



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 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 with a global application.

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.

We perform regular animal welfare audits of our animal facilities and CROs to ensure all Elanco animal studies are performed to the highest welfare standards. Auditors look for assessment of animal physical and psychological health, as well as training, attitude and competence of the staff. Elanco prides itself on consistently high audit results. 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 3R's committee to assist our scientists in implementation, training and study design refinements that incorporate these principles.



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 rehomed. 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.

Governance and Risk Management

Our animal welfare program is governed by Elanco's Global Animal Welfare Team of experts run by our Global Director of Animal Welfare, including our Institutional Animal Care and Use Committee (IACUC), global animal welfare officers and regional animal welfare experts. The program receives additional oversight from senior and executive leadership, who provide regular updates to our Elanco Executive Committee and regular updates to the Innovation, Science and Technology Committee of the Board of Directors.

External Affiliations and Collaborations

Elanco fosters collaboration across the farm animal value chain, lending our expertise to help solve industry challenges to farm animal welfare. One area of focus is determining the fitness-to-transport of cattle, which refers to each animal's ability to withstand transport without compromising their welfare. Robust fitness-to-transport protocols seek to ensure the right decisions are made regarding when and how to transport dairy cows and calves.



Elanco presented on this important topic at the 2022 World Dairy Expo in Madison, Wisconsin. We also partnered with industry stakeholders to develop a training video designed to inform and empower animal caretakers in fitness-to-transport decisions. The video has been presented at multiple conferences, featured in an American Association of Bovine Practitioners podcast 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 collaboration with industry leaders supports 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.

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)

Metrics and Targets

<p>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</p>	<p>In 2022, a CRO received a Form 483 for an Elanco sponsored study for minor observations. The findings had no influence on the quality and integrity of the study data. (Note: VAI and OAI procedures do not apply to animal health trials or pharmacovigilance reporting.)</p>
<p>Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries HC-BP-210a.3</p>	<p>None reported.</p>

The content of this brief is informed by the following ESG disclosure standards:

- *Policies and commitments to the material issue (GRI 3-3c)*
- *Impact Management of Resilience Issues (GRI 3-3d)*
- *Stakeholder engagement informing actions (GRI 3-3f)*
- *Describe targets related to the material issue (IFRS S1, GRI 3-3e)*

- *Describe processes used to track effectiveness and lessons learned (GRI 3-3e)*
- *Describe how stakeholder engagement has informed whether the actions have been effective (GRI 3-3f)*
- *Resilience and material issue action statements (IFRS S1)*
- *Mechanisms to integrate the material issue into strategy, decision-making and financial planning (IFRS S1)*
- *Describe the board and management responsibilities related to the material issue (IFRS S1, GRI 2-12, 2-13, 2-14)*
- *Describe any connections between the material issue and remuneration outcomes (IFRS S1, GRI 2-17, 2-18)*
- *Industry associations, other membership associations, and national or international advocacy organizations in which Elanco participates in a significant role (GRI 2-28)*