Fact Sheet
Regulatory Framework for GE Animals and their Products

BIO and its members engaged in animal biotechnology support a strong federal regulatory system to oversee development and approval of all genetically engineered (GE) animals and the products derived from them. BIO supports the use of the New Animal Drug framework by the FDA for regulation of GE animals.

The U.S. Food and Drug Administration (FDA) published its draft guidance for the regulation of GE animals on September 18, 2008, and took public comments until November 18, 2008. On January 15, 2009, FDA finalized the regulatory guidance. Under FDA's authority, the industry's goal is to ultimately provide to the marketplace approved products that have been deemed safe and beneficial.

Urging Support for NAD Framework

BIO is pleased that the FDA has made final the first U.S. government regulatory guidance governing genetically engineered animals. This system will ensure the products made available through this science will go through a thorough and transparent application process before being approved for the marketplace.

BIO supports the use of the New Animal Drug framework by the FDA for regulation of GE animals.

- The NAD process is consistent with key international standards as part of the food safety assessment for GE animals expected to be approved by the Codex Alimentarius Commission in July, 2008.

- The NAD pathway criteria can be applied to all GE animals equitably, including those agricultural animals developed for non-food production.

- The NAD pathway has been used by FDA for the last decade, after scientific, regulatory, and legal experts devised this consensus-based framework to ensure coordination among all centers within FDA.

- It is a mandatory process that leads to a formal FDA "approval." Such formal recognition by the agency is necessary for both domestic and international government and consumer acceptance of the technology, leading to successful commercialization of the technology and products.

- This rigorous, science-based approval process has been demonstrated to be critical to consumer acceptance of the technology and the products that will result.

Coordination Between FDA and USDA is Key

The coordination between FDA and USDA on this issue is important to ensure that regulations are thorough without being duplicative. The two departments have worked together since 2000 on the Office of Science and Technology Policy's (OSTP) Interagency Work Group on Regulation of Transgenic Animals.