

**IMPLEMENTING ARRANGEMENT  
BETWEEN THE  
FOOD AND DRUG ADMINISTRATION  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OF THE  
UNITED STATES OF AMERICA  
AND THE  
GENERAL ADMINISTRATION  
OF QUALITY SUPERVISION, INSPECTION AND QUARANTINE  
OF THE PEOPLE'S REPUBLIC OF CHINA  
REGARDING THE COOPERATIVE MECHANISM OF FOOD SAFETY  
REGULATORY STAFF**

The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of the People's Republic of China (hereinafter referred to together as "the Participants"), recalling the Agreement between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on the Safety of Food and Feed, signed December 11, 2007, ("2007 Agreement"), intend to clarify their understanding of the scope of activities of food safety regulatory staff posted in diplomatic posts in this Implementing Arrangement.

**Paragraph I. Purpose**

This Implementing Arrangement (IA):

- aims to identify the scope of activities under the 2007 Agreement for FDA and AQSIQ food safety regulatory personnel posted in one another's country;
- desires to further set out the framework for exchange of information and documents under Article IV of the Agreement related to observations and results from inspections of facilities that manufacture, process, package, label, transport, hold, or test Food and Feed or ingredients for Food and Feed;
- lays out a means through which each agency can obtain information to inform its regulatory decision-making; and
- provides further implementation of the 2007 Agreement by which each agency can save time and costs in meeting its statutory requirements, without a reduction in public health and safety or regulatory responsibilities.

## **Paragraph II. Principles**

In addition to acting in a manner consistent with the terms of the 2007 Agreement, the Participants intend for their food safety regulatory staff to follow the below principles when conducting inspections in one another's country:

1. The Participants intend to coordinate communication regarding activities through the competent authority or an identified point of contact posted in one another's country;
2. FDA intends to coordinate the activities undertaken by FDA food safety regulatory staff posted in China with AQSIQ. AQSIQ intends to coordinate the activities undertaken by AQSIQ food safety regulatory staff posted in the United States with FDA;
3. The Participants intend for their food safety inspectors to conduct their work, including obligations for the protection of confidential commercial information, in a manner compatible with their status as employees of their respective agencies, and to comply with the applicable requirements of both sides for protection of confidential commercial information.

## **Paragraph III. INSPECTION AND COOPERATION BY U.S. FDA REGULATORY PERSONNEL POSTED IN CHINA**

1. FDA intends to conduct inspections of Food and Feed establishments in China that export products to the United States consistent with the 2007 Agreement. FDA's inspections are conducted to assess the compliance with applicable FDA requirements of facilities that manufacture, process, package, label, transport, hold, or test Food or Feed to be exported to the United States or its territories.
2. For routine inspections conducted by FDA regulatory personnel posted in China, FDA intends to provide AQSIQ a generalized work plan early in each U.S. Government Fiscal Year. When FDA makes significant changes and additions to the submitted work plan, FDA intends to provide advance notice regarding these activities through an identified primary point of contact. FDA intends to provide advance notice regarding urgent or immediate activities, such as for-cause inspections and handling of severe incidents through the primary point of contact. FDA intends to undertake urgent or immediate activities to the extent required to protect public health. For all inspections conducted by FDA regulatory personnel in China, FDA intends to provide AQSIQ advance notice about the inspection dates through the primary point of contact.
3. The purpose of inspections conducted by FDA regulatory personnel in China is to determine whether firms comply with applicable FDA requirements. For each inspection, FDA intends to send an appropriate number of staff or government authorized qualified professional staff and AQSIQ intends to send the number of staff it feels is appropriate. After each inspection that both FDA and AQSIQ participate in, both Participants intend to share the observations found during the inspection on site. For establishments that have been listed in the Import Alerts, if FDA inspections identify that adequate corrective actions have been

made to address the basis for the Import Alert, FDA intends to remove the establishments from the relevant Import Alert in a timely manner, following normal FDA procedures.

4. FDA intends to provide AQSIQ with timely notification regarding manufacturing conditions or products that may constitute potential hazards to health or violations of applicable U.S. regulations. This notification may include, as deemed appropriate by FDA, and in compliance with laws and regulations relating to confidentiality of information, the exchange of redacted recall information, adverse product trends, warning letters, and copies of FDA's Form 483.

5. Upon request from AQSIQ, FDA intends to provide, in a timely manner, and in compliance with laws and regulations relating to confidentiality of information, redacted copies of establishment inspection reports from inspections of Chinese firms and product sample results that FDA deems appropriate.

6. On an ongoing basis, FDA intends to provide AQSIQ information on firms registered under the U.S. food regulatory system, including information regarding products firms produce, through electronic databases or information platforms, or through hard-copy records where no computer data exist.

7. FDA intends to designate to AQSIQ a primary point of contact for communications under this IA. This point of contact holds primary responsibility for communication and coordination related to inspection notifications; requests for inspection reports; and follow-up regarding compliance actions, recalls, alerts, adverse event reports, and meetings.

8. Beyond the coordination outlined above for inspectional activities, FDA intends to coordinate with AQSIQ the activities of its in-country policy and technical experts on foods on the following efforts: technical collaboration and policy coordination with Chinese food regulators, including AQSIQ; and efforts to leverage information from both Participants' food regulatory systems.

**Paragraph IV. INSPECTION AND COOPERATION BY AQSIQ  
REGULATORY PERSONNEL POSTED IN THE  
UNITED STATES OF AMERICA**

1. AQSIQ intends to conduct inspections of U.S. Food and Feed establishments that export to China consistent with the 2007 Agreement. AQSIQ's above inspections intend to assess the compliance with relevant Chinese requirements of facilities that manufacture, process, package, label, transport, hold, or test Food or Feed to be exported to China.

2. For routine inspections conducted by AQSIQ regulatory personnel posted in the United States, AQSIQ intends to provide FDA a generalized work plan early in each calendar year. When AQSIQ makes significant changes and additions to the submitted work plan, AQSIQ intends to provide advance notice regarding these activities through an identified primary point of contact. AQSIQ intends to provide advance notice regarding urgent or immediate activities, such as for-cause inspections and handling of severe incidents through

the primary point of contact. AQSIQ intends to undertake urgent or immediate activities to the extent required to protect public health. For all inspections conducted by AQSIQ regulatory personnel posted in the United States, AQSIQ intends to provide FDA advance notice about the inspection dates through the primary point of contact.

3. The purpose of the inspections conducted by AQSIQ regulatory personnel posted in the United States is to determine whether firms comply with applicable AQSIQ requirements. For each inspection, AQSIQ intends to send appropriate number of staff or government authorized qualified professional staff and FDA intends to send staff it feels is appropriate. After each inspection, both Participants intend to share the observations found during the inspection on site.

4. AQSIQ intends to provide FDA with timely notification regarding manufacturing conditions or products that may constitute potential hazards to health or violations of applicable Chinese requirements. This notification may include, as deemed appropriate by AQSIQ, the exchange of recall information, adverse product trends, warning letters, appropriately formatted copies of relevant AQSIQ inspection reports, and information from import measures put in place by AQSIQ.

5. Upon request from FDA, AQSIQ intends to provide, in a timely manner, appropriately formatted copies of inspection reports from inspections of U.S. firms and product sample results that AQSIQ deems appropriate.

6. On an ongoing basis, AQSIQ intends to provide FDA information on firms registered under China's food regulatory system, including information regarding firms' names and products firms produce, through electronic databases or information platforms, or through hard-copy records where no computer data exist.

7. AQSIQ intends to designate to FDA a primary point of contact for communications under this IA. This point of contact holds primary responsibility for communication and coordination related to inspection notifications; requests for inspection reports; and follow-up regarding compliance actions, recalls, alerts, adverse event reports, and meetings.

#### **Paragraph V. FINAL PROVISIONS**

All activities under this IA are to be carried out in compliance with both Participants' applicable laws and regulations including those relating to confidentiality of information. This IA does not affect existing arrangement or agreements between the Participants, including the 2007 Agreement.

Nothing in this IA diminishes or otherwise affects the authority of either Participant to carry out its respective statutory functions within its own territory.

All activities undertaken pursuant to the IA are subject to the availability of appropriated funds, personnel, and other resources. The terms of the 2007 HHS-AQSIQ Agreement, and all terms herein that are defined in the Agreement have the same meanings as in the

Agreement. Each Participant is expected to fund its own activities under the IA unless the Participants decide otherwise.

Cooperative activities under this IA may commence upon signature and remain in force for a period of five (5) years, unless terminated by either Participant. On the last day of the five-year period, and of each subsequent five-year period, the IA automatically renews for another five-year period, unless either Participant notifies the other Participant that it wishes to terminate the IA upon at least sixty (60) calendar days prior to the last day of the relevant five-year period. In addition, either Participant may terminate the IA upon sixty (60) calendar days' written notice to the other Participant. The Participants may amend the IA at any time, by mutual written agreement of the Participants.

Signed on the 16th day of December, 2014, at Chicago in English and Chinese.

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