TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS Guideline Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories	312.57 and 312.62(b)

¹The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (http://www.grants.nih.gov/grants/olaw/references/phspol.htm).

²AAALAC International Rules of Accreditation (http://www.aaalac.org/html/rules.html).

³ The NRC's "Guide for the Care and Use of Laboratory Animals" (1996).

II. Electronic Access

Persons with access to the Internet may obtain the guideline at http://www.fda.gov/cber/guidelines.htm.

Dated: May 23, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-13340 Filed 5-25-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-99-7000]

Memorandum of Understanding Between the Food and Drug Administration, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the U.S. Department of Defense, and the Environmental Protection Agency

AGENCY: Food and Drug Administration, HHS.

11113.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the U.S. Department of Defense, and the Environmental Protection Agency. The purpose of the MOU is to establish an interagency coordinating committee on animal production and food health with the goal of improving animal and public health.

DATES: The agreement became effective November 17, 1999.

FOR FURTHER INFORMATION CONTACT:

Robert C. Livingston, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-5903.

SUPPLEMENTARY INFORMATION: In

accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 19, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

The MOU is set forth in its entirety as follows:

BILLING CODE 4160-01-F

MOU 225-99-7000

MEMORANDUM OF UNDERSTANDING

Between The Following Departments and Agencies

THE UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE
AGRICULTURAL RESEARCH SERVICE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE
ECONOMIC RESEARCH SERVICE
FOOD SAFETY AND INSPECTION SERVICE
FOREIGN AGRICULTURAL SERVICE
GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION
OFFICE OF RISK ASSESSMENT AND COST-BENEFIT ANALYSIS

And

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION and the FOOD AND DRUG ADMINISTRATION (FDA) including FDA's

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION CENTER FOR VETERINARY MEDICINE

And

THE DEPARTMENT OF DEFENSE
UNITED STATES ARMY VETERINARY SERVICE

And

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES and the OFFICE OF WATER

RELATIVE TO

INTERAGENCY COORDINATING COMMITTEE ON ANIMAL PRODUCTION AND FOOD SAFETY

The parties to this Memorandum of Understanding are the following agencies of the United States Department of Agriculture: the Agricultural Marketing Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research, Education and Extension Service, the Economic Research Service, the Food Safety and Inspection Service, the Foreign Agricultural Service; the Grain Inspection, Packers and Stockyards Administration, and the Office of Risk Assessment and Cost-Benefit Analysis; the following agencies of the Department of Health and Human Services: the Food and Drug Administration's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine, and the Centers for Disease Control and Prevention; the Department of Defense's United States Army Veterinary Service; and the Environmental Protection Agency's Office of Prevention, Pesticides, and Toxic Substances and the Office of Water;

WHEREAS, the parties to the Memorandum of Understanding agree that the public policy issues surrounding food animal and public health and the marketing of food animals are integral to the work of each of the parties;

WHEREAS, the parties recognize that food animal production practices including production of livestock, poultry, eggs, and farm-raised fish may impact food safety;

WHEREAS, it is important to the success of the mission of each of the parties that each party know about food safety activities being undertaken by other parties and that the such activities of each of the parties be coordinated;

WHEREAS, President William J. Clinton has challenged those federal agencies involved in food safety/public health to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with all stakeholders;

WHEREAS, the parties to this agreement recognize the fundamental relationship between food safety and public health and food animal health and production practices;

THEREFORE, the parties to this Memorandum of Understanding agree to cooperate through an orderly exchange of information, jointly held meetings, and the appointment of liaison personnel and committees to gather and exchange background information relating to individual agency policies or use in risk analysis, to exchange information about ongoing agency activities, and to increase interaction among food animal health and public health experts with the goal of improving animal and public health, and for other purposes in the interest of the parties to improve the safety of food produced from animals.

I. RATIONALE

All federal agencies share a common objective of serving the American public. Although each agency has a defined set of responsibilities, it is only when they work in harmony

that the government is most efficient. The safety of food depends upon the integrated efforts of those agencies responsible for animal health, animal production, human health and food derived from livestock and aquaculture, including animal production practices on land and in water which may impact food safety. The complexity of the farm-to-table chain requires communication, coordination and cooperation among all these organizations in order to efficiently, effectively and rapidly achieve respective goals as well as to provide consumers with the safest, most abundant and economical food supply in the world.

Examples of this approach include the 1997 Presidential Food Safety Initiatives on produce and animal products. Therein, the President directed the many involved agencies to work cooperatively to develop systems improving food safety.

The signatory agencies to this Memorandum of Understanding share a common interest in maintaining a safe, wholesome and affordable food supply. While each signatory's mission area may focus on different aspects of animal production and food safety, the agencies agree that sharing food safety information, coordinating activities, and improving collaboration will collectively enhance the success of each agency's mission.

II. RELATIONSHIPS OF PARTIES

The Agricultural Marketing Service (AMS), USDA, administers standardization, grading, certification, promotion, and regulatory programs. Grading and classification services are provided to certify the grade and quality of meat, egg and poultry products. See 21 U.S.C. 601 et seq., 451 et seq., and 1031 et seq. These grading services are provided to buyers and sellers of live cattle, swine, sheep, poultry, rabbits, and other meat, egg and poultry products. These services are voluntary and provided upon request on a fee-for-service basis. The AMS also administers the Pesticide Data Program, in cooperation with States, in which fresh fruits and vegetables are sampled and analyzed for pesticide residues. See 7 U.S.C. 136i-1. Under a government-wide quality assurance program, AMS is responsible for developing specifications for government procurement of food used by the military and for civilians. The AMS is responsible for the development of an efficient agricultural transportation system for rural America. See 7 U.S.C. 1622. The system begins at the farm gate and moves agricultural and other rural products through the Nation's highways, railroads, etc., into domestic and international marketplaces. The AMS is also developing national organic standards. See 7 U.S.C. 6501-6522.

The Agricultural Research Service (ARS), USDA, is responsible for carrying out research programs to assist other USDA agencies in meeting their statutory objectives. Accordingly, it is responsible for developing research methodologies relating to both animal health and animal production food safety.

The Animal and Plant Health Inspection Service (APHIS), USDA, was established to conduct regulatory and control programs to protect and improve animal and plant health.

The agency administers Federal laws and regulations pertaining to plant and animal health and quarantine, and the control and eradication of plant and animal pests and diseases. APHIS is authorized to cooperate with State and local jurisdictions in achieving these objectives.

The Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA), U.S. Department of Health and Human Services (USHHS), is charged with enforcement of the Federal Food, Drug and Cosmetic Act (FD & C Act), 21 U.S.C. 301 et. seq., and the Public Health Service Act. 42 U.S.C. 201 et. seq., Under the FD & C Act, CFSAN is responsible for the regulation of foods for human consumption and cosmetics. The mission of the center is to (1) ensure that food is safe, (2) emphasize a preventive approach to protecting public health, (3) promote sound nutrition, (4) ensure that food and cosmetic products are honestly and accurately labeled, and (5) encourage industry innovation while upholding safety standards and maintaining consumer protection. CFSAN has responsibility for ensuring the general safety and wholesomeness of all human food except meat, poultry and egg products.

The Centers for Disease Control and Prevention (CDC) of USHHS is the Federal agency charged with protecting the public health of the Nation by providing leadership and direction to prevent and control diseases and other preventable conditions and to respond to public health emergencies pursuant to Section 301 of the Public Health Service Act (42 U.S.C. 241). It is composed of 11 major operating components including the National Center for Infectious Diseases. The CDC administers national programs for the prevention and control of communicable and vector-borne diseases, injury, and other preventable conditions. CDC develops and implements programs in chronic disease prevention and control in consultation with State and local health departments.

The Center for Veterinary Medicine (CVM), FDA, USHHS, has responsibility under the Federal FD & C Act for regulation of animal drugs and feeds, including the premarket approval of veterinary drugs and feed additives, and regulating the manufacture and distribution of animal drugs and feeds. Before approving an animal drug, CVM reviews the sponsor's data to assure the drug's effectiveness as well as safety to the animal being treated and to humans consuming food derived from animals treated with the drug. To assure human food safety, CVM sets safe concentration and tolerance levels for the approved drugs that may appear in animal tissue at the time of slaughter and investigates violations of residues above safe tolerance levels. CVM also ensures that animal feed is safe and wholesome and is free of illegal drug, pesticide, and industrial chemical residues. To address the potential public health risks from antibiotic resistant pathogens and resistance genes, in 1996 CVM established and coordinated the National Antimicrobial Resistance Monitoring System (NARMS), a collaboration between FDA, CDC and USDA/ARS. NARMS currently monitors shifts in susceptibility to antimicrobial drugs among Salmonella from animal isolates and Salmonella, E. coli O157 and Campylobacter from human isolates. CVM plans to greatly expand the program under the Food Safety Initiative.

The Cooperative State Research, Education, and Extension Service (CSREES), USDA, links the research and education resources and activities of USDA and works with educational institutions in each state and territory. CSREES provides focus to advance a global system of research, extension, and higher education in food and agricultural sciences and in related environmental and human sciences. The CSREES mission emphasizes partnerships with the public and private sector to maximize the effectiveness of limited resources.

The **Department of Defense** (DOD) also has defined functions impacting public health (food safety). The United States Army Veterinary Service, the United States Army Center for Health Promotion and Preventive Medicine, and the United States Air Force Biomedical Science Corps conduct training in public health, including food safety; inspect and test food processing facilities and delivered products; manage community public health programs; and coordinate these programs with other federal agencies. The U.S. Army Veterinary Service also participates in national/regional responses to natural and disease emergencies impacting public health, animal health, and economic stability. The DOD also contributes to food safety through research and surveillance on pathogens associated with the production and consumption of foods.

The mission of the **Economic Research Service** (ERS), USDA, is to provide agricultural economic and other agriculture-related social science information and analysis for public and private decisions on agriculture, food, natural resources, and rural America issues. ERS produces such information for use by the general public and to help the executive and legislative branches of the Federal government develop, administer, and evaluate agricultural and rural policies and programs.

The Food Safety and Inspection Service (FSIS), USDA, under the authority of the FMIA, PPIA, and the EPIA is responsible for the wholesomeness and safety of meat, poultry, and egg products intended for human consumption. This is accomplished by continuous inspection at slaughtering and processing establishments. The inspections include the sampling and analyzing of edible tissues taken from livestock and poultry at the time of slaughter to assure that meat and poultry do not contain adulterants such as drugs, pesticides, other industrial chemicals and harmful foodborne pathogens. FSIS also takes egg product samples to test for Salmonella. FSIS seeks to reduce the incidence of foodborne human pathogens on meat, poultry and egg products in order to reduce the incidence of foodborne.

The Foreign Agricultural Service (FAS), USDA, represents the diverse interests of US farmers and the food and agricultural sector abroad. It collects, analyzes, and disseminates information about global supply and demand, trade trends, and emerging market opportunities. FAS seeks improved market access for U.S. products and implements programs designed to build new markets and to maintain the competitive position of U.S. products in the global marketplace. In addition, FAS coordinates food safety issues for USDA in Washington, D.C. and overseas, as they impact on foreign trade.

The Grain Inspection, Packers and Stockyards Administration (GIPSA), USDA, plays a key part in USDA's efforts to ensure a productive and competitive global marketplace for U.S. agriculture products. One of GIPSA's program, the Packers and Stockyards Programs, ensures open and competitive markets for livestock, meat, and poultry. The other program, the Federal Grain Inspection Service, provides the U.S. grain market with Federal quality standards and a uniform system for applying them. GIPSA, as an impartial third party in American agriculture, helps ensure a fair competitive marketing system for all involved in the merchandising of grain and related products, livestock, meat and poultry.

The Office of Risk Assessment and Cost-Benefit Analysis, (ORACBA), USDA, is part of the Office of the Chief Economist. The primary mission of ORACBA is to ensure that major regulations proposed by USDA, which primarily affect human health, safety, or the environment, are based on sound scientific and economic analysis. Besides assuring that statutory requirements for risk assessment are met, ORACBA provides guidance and technical assistance and coordinates risk analysis work across USDA.

The U.S. Environmental Protection Agency, (EPA), Office of Prevention, Pesticides, and Toxic Substances (OPPTS) is responsible for registering pesticides, many of which control microorganisms that cause foodborne illness. Through ongoing testing and rigorous review of submitted data, OPPTS ensures the efficacy of antimicrobial pesticides that prevent growth of pathogenic microorganisms on raw agricultural commodities (fruits and vegetables) and on certain surfaces that contact food during processing. These actions are central to reducing the public's risk of foodborne disease.

The U.S. Environmental Protection Agency (EPA), **Office of Water**, is the Federal Agency responsible for insuring that drinking waters in the United States are safe for human consumption. Pursuant to the Safe Drinking Water Act, 42 U.S.C. 300 (f) et seq., the EPA provides regulations on acceptable treatment and monitoring of drinking water from chemically or microbiologically contaminated surface and ground water sources to protect public health. Pursuant to the Clean Water Act, 33 U.S.C. 1251 et. seq., the EPA provides for the protection of fresh and marine waters so they are swimmable and fishable. EPA also has responsibilities for ensuring adequate treatment and control of infectious disease contaminants that may occur in human and industrial wastes, manures and other waste products that can imperil the safety of ambient water resources. EPA conducts risk assessments on pathogens in various water exposure scenarios, provides research to develop analytical methods, conducts evaluation of pathogen occurrence and human exposure/health effects, and develops improved water, wastewater, and biosolids treatment technologies for pathogen reduction or elimination.

III. Establishment of Committee

The aforementioned agencies and centers (hereinafter "agencies" or the "parties") agree to establish an Interagency Coordinating Committee on Animal Production and Food Safety.

IV. Purpose and Function of the Committee

The purpose and function of the Interagency Coordinating Committee on Animal Production and Food Safety shall be:

- (a) To provide a forum where member agencies share information related to food safety, animal health, marketing and production, environmental safety, research, educational initiatives, risk analysis, policies, programs and other activities which may potentially impact public health and animal production practices.
- (b) To promote coordination of agency activities relating to (a) above, including policy development, rulemaking, educational initiatives, risk analysis and research; and
- (c) To promote collaboration whereby agencies, where authorized, might enter into joint activities which would make the most effective use of resources and avoid unnecessary duplication of activities relating to animal production practices and food safety.

V. Organization of the Committee

The parties hereby establish the Interagency Coordinating Committee on Animal Production and Food Safety, which shall consist of a **Steering Committee** and a **General Committee**.

The Steering Committee shall consist of one representative from each of the signatories, who shall be appointed by the Agency Administrator or Center Director or other authorized official of the agencies, who are parties to this Agreement. The Steering Committee provides leadership and logistical support for the work of the Interagency Coordinating Committee on Animal Production and Food Safety. The Steering Committee shall facilitate and coordinate the activities of agencies, where the agencies pursue joint action. Members of the Steering Committee are the official conduit to the agency Administrators or center Directors, as appropriate, for the determination of whether an agency or center shall commit resources for a project or activity, in accordance with each Agency's or Center's authorities. The Steering Committee may set up subcommittees to coordinate projects, as it shall deem appropriate. The Chairperson of the Steering Committee shall be chosen by the membership of the Steering Committee for a one-year term.

The purpose of the **General Committee** is to provide a forum to share information and to promote interagency collaboration and coordination of issues, including those issues prioritized by the Steering Committee. The General Committee may make recommendations to the Steering Committee. The General Committee shall consist of

representatives from each of the member agencies. The members of the General Committee shall be designated either by the Agency Administrator or Center Director, or by the member agency Steering Committee representative, as determined by each member agency. A member agency may have more than one representative on the General Committee, but no more than three per agency. Official representatives to the General Committee may ask appropriate staffs of their agencies to attend General Committee meetings to ensure adequate information sharing. Agencies that are not signatories to this Memorandum of Understanding may become members of the General Committee upon application to, or nomination by a signatory agency, and approval by the Steering Committee. The Chairperson of the General Committee shall be chosen by the membership of the General Committee for a one-year term.

There shall be an **Executive Secretary** appointed by the Steering Committee for the purpose of supporting the activities of the Interagency Coordinating Committee on Animal Production and Food Safety. The Executive Secretary shall be responsible for making meeting arrangements, organizing committee and sub-committee activities, and publishing committee reports.

VI. Sunset of the Committee

The Interagency Coordinating Committee on Animal Production and Food Safety will cease to exist five years after the signature of all of the parties, but may be re-authorized and thereby extended through amendment of this Memorandum of Understanding by the signatories.

VII. General Provisions

It is mutually agreed and understood by and among the parties to this Agreement that:

- A. Specific work projects or activities that involve transfer of funds, services, or property among the parties will require execution of separate interagency agreements, contingent upon availability of funds as appropriated by Congress. Each subsequent agreement or arrangement involving transfer of funds, services, or property among the parties must comply with all applicable statutes and regulations, including those statutes and regulations governing procurement activities, and must be authorized by appropriate statutory authority.
- B. This Memorandum of Understanding in no way restricts the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.
- C. Nothing in this Memorandum of Understanding supersedes any other memorandum of understanding held by any of the participating agencies.
- D. Nothing in this Memorandum of Understanding shall obligate the parties to expend appropriations to enter into any contract or other obligations. Each party

to this Memorandum of Understanding shall handle its own activities and utilize its own resources, including expenditure of its own funds. This Memorandum of Understanding is neither a funds obligation or funds transfer document.

- E. This Memorandum of Understanding will become effective upon the signature of all of the parties and shall remain in effect for 5 years from the date of execution. This Memorandum of Understanding may be extended or amended upon written request of any party hereto and the subsequent written concurrence of all of the parties. Parties' participation in the Memorandum of Understanding may be terminated by providing 60-day written notice to all the other parties. Additional parties may be added to this Memorandum of Understanding with the agreement of the signatories.
- F. This Memorandum of Understanding is intended only to improve the internal management of the executive branch and is not intended to, nor does it create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.
- G. The terms of this Memorandum of Understanding are not intended to be enforceable by any party other than the signatories.

The following member agencies have agreed to the aforementioned Memorandum of Understanding establishing the Interagency Coordinating Committee on Animal Production and Food Safety on the dates set forth below.

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

BY:

THOMAS J. BILLY

ADMINISTRATOR

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION CENTER FOR VETERINARY MEDICINE

BY:

STEPHEN F. SUNDIJOF

DIRECTOR

DATE:

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE AGRICULTURAL RESEARCH SERVICE

BY: Thouse I form

FLOYD HORN

ADMINISTRATOR

DATE: 5-25-99

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

BY: Jun Action, acting COLIEN HERBERAN ADMINISTRATOR

DATE: May 17, 1999

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION

BY: Amus K. Daw JAMES R. BAKER ADMINISTRATOR DATE: 1-20-99

APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

SUSAN H. WAYLAND

DEPUTY ASSISTANT ADMINISTRATOR ASSISTANT

DATE: 8 9 99

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL PREVENTION, NATIONAL CENTER FOR INFECTIOUS DISEASES

JAMES M. HUGHES

DIRECTOR

DATE: 9/16/9

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING

SERVICE

BY: ENRIQUE FIGUEROA

ADMINISTRATOR DATE: <u>5-11-9</u>

APPROVED AND ACCEPTED FOR THE U. S. DEPARTMENT OF DEFENSE DEPARTMENT OF THE ARMY

BY: MAJOR GENERAL JOHN J. CUDDY DEPUTY SURGEON GENERAL DATE: 12-23-98

APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF WATER

BY: JCHARLES FOX

ASSISTANT ADMINISTRATOR

DATE: 4799

APPROVED AND ACCEPTED FOR THE
U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF RISK ASSESSMENT AND COST
BENEFIT ANALYSIS
BY:

ALWYNELLE S. AHL

DIRECTOR
DATE:

APPROVED AND ACCEPTED FOR THE
U.S. DEPARTMENT OF AGRICULTURE
FOREIGN AGRICULTURAL SERVICE
BY:

Tigothy J. Galvin

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

BY:

CRAIG A REED ADMINISTRATOR

DATE: N/17/99

[FR Doc. 00–13208 Filed 5–25–00; 8:45 am]

BILLING CODE 4160-01-C

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF AGRICULTURE ECONOMIC RESEARCH SERVICE

BY:

SUSAN OFFUTT

ADMINIŞTRATOR

DATE: ___3

APPROVED AND ACCEPTED FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

JOSEPH A. LEVITT
DIRECTOR

DATE: 11/12/55