

JOINT PROGRESS STATEMENT REGARDING THE FIVE-YEAR WORK PLAN
UNDER THE AGREEMENT ON THE SAFETY OF FOOD AND FEED
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

Based on the provisions of 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, done December 11, 2007 ("Agreement") and signed by the Department of Health and Human Services ("HHS") of the United States of America ("United States") and, the General Administration of Quality Supervision, Inspection and Quarantine ("AQSIQ") of the People's Republic of China ("China") (hereinafter referred to as "the Sides" and individually as "the U.S. Side" and "the Chinese Side", respectively) during the third session under the United States (U.S.)-China Strategic Economic Dialogue ("SED"), the Sides have made significant progress in strengthening food and feed safety. Using a science-based, pragmatic approach and sharing a cooperative spirit, the Sides have worked to improve cooperation on the safety of food and feed exchange between the countries, have made positive progress and are developing a collaborative five-year work plan under the terms of the Agreement.

1. The Sides convened a very successful and productive first Bilateral Meeting on the Agreement in Beijing, March 19-21, 2008. The Sides discussed key areas of mutual interest, including the establishment of a mechanism for cooperation on significant events related to food and feed safety; the enhancement of information exchange on food and feed safety; and effective collaboration on the Sides' respective regulatory systems. The Sides also planned future cooperative activities including the following: on-site review of Chinese inspection and monitoring system by HHS/FDA; exchange of electronic certificates and data; and finalizing the process to exempt the 13 Chinese aquatic products enterprises from Detention Without Physical Examination.
2. The initial focus of the Sides is cooperation/exchange on "Inspections and Supervision", and "Laboratory Testing" standards to ensure food and feed safety. The Sides planned a timetable as follows: before the opening of the 29th Summer Olympic

Games in Beijing, the U. S. side should work to gain a more thorough understanding of the Chinese regulatory system; in the Fall of 2008, United States side should conduct training for Chinese officials on U.S. standards and requirements to facilitate Chinese side's understanding of the United States relevant requirements; and in early 2009, United States side should conduct an onsite review in China.

3. The Sides have consistently emphasized the following: the importance of food-safety assessments being both science- and risk-based; the importance of establishing a cooperative mechanism for U.S.-China food safety protection; the importance of the use of science-based methods and information technology; and the administration of measures throughout the lifecycle of products to ensure the safety and hygiene of the entire food supply chain.
4. The Sides plan to establish a cooperative mechanism to notify each other of significant risks to public health related to product safety, manufacturing conditions, recalls and other instances that involve imminent or significant danger to health, or the gross deception of consumers. The Sides intend to share in a timely manner available updated information to facilitate each other's investigations. In the event of a risk to public health, the Sides are to release to the public science-based, factual information as it becomes available.
5. Together, the Sides issue the attached "Report From the First Bilateral Meeting Between the Food and Drug Administration within 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 at Washington, this _____ day of June, 2008, in duplicate, in the English and Chinese languages.

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

For
THE GENERAL ADMINISTRATION
OF QUALITY SUPERVISION,
INSPECTION AND QUARANTINE OF
THE PEOPLE'S REPUBLIC OF CHINA

REPORT FROM THE FIRST BILATERAL MEETING
BETWEEN
THE FOOD AND DRUG ADMINISTRATION WITHIN 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

On March 19th-21st, 2008 in Beijing, China, the delegation from the Food and Drug Administration (“FDA”), Department of Health and Human Services of the United States (“HHS/FDA”) and the Chinese delegation from the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China (“AQSIQ”) (hereinafter referred to as “the Sides” and as “the U.S. Side” and “the Chinese Side”, respectively) held the First Bilateral Meeting on the Agreement on the Safety of Food and Feed, done December 11, 2007 (“Agreement”).

During the meeting, the Sides acknowledged the efforts and positive outcomes made on the implementation of the Agreement and pledged to continue strengthening the cooperation between FDA and AQSIQ. The Sides conducted in-depth consultations regarding the Chinese registration and certification system, the implementation of the Agreement and reached understandings on a number of issues. The meeting was conducted in a friendly and frank atmosphere. The U.S. delegation also visited the AQSIQ Video Monitoring Centre and observed the registration and health certificate issuing systems at the Beijing Entry-Exit Inspection and Quarantine Bureau.

Below is a summary of discussions:

1. The Sides reviewed the cooperation in the past three months on the implementation of the Agreement and determined that the effort has promoted mutual understanding and progress toward improvements in food and feed safety. The Sides are to continue the bilateral cooperation on scientific and regulatory requirements to strengthen import and export food and feed safety.
2. The Sides conducted in-depth consultations on the Manufactured Food Regulatory Program Standards (hereinafter referred to as the “Standards”). HHS/FDA gave a detailed presentation on the requirements under the Standards. AQSIQ gave a presentation on their existing measures, and stated that fundamental elements of the Chinese program are similar to the Standards. AQSIQ is to provide HHS/FDA with a comparison of their measures to the

Standards in writing. AQSIQ reiterated its goal of having HHS/FDA recognize AQSIQ's system. The Sides expect to focus initial consultations and cooperation on Standards No. 3 "Inspection and Supervision" and No.10 "Laboratory Testing". AQSIQ is to further study the Standards for reference in the inspection, quarantine and supervision of food and feed exported from China to the United States.

3. The Sides plan to establish an emergency notification mechanism as specified under the framework of the Agreement. Each Side is to inform the other Side in a timely manner when a major food safety incident occurs within its own country that involves a product exported from or imported to the other country.

The working-level Points of Contact are:

HHS/FDA:

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Associate Director for Asia and the Pacific

Office of International Programs

Office of the Commissioner

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AQSIQ:

Zhao Zenglian

Division Director, Import and Export Food Safety Bureau

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Telephone: 011-86-10-82262013

Fax: 011-86-10-82260174

4. The Sides intend to conduct a review of AQSIQ's supervision system in accordance with the following process:

a. HHS/FDA gains further understanding of the Chinese monitoring and management system. AQSIQ sends its technical working groups to the United States to meet with HHS/FDA technical working groups for consultation on their respective inspection and supervision processes and on other relevant issues.

b. Training and personnel exchange

HHS/FDA provides to relevant AQSIQ officials regulatory requirement and auditing procedure training specific to Standards # 3 and #10. In the meantime, HHS/FDA also

reviews AQSIQ's monitoring system.

c. HHS/FDA conducts on-site evaluation in China.

Based on the progress made in technical working groups, HHS/FDA sends officials to China for on-site review of AQSIQ's inspection organizations and laboratories. HHS/FDA provides a detailed list of evaluation criteria for laboratories.

d. Based on the progress on the evaluation of AQSIQ registration and certification system and the installation of a secure electronic certification exchange program, HHS/FDA may begin accepting AQSIQ certificates in its import decision making for designated aquaculture seafood and designated ingredient products with a goal date of March 2009.

5. AQSIQ and HHS/FDA Technical Working Groups (Aquatic Products Working Group and Ingredient Working Group) reached understanding on the following projected timetable for the designated products:

a. HHS/FDA identifies the information and documents required of AQSIQ by 15th April, 2008*.

b. AQSIQ provides HHS/FDA with the required information and documents by 15th June, 2008*.

c. HHS/FDA completes the evaluation of the Chinese documents and information by 20th August, 2008.

d. Both sides exchange evaluation results, communicate with each other and exchange any additional relevant documents by 20th September, 2008.

e. The Sides finalize the on-site review dates, sites, personnel and content by 20th October, 2008.

f. The on-site review should be conducted at the beginning of 2009.

(*: After the meeting, the Sides adjusted the due dates, due to unforeseen circumstances)

6. The Aquatic Working Group discussed the information exchange regarding Chinese firms that appeared on FDA Import Alert. AQSIQ reported on their investigations of firms listed in 2007. The Sides also discussed that some information published on the HHS/FDA refusal lists was the result of illegal shipments, duplicated reports, as well as discrepancies in testing methods. The Sides' plans include:

a. The Points of Contact for the Aquatic Working Group have been identified as follows:

HHS/FDA

Mr. William Jones,

Director, Division of Seafood Safety, Office of Food Safety

Center for Food Safety and Applied Nutrition (CFSAN)

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AQSIQ

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b. The Sides continue the reviewing process to exempt the 13 Chinese aquatic products enterprises from the "Detention Without Physical Examination". HHS/FDA begins discussions with AQSIQ concerning the scheduling of on-site inspections as soon as possible after the bilateral meeting.

7. Wheat gluten, rice gluten and corn gluten should be the first three ingredients covered during the first phase of the Agreement.

The Points of Contact for the Ingredient Working Group have been identified as follows:

HHS/FDA:

Food and feed ingredients

Mr. Martin Stutsman

Division of Plant and Dairy Food Safety, Office of Food Safety.

CFSAN

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AQSIQ:

Food Ingredients

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Feed Ingredients

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8. In accordance with the spirit of the Agreement, the Sides are to exchange information related to food safety such as laws, regulations, standards and testing methods on a timely basis. Through rapid information exchange, both agencies are to cooperate to ensure food/feed safety and the protection of public health.

In cases with significant public health implications, each Side is to provide the other available information related to shipments between countries to facilitate trace back investigations.

9. The Sides discussed and reached understanding regarding electronic data exchange. AQSIQ is to store the health certificate electronic data information in XML documents format on the Chinese e-Cert information exchange platform, and to provide the function of browsing and searching single certificate data and downloading multi-volume certificate data in batch. AQSIQ is to provide the electronic key for the HHS/FDA to land Chinese e-Cert certificate information exchange platform for information searching and downloading. HHS/FDA indicated its interest in obtaining a data standard to be used between AQSIQ and Australia and New Zealand. AQSIQ suggested that HHS/FDA offer food and feed requirements to AQSIQ within one month after the meeting. The Sides plan to consult and confirm the format and content of health certificate as soon as possible to facilitate the establishment of electronic information exchange.

10. The sides reiterated the provision of the Agreement - Annex Section II(A)(2), which states, "...The Parties may discuss in the future amending the Agreement to reflect the role of recognized third party testing and certification in promoting product safety".