OMB Control Number: 0572–0107.

Summary of Collection: The Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.*, as amended, (RE ACT) in Sec. 4 (7 U.S.C. 904) authorizes and empowers the Administrator of the Rural Utilities Service (RUS) to make loans in the several States and Territories of the United States for rural electrification and the furnishing and improving of electric energy to persons in rural areas. These loans are for a term of up to 35 years and are secured by a first mortgage on the borrower's electric system. In the interest of protecting loan security and accomplishing the statutory objective of a sound program of rural electrification, Section 4 of the RE Act further requires that RUS make or guarantee a loan only if there is reasonable assurance that the loan, together with all outstanding loans and obligations of the borrower, will be repaid in full within the time agreed. RUS will collect information using various RUS forms.

Need and Use of the Information: RUS will collect information to implement certain provisions of the RUS standard form of loan documents regarding the borrower's purchase of materials and equipment and the construction of its electric system by contract or force account. The information will be used by RUS electric borrowers and their contractors and by RUS. If standard forms were not used, borrowers would need to prepare their own documents at a significant expense; and each document submitted by a borrower would require extensive and costly review by both RUS and the Office of the General Counsel.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 1,210.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 104.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E8–21907 Filed 9–18–08; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2006–0188]

RIN 0579–AC37

Genetically Engineered Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for information.

SUMMARY: The Animal and Plant Health Inspection Service (APHIS) is seeking public comment and scientific and technical empirical data and information concerning ongoing and future research on genetically engineered animals. APHIS' interest is to ensure that genetically engineered animals imported into the United States or moved interstate do not present risks to U.S. livestock health. We also seek comment on what types of actions and approaches APHIS should consider in addressing any such risks that would complement the Food and Drug Administration's (FDA's) oversight, described in draft guidance elsewhere in this issue of the **Federal Register**.

DATES: We will consider all comments that we receive on or before November 18, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2006–0188* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2006–0188, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0188.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737–1236; 301–734–5720.

SUPPLEMENTARY INFORMATION:

Background

In 1986, the Office of Science and Technology Policy (OSTP) under the Executive Office of the President published a policy document known as the Coordinated Framework for the Regulation of Biotechnology (the Coordinated Framework).[1] This policy document describes the system for coordinating the activities of the Federal agencies responsible for regulating all GE organisms:[2] The Environmental Protection Agency (EPA), the U.S. Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA), specifically the Animal and Plant Health Inspection Service (APHIS). The foundation of the Coordinated Framework is that existing health and safety laws administered by these Federal agencies provide a sound network of agency authorities for the regulation of GE organisms and products.

Roles of APHIS and Other Agencies in the Regulation of GE Animals

USDA and FDA both have authorities relevant to the oversight of GE animals. FDA has authority over new animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. 321 *et seq.*). Elsewhere in the issue of the **Federal Register**, FDA is announcing the availability of draft guidance for public comment clarifying its oversight of GE animals under the new animal drug provisions of the FFDCA. The draft guidance explains that where a recombinant DNA construct in a GE animal is intended to affect the structure or function of the body of the GE animal, that construct is a new animal drug [3] regardless of the intended use of products that may be produced by the GE animal. The FFDCA requires that each new animal drug be approved through a new animal drug application (NADA) based on a demonstration that it is safe and effective for its intended use. FDA has been working with developers of GE animals for almost 20 years and the draft guidance is intended to clarify requirements and recommendations for producers and developers of GE animals and their products.

[1] Coordinated Framework for the Regulation of Biotechnology: June 26, 1986; 51 FR 23302; *http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf.*

[2] In addition to discussing the regulatory responsibilities of these agencies for GE organisms and other products, the Coordinated Framework also discusses the responsibilities of agencies with jurisdiction over GE research (the National Institutes of Health, the National Science Foundation, EPA, and USDA's Agricultural Research Service).

[3] In accordance with the definition of ''new animal drug'' in 21 U.S.C. 321(v).

The USDA has provided Federal leadership in protecting U.S. livestock health for more than 120 years. APHIS is authorized, under the Animal Health Protection Act (AHPA) (7 U.S.C. 8301 *et seq.*), to protect the health of U.S. livestock by preventing the introduction and spread of livestock diseases and pests into and within the United States. Based on that authority, APHIS may broadly consider the potential effects of animals with GE traits on the health of the overall U.S. livestock population, while FDA is more focused on the direct effects of genetic engineering on individual animals based on their authority under the FFDCA. Given these complementary authorities, APHIS and FDA have been discussing their respective roles in overseeing GE animals for some time. FDA's release for public comment of its draft guidance on GE animals provides an excellent opportunity for APHIS to solicit public comment on the potential effects of animals with GE traits on U.S. livestock health.

APHIS particularly seeks the following information:

1. What research on GE animals is currently being conducted or planned for the future?

2. What, if any, implications would activities such as the importation and interstate movement of such animals have for the health of the U.S. livestock population?

3. What, if any, activities should APHIS consider with respect to U.S. livestock health under the AHPA that would complement the requirements and recommendations described in FDA's draft guidance?

APHIS welcomes comments and scientific and technical information and data relevant to these issues. We will consider all comments and information we receive in determining the appropriate role for APHIS with regard to GE animals and will continue to collaborate closely with FDA.

This action has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.

Done in Washington, DC, this 16th day of September 2008.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. E8–21977 Filed 9–18–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0032]

Codex Alimentarius Commission: 2nd Session of the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance

AGENCY: Office of the Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting.

SUMMARY: The Office of the Under Secretary for Food Safety, United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA) are sponsoring a public meeting on September 25, 2008, to discuss the agenda items coming before the 2nd session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (AMR) and to present draft U.S. positions on the agenda items. The 2nd session of the AMR will be held in Seoul, Korea, October 20–24, 2008. The Under Secretary and FDA recognize the importance of providing interested parties the opportunity to comment on the agenda items that will be discussed at this forthcoming session of AMR.

DATES: The public meeting is scheduled for Thursday, September 25, 2008, from 1 p.m. to 3 p.m.

ADDRESSES: The public meeting will be held at FDA, 7519 Standish Place, Room 152, Rockville, MD.

Documents related to the 2nd session of the AMR will be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp.*

For Further Information About the 2nd Session of the AMR Contact: U.S. Delegate, Dr. David White, Director, National Antimicrobial Resistance Monitoring System (NARMS), FDA, Center for Veterinary Medicine, Office of Research, 8401 Muirkirk Rd., Laurel, MD 20798, *Phone:* (301) 210–4181, *E-mail: david.white@fda.hhs.gov.*

For Further Information About the Public Meeting Contact: Edith Kennard, Staff Officer, U.S. Codex Office, Food Safety and Inspection Service (FSIS), Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, *Phone:* (202) 720–5261, *Fax:* (202) 720–3157, *E-mail: edith.kennard@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius (Codex) was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure that fair practices are used in trade.

The Codex *ad hoc* Intergovernmental Task Force on AMR was established by the 29th Session of the Codex Alimentarius Commission in 2006 to develop science-based guidance to be used to assess the risks to human health associated with the presence in food and feed, including aquaculture, and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes. The AMR Task Force would also consider appropriate risk management options to reduce such risk. The Task Force is hosted by the Republic of Korea.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 2nd session of the AMR will be discussed during the public meeting:

- Matters Referred to the Committee from Other Codex Bodies
- Information on the Work by FAO, WHO, and the World Organization for Animal Health on Antimicrobial Resistance
- Proposed Draft Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Microorganisms (Report of the Working Group)
- Proposed Draft Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microorganisms for Setting Risk Assessment and Management Priorities (Report of the Working Group)
- Proposed Draft Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms (Report of the Working Group)

Each issue listed will be fully described in documents distributed, or to be distributed, by the Korean Secretariat to the meeting. Members of the public may access copies of these documents at *http://www.codexalimentarius.net/current.asp.*

Public Meeting

At the September 25, 2008, public meeting, draft U.S. positions on these agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S.