Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

Memorandum of Understanding Between the United States Customs Service and the United States Food and Drug Administration

The parties of this Memorandum of Understanding (MOU) are the United States Food and Drug Administration, hereinafter called Customs.

The purpose of this MOU is to establish a partnership between both agencies to participate in an international trade Compliance Measurement (CM) Program.

The Customs CM Program assesses the potential risk that importations do not comply with the law based on a statistically valid random methodology. Customs has the authority to examine and detain all imported merchandise for the purpose of ensuring that such merchandise complies with all U.S. laws governing admissibility; or, Customs may conditionally release the merchandise under bond pending a final admissibility determination. This authority applies to merchandise for which a particular determination relating to admissibility is vested in other government agencies. To streamline initiatives in the area of public health and safety, Customs intends to work more closely with other Government agencies regarding commodities which pose a risk to the United States from a public health and safety standpoint. By working jointly with FDA to determine the compliance rates of specific commodities entering the United States, each agency intends to gain a better understanding of the public health and safety threat these commodities pose to the public. Coordinating activities as part of the CM Program is intended to enhance each agency's overall mission performance.

Specifically, this MOU provides the framework for the cooperative efforts of Customs and FDA under the Compliance Measurement Program to ensure maximum compliance with the laws enforced by both agencies and the regulations promulgated thereunder, and that appropriate procedures pertaining to importation are followed. This MOU is intended to establish improved communications between the signatories. Further, the goals of the MOU include increasing efficiency, reducing individual agency costs through the pooling of resources, and expediting clearance of compliant imported products into the United States. Having both agencies working together on the Customs CM Program assists in the implementation of the aforementioned goals.

This MOU serves to solidify our positions regarding cooperation among government agencies as described in Vice President Al Gore's Reports of the National Performance Review, From Red Tape to Results: Creating a Government That Works Better & Costs Less (1993) and the Government Performance and Results Act of 1993, 103 Pub. L. No. 62, 107 Stat. 285.

Both Customs and the FDA recognize that this MOU in no way compromises the efforts of both agencies in protecting the public health and safety of the United States from merchandise that falls outside the parameters of the Customs CM Program.

I. Customs Agrees To:

1. Incorporate into Customs FY 96 CM Program for the second quarter of the fiscal year (FY), the Harmonized Tariff Schedule (HTS) numbers FDA and Customs jointly agree to include in the program. These HTS numbers may be modified in the second quarter of FY 96 and beyond.

2. Notify FDA of all compliance measurement examination results of these selected products.

3. In accordance with FDA's written instructions, examine the products FDA and Customs jointly agree to be included in the CM Program.

4. Assign a representative to facilitate communication and interaction between Customs and FDA.

II. FDA Agrees To:

1. Provide Customs with written instructions to use to examine the products FDA and Customs jointly agree to be included in the CM Program.

2. Provide Customs with a list of HTS numbers and advise Customs of any changes to the list.

3. Provide training and/or material necessary to accomplish examination procedures, e.g., equipment, tools, forms, etc., as outlined in the examination instructions written by FDA.

4. Assign a representative to facilitate communication and interaction between Customs and FDA.

III. It is Mutually Understood And Agreed That:

1. This MOU is to develop a partnership between the two agencies with respect to Customs CM Program solely. This MOU does not supersede, or relate in any way, to any other MOU's signed by the two agencies. This MOU is to define in general terms the basis on which the parties concerned will cooperate and, as such, does not constitute a financial obligation to serve as a basis for expenditures. No transfer of Federal funds will be involved under this MOU.

2. This MOU is a FY 96–97 planning document. Implementation of the CM Program initiatives commence October 1, 1995.

3. The above provisions will be exercised to the extent authorized by law, Customs and FDA directives, statutes, and regulations, and will be consistent with the respective agency's missions. To that extent, it is understood that a Customs compliance measurement determines only whether there is reason to believe merchandise is noncompliant. Furthermore, Customs release of merchandise following a compliance measurement examination does not constitute a determination by Customs that the merchandise does or does not comply with FDA law. Any final determination of admissibility under FDA law remains vested in the FDA.

4. If, for any reason, the HTS numbers, examination instructions, or necessary training/materials, are not acceptable to either Customs or FDA, modifications will be made to ensure mutual agreement by both agencies.

5. This MOU is an internal Government agreement and is not intended to confer any right or benefit on any private person or party.

6. Information gathered as a result of the CM Program may be highly sensitive, proprietary information. Any information obtained by one agency from the other will be used only for the purpose of enforcing applicable laws and regulations; the information will not be released to third parties except as provided by statute or regulation. In accordance with 44 U.S.C. 3510, any information obtained by one agency from the other will continue to be subject to all the provisions of law of the originating agency.

7. Access to the information described in this MOU is based on the compliance of both FDA and Customs with the Privacy Act of 1974 (5 U.S.C. 552a).

8. This MOU shall become effective upon the date of final signature by both agencies and remain in effect for 5 years or until cancelled by either party upon a 30-day notice in writing.

This MOU may be amended or continued by mutual consent of the parties hereto in writing.

By: George J. Weise.

Title: Commissioner, United States Customs Service.

Date: October 23, 1995.

By: Mary K. Pendergast,

Title: Deputy Commissioner/Senior Advisor to the Commissioner, United States Food and Drug Administration, for the Commissioner of Food and Drugs.

[FR Doc. 96–32274 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–96–4006]

Memorandum of Cooperation Between the Food and Drug Administration and the Economy, Development, and Reconstruction Ministry of Chile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of cooperation (MOC) between FDA and the Economy, Development, and Reconstruction Ministry of Chile. The purpose of the MOC is to facilitate the trade of safe and wholesome fish and fishery products.

DATES: The agreement became effective May 13, 1996.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Office of Seafood (HFS–400), Food and Drug Administration, 1110 Vermont Ave. NW., Washington, DC 20005, 202–418–3150.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of cooperation between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of cooperation.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination

Memorandum of Cooperation Between the Food and Drug Administration (FDA) Department of Health and Human Services of the United States of America and Servicio Nacional de Pesca (SERNAP) the Economy, Development and Reconstruction Ministry of Chile Concerning an Exchange of Information and Technical Cooperation With Regard to Food Control Practices to Protect Public Health and to Facilitate Trade in Fish and Fishery Products

In keeping with a mutual desire of the Governments of the United States and Chile to facilitate the trade of safe and wholesome fish and fishery products, and

Desiring to strengthen the bonds of cooperation between the two governments, and

Recognizing that both countries wish to ensure the public health and the wholesomeness of foodstuffs consumed by their citizens, and

Noting that increasing global trade of foodstuffs and the related global trade agreements provide an incentive for countries to harmonize food safety control measures and sanitary practices to facilitate trade without compromising food safety, sanitation and wholesomeness, and

Recognizing that the existing Memorandum of Understanding between the United States and Chile regarding the safety and wholesomeness of shellfish remains in place, and that shellfish are separate and apart form the fish and fishery products considered in this Memorandum of Cooperation,

FDA of the Department of Health and Human Services of the United States and SERNAP, of the Economy, Development and Reconstruction Ministry of Chile, have reached the following general understanding to guide their cooperation:

I. Objectives

The objectives of this Memorandum of Cooperation are to:

A. Exchange information about food laws, regulations, standards, food inspection and the enforcement practices that comprise the fish and fishery products control procedures and practices of each country.

B. Determine whether there exist appropriate food safety laws, regulations, guidelines, and an inspection infrastructure for exported fish and fishery products that will, at a minimum, provide assurances that these products meet the same level of protection as for the domestic fishery products of the trading partner, or meet other stipulated standards. Particular areas of interest include: Laboratories and analytical methodologies and standards, use of Hazard Analysis Critical Control Point (HACCP) controls, extent and provisions for HACCP training, permitted food and color additives, permitted drugs and allowable drug residues in aquacultured fishery products.

C. Determine whether each country is prepared to adhere to the principle of ''transparency'' (the continuing open exchange of regulatory and compliance information or changes therein) as described in the World Trade Organization agreement on Sanitary and Phytosanitary Measures.

D. Provide confidence in the ability of government agencies or government sanctioned agencies to effectively oversee the compliance of the fish and fishery products industry with acceptable sanitary and food safety practices, and thereby provide a foundation for future agreements on measures to facilitate the unencumbered trade of these products between the United States and Chile.

E. Discuss the development of a framework for the resolution of issues of mutual concern related to differences in regulations or practices that may have an effect on the level of protection afforded consumers with regard to the safety, sanitary processing methods, identification of species, and the wholesomeness of exported fish and fishery products.

II. Implementation

Both sides will seek to:

A. Establish a procedure for the exchange of information and documents as permitted by law, as may be deemed necessary by either participant, that establish, support, or explain fish and fishery products safety, sanitation, and enforcement procedures used by either country, and the level of public health protection afforded by them. All information and documents exchanged under this Memorandum may not be further disclosed by the receiving participant without the written consent of the other participant.

B. Discuss, explain, and promote an understanding of how these legal and regulatory provisions work in practice, identify the government departments or authorities that are responsible for ensuring their effectiveness (identification of the competent authorities), and explain their operations, with particular regard for their role in the import and export of fishery products and the oversight of HACCP control measures.

C. Facilitate visits by representatives of the competent authorities of each country, at their own expense, to an agreed-upon number of facilities in the other country that process fish and fishery products for export, to evaluate inspection methods and other regulatory practices in these facilities.

D. Establish procedures to discuss emerging issues and promote cooperation in carrying out these objectives. The discussions should alternate between countries and be held on mutually agreeable dates and at mutually agreeable places. The host country should designate a Chairperson for the discussions who should develop an agenda and circulate appropriate information and materials to participants prior to the talks. Agenda topics and briefing papers should be identified as items for active discussion or information requests. In addition, the Chairperson will obtain agreement on the minutes of the talks.

III. Records

A. The working language and the draft minutes of discussions will be in Spanish and English. The Chairperson should obtain interpreters for the talks, as may be necessary.

B. Each participant to this Memorandum should name a contact person to implement the decisions reached during the discussions.

Cooperation under this Memorandum will begin on the last date of signature of the participants. After five years the participants plan to evaluate the Memorandum and may mutually consent in writing to additional five year periods. It may be amended by mutual written consent of both participants and may be terminated by either participant upon thirty days written notice to the other participant.

For the Servicio Nacional de Pesca of the Economy, Development and Reconstruction Ministry of Chile:
By: Juan Rusque Alcaino
Title: Director Nacional de Pesca
Date: May 13, 1996
Place: Washington, DC

For the Food and Drug Administration, Department of Health and Human Services of the United States of America:
By: William B. Schultz
Title: Deputy Commissioner for Policy
Date: May 13, 1996
Place: Washington, DC

[FR Doc. 96–32187 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

Memorandum of Understanding Revised Annex Between the Food and Drug Administration and the Russian Federation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Revised Annex to a Memorandum of Understanding Between the FDA and the Russian Federation. The purpose of the Revised Annex is to reaffirm their cooperation under the principles of cooperation established in the MOU initially