

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Cooperative Arrangement Between the United States Departments of Health and Human Services and Agriculture and the Secretariats of Health and Agriculture, Livestock, Rural Development, Fish, and Food of the United Mexican States Regarding Cooperative Activities to Enhance the Safety of Food for Human Consumption**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a cooperative arrangement

between the Department of Health and Human Services and the Department of Agriculture of the United States of America and the Secretariat of Health and the Secretariat of Agriculture, Livestock, Rural Development, Fish, and Food of the United Mexican States. The purpose of this arrangement is to strengthen existing scientific and public health protection cooperative activities related to the regulation of the safety of food to achieve a reduction in the incidence of foodborne illnesses in both countries.

DATES: The arrangement became effective September 4, 2001.

FOR FURTHER INFORMATION CONTACT: Camille Brewer, International Activities Coordinator for Food, Center for Food Safety and Applied Nutrition (HFS-032), Food and Drug Administration,

200 C St. SW., Washington, DC 20204, 202-260-2314. (After December 14, 2001, the Center for Food Safety and Applied Nutrition's address will be 5100 Paint Branch Pkwy., College Park, MD 20740.)

SUPPLEMENTARY INFORMATION: This cooperative arrangement is being published in accordance with 21 CFR 20.108(c) which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**.

Dated: December 13, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

The arrangement is set forth in its entirety as follows:

BILLING CODE 4160-01-S

COOPERATIVE ARRANGEMENT
AMONG
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE DEPARTMENT OF AGRICULTURE
OF THE UNITED STATES OF AMERICA
AND
THE SECRETARIAT OF HEALTH
AND
THE SECRETARIAT OF AGRICULTURE, LIVESTOCK,
RURAL DEVELOPMENT, FISH, AND FOOD
OF THE UNITED MEXICAN STATES
REGARDING COOPERATION TO ENHANCE ACTIVITIES OF MUTUAL INTEREST IN
THE AREA OF THE SAFETY OF FOODS
FOR HUMAN CONSUMPTION

The Department of Health and Human Services (DHHS) and the Department of Agriculture (USDA) of the United States of America and the Secretariat of Health (SSA) and the Secretariat of Agriculture, Livestock, Rural Development, Fish, and Food (SAGARPA) of the United Mexican States, hereinafter referred to as the "participants,"

RECOGNIZING

The special relationship between the participants and their mutual commitment to achieve a significant reduction in the incidence of food-borne illnesses in both countries as evidenced by the United Mexican States and the United States of America Joint Statement on Food Safety signed on June 10, 1998;

Food safety officials and competent authorities of the participants can better achieve this goal by sharing information and experience concerning the regulation of food products;
The trade links between the United States and Mexico under the North American Free Trade Agreement, the common border, and the high degree of trade in food products between our two countries;

In particular, that close bilateral cooperation with regard to those food products that are traded, or may be traded, between the two countries has the potential to significantly increase public health protection in both countries;

That effective food safety programs, both in the United States and in Mexico, require close cooperative efforts of public health and regulatory officials and agencies at the federal, state, and local levels; that such programs require the active participation by other non-government entities such as consumers, industry, and academia that are responsible for and concerned about food safety and reducing the incidence of food-borne health hazards; and that this Arrangement does not diminish any of the existing and ongoing cooperative efforts of these government and non-government agencies, groups, and individuals working to enhance and effect food safety; and

The importance of reducing potential hazards related to situations involving processed and unprocessed food products in both countries through enhanced regulatory and scientific collaboration and through the implementation of specific cooperative activities

Have reached the following understanding:

Article 1
Purpose

This Arrangement is intended to affirm the intention between the participants to strengthen existing scientific and public health protection cooperative activities related to the regulation of the safety of food, including products and feed for food-producing animals.

Article 2
Products

In order to achieve the goal of this Arrangement, the cooperative activities include the following products:

- foods and food products for human consumption, both processed and unprocessed
- feeds intended for use in food-producing animals
- foods derived from biotechnology;
- additives intended for use in such foods and feeds
- pesticide residues and other contaminants in food agricultural commodities
- animal drugs intended for use in food-producing animals

And, the following activities related to the above-mentioned products:

- antimicrobial resistance
- good agricultural practices
- good manufacturing practices
- good laboratory practices
- biotechnology
- nutrition
- labeling requirements
- incidents or outbreaks of disease, health hazard, contamination, injury, adverse event, or adverse finding that may arise in routine or emergency situations

Article 3
Activities

The participants, in accordance with their legal authority, intend to develop joint efforts to effectively and appropriately exchange information and enhance and develop programs and intend to coordinate as appropriate with other relevant food safety agencies, groups, and individuals within their countries. These information exchanges and programs may include the following activities:

A. Development of specific procedures for the exchange of regulatory and public health information, both for routine and emergency purposes. This information includes laws, regulations, proposed amendments, guidelines, procedures, and technical documents (such as evaluation of foreign suppliers of regulated products and enforcement decisions, including inspection reports, reports of injury related to processed or unprocessed food products, recalls or rejected shipments of products, and training material from regulatory agencies pertaining to regulated products).

B. Development of specific procedures for exchanging information in the early stages of an investigation, whenever possible, rather than in the last stages or at the conclusion of the investigation, during emergency situations such as the seizure, detention, or withdrawal of products because of safety reasons or other reasons.

C. Determining the information that should be exchanged among the participants prior to making information related to emergency situations public.

D. Dialogue and other communication intended to achieve, where appropriate, common positions on emerging international standards or practices in meetings of international organizations such as the Codex Alimentarius Commission and the Organization International des Epizooties.

E. Identification of research projects and studies to support the scientific basis for regulatory requirements and actions that are of mutual interest, such as those related to epidemiology, exposure estimates, risk identification, and other information that would form the bases for pre- and post-market risk assessments, risk analysis, and safety evaluations.

F. Identification of regulatory and scientific standards, procedures, and other requirements where there is potential for immediate and future harmonization.

G. Identification and implementation of joint training for the purpose of mutual understanding and harmonization of surveillance and compliance activities.

H. Exchange of information and data resulting from an investigation conducted by the participants when these investigations have been related to food-borne illnesses.

Article 4 Confidentiality

The participants expect that most of the information exchanged under this Arrangement may be provided in a form appropriate for public dissemination under the laws of the transmitting participants. Information that is not appropriate for public dissemination should be shared according to the procedures and policies of the participants as permitted by the laws of the participants.

The participants also should provide the other participants with copies of their laws and regulations governing their ability to maintain information as confidential.

With regard to any non-public information that may be provided to SAGARPA or SSA by U.S. participants, such transmissions should be made in accordance with the specific signed confidentiality commitments and other requirements of those participants.

Article 5 Funding

Each participant intends to fund its own activities subject to the availability of appropriated funds, personnel, and other resources.

Article 6 Plan of Work

The participants intend to develop a Plan of Work describing specific activities to be carried out under this Arrangement. Liaison Officers intend to meet at least once a year to review and revise the Plan of Work.

Liaison Officers will be as follows:

A. For DHHS

Director
Division of Emergency and Investigational Operations
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857
Telephone: 301- 443-1240 or 301- 827-5660
Fax: 301- 443-3757

International Activities Coordinator for Food
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204
Telephone: 202-260-2314
Fax: 202-260-9653

B. For USDA

Assistant Deputy Administrator
Program Coordination and Evaluation
Office of Policy, Program Development, and Evaluation
Food Safety Inspection Service
Department of Agriculture
1400 Independence Avenue, SW
Room 4866 South Building
Washington, D.C. 2500-3700
Telephone: 202-720-3473
Fax: 202-720-3856

C. For SSA

Federal Commission Against Sanitary Risks
Direction General of Sanitary Control of Products and Services
Donceles 39, 1er Piso
Col.Centro. 06010 México, D.F.
Telephone: 525-512-3050 or 525-521-9134
Fax: 525-521-9628

D. For SAGARPA

Director in Chief
Comision Nacional de Seguridad Agropecuaria (CONASAG)
Amores 321, 1er Piso
Col. Del Valle, C.P. 03100, México, D.F.
Telephone: 525-536-6626 or 525-687-7954
Fax: 525-687-7938

Article 7
Settlement of Disputes

The participants should strive to resolve by mutual decision any disputes that arise from the interpretation or application of this Arrangement.

Article 8 Duration

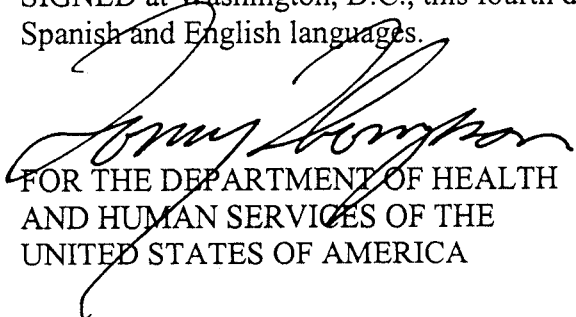
This Arrangement commences upon signature by all participants for ten (10) years. It may be extended for an additional ten-year period, after evaluation by the participants.

The participants may amend this document, by mutual written consent, specifying the date the amended Arrangement commences.

This Arrangement may be terminated by any participant upon thirty days advance written notice to the other participants.

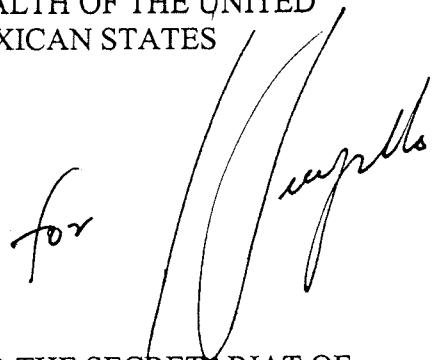
Termination of this Arrangement does not affect the completion of cooperation activities that may have been formalized prior to termination.

SIGNED at Washington, D.C., this fourth day of September 2001, in quadruplicate, in the Spanish and English languages.


 FOR THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES OF THE
UNITED STATES OF AMERICA


 FOR THE SECRETARIAT OF
HEALTH OF THE UNITED
MEXICAN STATES


 FOR THE DEPARTMENT OF
AGRICULTURE OF THE
UNITED STATES OF AMERICA


 FOR THE SECRETARIAT OF
AGRICULTURE, LIVESTOCK,
RURAL DEVELOPMENT, FISH,
AND FOOD OF THE UNITED
MEXICAN STATES

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 10, 2002, from 9:30 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on premarket approval application (PMA) for a spinal fusion cage with a growth