ABSTRACT: Recent progress in the field of biotechnology and the production of transgenic livestock has raised a question regarding the need for the regulation of these animals. There is also the need to regulate nontransgenic animals resulting from transgenic animal research. It is anticipated that several governmental agencies will be involved in regulatory issues pertaining to these animals. The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) will ultimately be responsible for ensuring that transgenic animals intended for human consumption are wholesome, unadulterated, and properly labeled. The FSIS has implemented a program for the regulation of slaughtering nontransgenic animals resulting from transgenic animal experiments. However, the FSIS has not yet approved any transgenic livestock for slaughter. Scientists from the FSIS, in conjunction with other government agencies, are currently developing guidelines for the slaughter of transgenic animals.

Key Words: Transgenic, Food Safety, Biotechnology, Regulation

Introduction

The Food Safety and Inspection Service of the U.S. Department of Agriculture enforces the Federal Meat Inspection Act and Poultry Products Inspection Act. Under these acts, the FSIS provides inspection for food-producing establishments to ensure that meat and poultry and their products sold in intrastate, interstate, and foreign commerce for human consumption are wholesome, unadulterated, and accurately labeled.

Recent progress in the field of biotechnology and the production of transgenic livestock has raised the need for regulation of disposition of these animals. Transgenic animals, for the purpose of this document, are animals whose genetic composition has been changed by introducing selective genes (e.g., recombinant DNA) from exogenous sources other than parental germplasm into the line from which the animals are derived. An important characteristic, according to the definition of transgenic animals by Gordon and Ruddle (1981), is that the inserted genetic material has become a permanent part of the genome, transmitted by sexual reproduction.

Some possibilities for transgenic animals that are on the horizon include animals with leaner meat, animals that use feed more efficiently, animals with better growth performance, and animals that manufacture biopharmaceuticals for human or animal therapy.

The FSIS is proposing to regulate the slaughter of animals derived from biotechnology experiments under the experimental animal regulations as defined in 9 CFR 309.17 and 9 CFR 381.75. Experimental animals are defined by the regulations as animals treated with an experimental biological product, drug, or chemical. Transgenic animals can be included under this definition of experimental animals because the technique for producing the first generation of transgenic animals would involve the introduction of new genetic material considered to be either an experimental biological product, drug, or chemical. Experimental status would remain with future generations of these animals because the genetic material remains in edible tissues through subsequent generations.

Current Guidelines

The efficiency of producing transgenic livestock is very low (< 2%). As a result of extreme inefficiency, there is a large number of "no-takes," or nontransgenic animals. "No-takes" is a term commonly used to refer to animals that have not successfully incorporated a transgene and elaborated the gene protein. Due to the large number of nontransgenic animals that result from transgenic animal experiments, there is a high level of interest from corporations and researchers in slaughtering these animals for food.
There are two key questions for the evaluation of experimental animals. First, How can transgenic animals be distinguished from nontransgenic animals? A variety of methods are used to test the animals that result from transgenic animal experiments for the presence of the transgene. The most commonly used method is Southern hybridization of either directly extracted or polymerase chain reaction (PCR) amplified DNA to demonstrate incorporation of the foreign DNA. Data from application of these methods will be used by the FSIS to determine whether an animal is transgenic.

In the Federal Register Notice 23336, Vol. 51, No. 123, of June 26, 1986 titled "Final Policy Statement for Research and Regulation of Biotechnology Processes and Products" the Department's intention to regulate foods produced by new methods, such as recombinant DNA techniques, within the existing statutory and regulatory framework was stated. On December 27, 1992, Federal Register Notice 67054, Vol. 56, No. 249, was published by the FSIS, titled "Livestock and Poultry Connected with Biotechnology Research." This notice announced the availability of the document "Decision Criteria for the Evaluation of Nontransgenic Animals from Transgenic Research." The decision criteria paper was reviewed by the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and was unanimously endorsed by USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC). This document outlines the FSIS regulation for slaughter of nontransgenic animals resulting from transgenic animal experiments. These policies are in line with the President's federal biotechnology policy announced in February 1992 (Office of Science and Technology Policy, 1992), which emphasizes that federal oversight should be based on risk, and not triggered simply by the use of an innovative technology.

The second important question to ask concerning evaluation of these animals is, How can a regulatory agency determine the food safety of these experimental animals? This second question was dealt with when a research corporation in Texas submitted a request to the FSIS for evaluation of its "no-take" cattle for slaughter. In this petition the company provided sufficient data for the FSIS to conclude that the animals were not adulterated by virtue of the attempted gene insertion. The following criteria were used for determination of the food safety of these animals: 1) failure to detect the presence of the transgene by genetic methods, 2) absence of a measurable gene product, 3) absence of transgene-associated traits, and 4) physical condition and appearance of the animal prior to slaughter.

The company submitted the results on DNA isolation from two tissues: blood and skin. The FSIS scientists reviewed Southern hybridization and PCR data submitted by the company and all negative animals, in which insertion of the transgene was not detected, were released for food consumption.

**Future Guidelines**

The FSIS has not yet approved any transgenic livestock for slaughter. The FSIS, in concert with other federal agencies, is currently developing a policy for the slaughter of transgenic animals. Because the field of biotechnology is evolving rapidly, it is recognized that regulatory oversight will have to keep pace with technological advances. The plan is to publish, after appropriate review, a notice in the Federal Register announcing the availability of "Points to Consider Pertaining to the Food Safety and Evaluation of Transgenic Animals and Other Products of Biotechnology." It is anticipated that in evaluating the food safety of transgenic livestock, a cooperative effort between the FSIS, APHIS, and FDA will be required.

**Implications**

The Food Safety and Inspection Service has outlined the requirements for the slaughter of nontransgenic animals resulting from transgenic animal experiments. This provides an avenue for slaughter of the "no-takes" resulting from transgenic experiments. This is beneficial to the producers of such animals due to the low efficiency rate of producing transgenic animals.

**Literature Cited**
