

# **COOPERATIVE ARRANGEMENT**

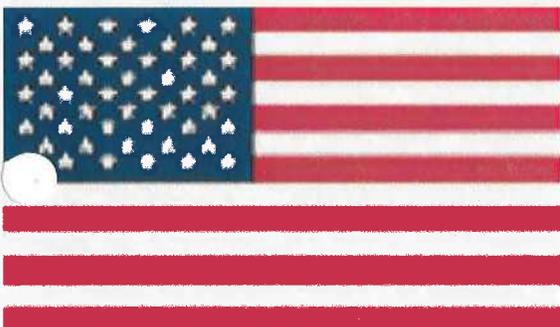
---

**BETWEEN**  
**THE FOOD AND DRUG ADMINISTRATION**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**OF THE UNITED STATES OF AMERICA**  
**AND**  
**THE NEW ZEALAND FOOD SAFETY AUTHORITY**  
**OF NEW ZEALAND**

---



**March 18, 2005**



**COOPERATIVE ARRANGEMENT**

**BETWEEN**

**THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OF THE UNITED STATES OF AMERICA**

**AND**

**THE NEW ZEALAND FOOD SAFETY AUTHORITY  
OF NEW ZEALAND**

**REGARDING COOPERATION TO ENHANCE ACTIVITIES OF MUTUAL  
INTEREST IN THE AREA OF THE SAFETY AND DEFENSE OF  
FOODS FOR HUMAN CONSUMPTION AND ANIMAL FEEDS**

The Food and Drug Administration (FDA), Department of Health and Human Services, of the United States of America and the New Zealand Food Safety Authority (NZFSA) of New Zealand (collectively "the Participants"),

1. Recognizing the special relationship between the Participants and their shared goal of protecting the life and health of the citizens of both countries with respect to food and feed safety and food defense associated with traded commodities, and
2. Acknowledging their mutual commitment to a science and risk-based approach to food and feed safety and food defense, and
3. In keeping with the long-established close and cooperative relationship between the Participants on food safety issues as manifested by the various existing cooperative arrangements, and
4. Desiring to further develop and coordinate existing and future cooperation in a structured and consistent manner, and
5. Wishing to extend the scope of the cooperation to include other areas of mutual interest regarding food and feed safety and food defense, and
6. Seeking to ensure that emerging food and feed safety and food defense issues that arise in either country are brought to the attention of the other country in an appropriate and timely manner so as to prevent or mitigate any adverse public health impact, and
7. Acknowledging the desire to further facilitate the trade of safe food and animal feed products between the countries,

Have hereby reached the following understanding.

## **I. PURPOSE**

This Arrangement is intended to affirm the intention between the Participants to further coordinate, strengthen and extend the existing scientific and public health protection cooperative activities related to the regulation of food and feed safety and food defense with the aim of better assuring consumer protection while facilitating trade.

This Arrangement is intended to establish a structured means to communicate and cooperate on a variety of food and feed safety issues as well as food defense concerns as mutually decided by the Participants.

## **II. SCOPE**

The provisions set out in this Arrangement apply to regulatory and scientific cooperation between the United States of America and New Zealand in food and animal feed products for the purpose of improving consumer protection and the public health, while facilitating trade. This Arrangement is limited to the sanitary and food defense measures applied or required by either Participant, and/or cooperation in consumer protection issues, related to food and feed products for which each Participant has regulatory authority. USFDA and NZFSA are the national regulatory bodies with responsibility to ensure that the laws stipulated in Annex I are applied. Areas of cooperation are to be determined by mutual decision.

## **III. DEFINITIONS**

For the purposes of this Arrangement the following definitions apply:

- (a) Sanitary measures means sanitary measures as defined in Annex A, paragraph 1, of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and falling within the scope of this Arrangement. A reference to sanitary measures may cover individual sanitary measures or groups of sanitary measures for product areas, sectors, or parts of sectors, as appropriate; appropriate level of sanitary protection means the appropriate level of sanitary protection as defined in Annex A, paragraph 5, of the SPS Agreement;
- (b) Food defense means implementing preventive measures to provide assurance against an intentional act of contamination that may result in harm or illness to humans or animals.
- (c) Arrangement means the entire text of this Arrangement and all its Annexes.

#### **IV. CONFIDENTIALITY**

Information exchanged under this Arrangement may include non-public information exempt from public disclosure under the laws and regulations of the United States and New Zealand. Information that is not appropriate for public dissemination is only to be shared according to the procedures and policies of the Participants as permitted by their respective laws. Neither FDA nor NZFSA are to share trade secret information without the consent of the owner. With regard to any non-public information that may be provided to NZFSA by the USFDA or to the USFDA by NZFSA, such transmissions are to be made in accordance with the specific signed confidentiality commitments and other requirements of the Participants.

#### **V. MULTILATERAL OBLIGATIONS**

Nothing in this Arrangement limits the rights or obligations of the United States of America or of New Zealand under the Agreement Establishing the World Trade Organization and its Annexes, including the Agreement on the Application of Sanitary and Phytosanitary Measures.

This Arrangement is not intended to create any obligations under international or other laws.

#### **VI. GENERAL PRINCIPLES**

The Participants, in accordance with their respective legal authorities, intend to revise existing cooperative arrangements and further develop and apply cooperative activities in line with the following overarching general principles.

The Participants intend to:

1. Work together to achieve the necessary public health and safety objectives while minimizing any unnecessary impediments to trade;
2. Cooperate, as appropriate, to share information on regulatory and scientific issues concerning food and feed that impact the health and safety of consumers. This information may include the notification, prevention, or control of newly identified or significant food or feed safety and/or food defense risks being exported to the other Participant and, as resources permit, matters involving the export of fraudulent or misbranded products;
3. Cooperate to provide appropriate support for cross-jurisdictional food or feed safety or food defense investigations;
4. Utilize a risk-based and outcome-focused approach whenever an assessment of a Participant's assurance system is deemed necessary. Historical trade and associated experiences may form a substantive part of such determinations;

5. Take into consideration, as appropriate, international standards developed by the Codex Alimentarius Commission and the International Office of Epizootics (OIE) guidelines; and
6. Maximize, where practicable, the use of existing regulatory assurance mechanisms in the exporting country to provide assurances for the safety of imported products from the exporting country.

## **VII. ANNEXES**

This Arrangement, including the General Principles, will serve as the overarching framework for developing and applying understandings covering areas of mutual interest as decided between the Participants. Understandings reached subsequent to the signing of the Arrangement are to be referenced in Annex III and/or attached as annexes to this Arrangement. Prior understandings are to be listed in Annex II.

## **VIII. SOURCE OF FUNDING**

Each Participant to this Arrangement recognizes the other's responsibility to fund and carry out its own activities subject to, and to the extent made possible by, the availability of appropriated funds, personnel, and other resources.

## **IX. DURATION AND PROCESS**

The Participants intend to meet, as appropriate, to develop and implement a work program governing specific areas of cooperation and to update existing understandings to ensure they are consistent with the intent and principles contained within this Arrangement. Such meetings may be in person or via tele or videoconference. All understandings reached are to be mutually determined and thereafter attached as Annexes to this Arrangement and/or listed in Annex III.

The Participants may, as warranted by particular circumstances and if possible given their respective resources, form Working Groups to address specific issues bearing on the successful implementation of this Arrangement.

The Participants intend to convene a Working Group to update or modify any current understanding between FDA and NZFSA listed in Annex II of this Arrangement, as mutually decided upon by the Participants. Upon modification of any current understanding, the Participants intend to attach the revised understanding directly as an Annex to this Arrangement and/or list the revised arrangement in Annex III.

This Arrangement is effective upon signature by both Participants and remains in effect for a period of five (5) years. It may be extended for additional five-year periods after evaluation by the Participants.

The Participants may amend this document in writing by mutual consent.

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

All activities undertaken pursuant to this Arrangement are to be conducted in accordance with the laws and regulations of the United States of America and New Zealand and are subject to the availability of personnel, resources, and appropriated funds.

**X. CONTACT POINTS**

The contact points for the application of this Arrangement are to be as contained in Annex V.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective Government agencies, have signed this Arrangement.

Signed at Washington, in duplicate, this 18th day of March, 2005.



FOR THE FOOD AND DRUG  
ADMINISTRATION  
DEPARTMENT OF HEALTH  
AND HUMAN SERVICES OF THE  
UNITED STATES OF AMERICA:



FOR THE NEW ZEALAND  
FOOD SAFETY AUTHORITY OF  
NEW ZEALAND:

## ANNEX I

### **Legislation concerning food and animal feed sanitary and food defense measures applied by either Participant:**

1. For the United States of America:

The Federal Food Drug and Cosmetic Act, the Public Health Service Act, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Food and Drug Administration Modernisation Act of 1997.

2. For New Zealand:

The Food Act 1981, the Animal Products Act 1999, the Dairy Act 1956 and the Agricultural Compounds and Veterinary Medicines Act of 1999.

## ANNEX II

### List of Understandings:

#### Generic Understandings:

1. New Zealand Food Safety Authority Confidentiality Commitment to the United States Food and Drug Administration.
2. United States Food and Drug Administration Confidentiality Commitment to the New Zealand Food Safety Authority.

#### Commodity Specific Understandings:

1. The 1980 Memorandum of Understanding on: The exportation of fresh and fresh frozen shellfish to the United States.
2. The 1995 Cooperative Arrangement: To ensure the safety of imported fish and fishery products.
3. The 1975 Memorandum of Understanding on: Exporting dry milk products to the United States.
4. The 1995 Exchange of Letters on: Residue Compliance Assurance program for the export of New Zealand horticultural produce to the United States of America.

## **ANNEX III**

### **List of Revised and New Understandings under this Arrangement**

## **ANNEX IV**

### **Contacts**