobility assessment program, our swine transport loss program and our Health Tracking System (HTSi) program in poultry, which use data tracking to capture and monitor specific health and welfare indicators in herds or flocks. The information gathered from these programs has empowered producers and packers to make timely, data-based decisions that improve the health, performance and welfare status of the animals in their care.

Elanco offers a range of training services for customers and their crews, focusing on animal handling, appropriate living conditions, animal health and nutrition, and other topics. When workers are equipped with the right tools and knowledge, they can provide better care and improved human-animal interactions, leading to better outcomes for both animals and humans. Some examples of training initiatives we have championed:

- The Elanco Pig Academy series, designed to promote better management practices for swine producers globally.
- Participating in webinars and trainings by the Professional Animal Auditor Certification Organization (PAACO).
- Translating the North American Meat Institute's Animal Care and Handling Guidelines and Audit Tool (an industry-wide resource used across species by the packer industry) into Spanish, to reach a greater number of animal handlers.
- Translating protocols and training materials into Spanish for numerous livestock organizations, programs and customers, to positively impact more animal handlers and caregivers.

Addressing Challenges Across the Value Chain

Elanco fosters collaboration across the farm animal value chain, lending our expertise to help solve systemic industry challenges. One area of focus for dairy cattle welfare is fitness-to-transport decisions, which refers to making critical management decisions for transporting animals without compromising their welfare. Robust fitness-to-transport protocols seek to ensure the right decisions are made regarding when and how to transport cows and calves.



In collaboration with Dr. Lily Edwards-Callaway at Colorado State University, Elanco has presented on this important topic at numerous industry events, including the 2022 World Dairy Expo in Madison, Wisconsin and on the American Association for Bovine Practitioners (AABP) podcast “Have you herd.” We also partnered with industry stakeholders to develop a training video designed to inform and empower animal caregivers in fitness-to-transport decisions. The video has been presented at multiple industry conferences and is freely available to all producers and veterinarians on the National Dairy Farmers Assuring Responsible Management (FARM) Program website.

Organizations across the dairy value chain recognize the risks associated with poor fitness-to-transport decisions. Elanco’s efforts support progress toward a systemic solution that improves awareness of challenges and empowers workers to make decisions that support both the welfare of animals and the success of their farms.

Governance and Risk Management

Our animal welfare program is governed by Elanco’s Global Animal Welfare Team of experts led by our Vice President of Clinical Development (reporting to the Executive Vice President of Innovation, Regulatory and Business Development) and including our Institutional Animal Care and Use Committee (IACUC), local animal welfare officers at our animal centers, and regional animal welfare officers to cover our CRO network. The program receives additional oversight from senior and executive leadership, who provide regular updates to our Elanco Executive Committee and the Innovation, Science and Technology Committee of the Board of Directors.

External Affiliations and Collaborations

We collaborate with industry stakeholders and associations to exchange ideas, share best practices and improve standards to advance animal welfare. These include:

- Institutional Official Consortium (IOC)
- Food Safety Program (FSP)
- Dairy Data Warehouse (DDW)
- Cãobinado Animal Shelter companion matching collaboration

Metrics and Targets

Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI) HC-BP-210a.2	In 2023, no Form 483's were received.
Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries HC-BP-210a.3	None reported.

The content of this brief is informed by global ESG disclosure standards and frameworks.

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