

**MEMORANDUM OF UNDERSTANDING  
BETWEEN  
THE EXPORT INSPECTION COUNCIL OF INDIA,  
MINISTRY OF COMMERCE AND INDUSTRY  
AND  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION OF  
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The Export Inspection Council (EIC), Ministry of Commerce and Industry (MoCI) and the United States Food and Drug Administration (FDA), Department of Health and Human Services (HHS), EIC and FDA, hereinafter collectively referred to as the "Participants" and individually referred to as a "Participant," recognize the importance of timely and effective collaboration, communication, and information exchange in the promotion of food safety and food defense to facilitate trade. The Participants share a mutual high regard for the crucial role that their respective regulatory systems perform to ensure the food and food ingredients that each Participant regulates are safe. The Participants intend to strengthen existing cooperation in scientific and regulatory areas.

**I. PURPOSE**

This Memorandum of Understanding is intended to develop opportunities for cooperative engagement in regulatory, scientific, and technical matters and public health protection that are related to the food products the Participants regulate. Further, this Memorandum of Understanding may serve as a precursor for product specific memoranda of understanding between the Participants after the Participants develop further confidence in each other's regulatory capability and abilities to assess the risk of certain food products.

The Participants share a common interest in advancing food safety, and in sharing expertise in support of mutually beneficial public health outcomes. Activities of mutual interest may be developed consistent with the Participants' missions and strategic plans.

The Participants, in accordance with their respective laws and regulations, intend to work together as appropriate to implement the intent of this Memorandum of Understanding. This work is intended to facilitate the effective exchange of information, develop new or strengthen existing cooperative efforts/initiatives, and coordinate, when appropriate, with other countries and stakeholder groups relevant to product regulation within their respective countries or in a broader global context.

**II. SCOPE**

This Memorandum of Understanding covers food products regulated by both Participants.

The Participants intend to explore mechanism(s) for regular meetings and other types of engagements for the development of plans for exchanging information, capacity building, and strengthening regulatory cooperation.

The activities intended to be planned and performed under this Memorandum of Understanding may include, but are not limited to, the following activities.

- A. Exploring the development of procedures for the timely exchange of regulatory and public health information for routine and/or emergency purposes.
- B. Collaborating to increase knowledge and understanding of the Participants' respective regulatory systems, and, whenever possible, exploring opportunities for leveraging the Participants' resources in ways that help to expand the safety net for the products the Participants regulate. Activities may include:
- Sharing information on product refusals, recalls, emergency notification procedures to be followed in case of contaminated food and their ingredients, or other situations that could potentially affect the public health;
  - Exchanging information resulting from investigations, in progress or completed, that are conducted by the Participants when their investigations are related to product-associated risks;
  - Engaging collaboratively as observers in food inspections conducted by one of the Participants, i.e., FDA may observe EIC-led inspections and EIC may observe FDA-led inspections to gain further understanding of both Participants' inspectional systems;
  - Sharing information on the lack of adherence to current good manufacturing practices as prescribed by the Participants' respective laws by manufacturers of food in one another's country; and
  - Sharing applicable information on regulatory findings and science-based decision making.
- C. FDA may request EIC to share the results of its internal or other entities' assessments of its food safety or regulatory system, if EIC chooses to do so.
- D. Collaborating in appropriate knowledge- and capacity-building activities including:
- Participating in relevant scientific meetings, symposia, seminars, and other appropriate venues that may be organized by either Participant;
  - Exploring development of collaborative activities to strengthen food safety through preventive control mechanisms and regulatory science;
  - Promoting and facilitating exchanges of technical experts, relevant technical materials and appropriate training programs (e.g., food inspections, good aquaculture practices, seafood Hazard Analysis and Critical Control Points (HACCP) protocols, spice & botanical food safety practices, good agricultural practices, food safety plan design and implementation, etc.), as mutually arranged;
  - Increasing the understanding of regulatory standards, guidelines and best practices through participation in various appropriate international venues and activities and using these venues to encourage harmonized practices more routinely;
  - Collaborating and sharing technical information on the application of current good laboratory practices and current good regulatory practices; and
  - Exploring opportunities for the exchange of information relating to such areas as risk management measures, nutrition and product labeling, and the international harmonization of food safety standards.
- E. Exploring the development of an understanding to structure FDA's evaluation of whether to accept or leverage the export inspection and certification system of EIC.

- F. Encouraging sustainability of this Memorandum of Understanding in food safety by building linkages with various ministries and agencies, state and local governments, industry and trade groups, universities and other educational institutions, professional societies, and other relevant stakeholders.
- G. Facilitating senior leadership and staff of the Participants in holding (in person or by teleconference) periodic discussions to report and assess progress on current collaborations and implementation, address concerns and resolve issues leading to strengthening and improving the bilateral relationship and transparency and, as appropriate, identify new areas for collaboration.

### **III. CONFIDENTIALITY**

- A. The Participants intend most of the information exchanged under this Memorandum of Understanding to be provided in a form appropriate for public dissemination under the law of the transmitting Participant.
- B. With regard to any non-public information that may be provided, the exchange of such information is intended to be consistent with signed confidentiality commitments and other legal requirements of the Participants.

### **IV. SOURCE OF FUNDING**

Each Participant recognizes that it intends to fund and implement its own activities under this Memorandum of Understanding, subject to, and only to the extent made possible by, the availability of appropriated funds, personnel, and other resources. .

### **V. NON-BINDING**

This Memorandum of Understanding does not create any binding obligations. Nothing in this Memorandum of Understanding negatively affects the Participants' responsibilities or abilities to carry out their regulatory activities and programs in accordance with their respective laws and regulations.

### **VI. DISPUTES**

The Participants intend that any dispute arising under this Memorandum of Understanding be solved amicably through consultations, discussions and negotiations between the Participants.

### **VII. DURATION AND PROCESS**

The Participants intend for this Memorandum of Understanding to commence upon the Participants' signatures thereof and to continue for a period of five (5) years. The Participants also intend that this Memorandum of Understanding may be modified by mutual decision in writing, specifying the date the modifications are intended to commence.

The Participants intend that the duration of this Memorandum of Understanding may be extended as mutually decided by the Participants.

The Participants intend that this Memorandum of Understanding may be discontinued by either Participant. A Participant should endeavor to give sixty (60) calendar days' advance written notice to the other Participant of its intent to discontinue this Memorandum of Understanding.

### VIII. POINT OF CONTACT

Both the Participants designate the below-mentioned contact points to ensure smooth cooperation under this Memorandum of Understanding and intend that all future communication relating to this Memorandum of Understanding be addressed to:

Associate Commissioner for International Programs  
Office of International Programs  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
United States of America  
Tel. +1.301.796.4600  
Facsimile: +1.301.595.7937

Director (I&Q/C)  
Export Inspection Council of India (EIC)  
3<sup>rd</sup> Floor, NDYMCA Cultural Centre Building,  
1, Jai Singh Road  
New Delhi-110001  
India  
Tel. +91.11.2374.8025  
Facsimile: +91.11.2374.8186

Signed at New Delhi; on this 23 day of March 2011, in duplicate in the English and Hindi languages.

DEPUTY COMMISSIONERS  
THE UNITED STATES  
FOOD AND DRUG ADMINISTRATION

EXPORT INSPECTION COUNCIL,  
MINISTRY OF COMMERCE AND INDUSTRY,

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Michael R. Taylor  
Deputy Commissioner for Foods  
and Veterinary Medicine

28/03/2011  
S.K. Saxena  
Director, Inspection & Q/C

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Howard R. Sklamberg, J.D.  
Deputy Commissioner for Global  
Regulatory Operations and Policy