

# Fact Sheet

## Regulatory Framework for Ensuring Animal Well-Being



Research institutions, companies and producer groups engaged in the growing field of animal biotechnology place animal well-being as a top priority. The humane care and use of animals in genomics, cloning and transgenics is guided by rigorous regulatory review and, in some instances, third party review.

### Regulatory Overview

- The U.S. Department of Agriculture is responsible for regulating the use of animals in biomedical research under the auspices of the Animal Welfare Act and according to the guidelines established in the Institutional Laboratory Animal Research Guide (ILAR).
- The USDA's Animal and Plant Health Inspection Service has adopted by final rule the use of the ILAR Guide and the Guide for Care and Use of Agricultural Animals in Research and Teaching (Ag Guide) developed by the Federation of Animal Science Societies.
- For universities and private organizations receiving funding from the National Institutes of Health (NIH), compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) is mandatory.

### Internal and Third Party Overview

- All Land Grant Institutions and all practicing private industry entities that conduct research for the purpose of improving food and fiber and using agricultural animals have adopted the Ag Guide, and require the use of Institutional Animal Care and Use Committees (IACUC) protocols. The IACUC is devoted to the principle of carrying out meaningful scientific research through the use of animals in accordance with humane standards
- The vast majority of laboratories conducting animal research are accredited by the Association for Assessment and Accreditation Laboratory Animal Care International. AAALAC is an internationally recognized organization that accredits both biomedical and agricultural research institutions and private firms.
- In the United States, all commodity groups for agricultural animals have set up programs for animal care and use on the farm, which are endorsed by the organization and adopted by their members.

### International Review

- In July 2008, the Codex Alimentarius Commission approved a new international guideline for use of animal biotechnology for food production entitled "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals." Animal health is regarded as an important factor in food safety risk assessment.

- The World Animal Health Organization (the OIE) is currently planning to address animal health related to genetic engineering technology including development of biotech-derived vaccines.
- The OIE is developing a guideline regarding health of animal clones.
- The International Embryo Transfer Society (IETS) is developing a set of standards for care of neonatal agricultural animal clones and surrogate animals, which will provide guidelines for the use of somatic cell nuclear transfer. IETS standards for embryo transfer, another assisted reproductive technology, have already been adopted and recognized by the OIE, the Food & Agriculture Organization, the World Health Organization and the World Trade Organization.
- The IETS is also developing a comprehensive international database on the health of agricultural animal clones and the composition of their food products which will be available internationally.