HEALTH

Food and Feed

Agreement Between the
UNITED STATES OF AMERICA
and CHINA

Signed at Beijing December 11, 2007

with

Annex

NOTE BY THE DEPARTMENT OF STATE

Pursuant to Public Law 89—497, approved July 8, 1966 (80 Stat. 271; 1 U.S.C. 113)—

". . .the Treaties and Other International Acts Series issued under the authority of the Secretary of State shall be competent evidence . . . of the treaties, international agreements other than treaties, and proclamations by the President of such treaties and international agreements other than treaties, as the case may be, therein contained, in all the courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States, and of the several States, without any further proof or authentication thereof."

CHINA

Health: Food and Feed

Agreement signed at Beijing December 11, 2007;
Entered into force December 11, 2007.
With annex.

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

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 together as "the Parties"):

Understanding the mutual benefits of protecting the public health through bilateral cooperation and exchange between the Parties with regard to the safety of food and feed;

Appreciating the long-standing collaboration between the United States Food and Drug Administration of HHS ("HHS/FDA") and AQSIQ and the history of the AQSIQ registration and certification program;

Desiring to continue to work together to protect the safety and health of consumers and animals in the United States and the customs territory of China to prevent, intervene, and respond to any safety issues related to food and feed exported from one country to another;

Recognizing that such cooperation can improve and promote the health of people in the United States and in China, and enhance confidence in safety of food and feed exported from one country to another;

Have agreed as follows:

Article I

Purpose

The purpose of this Agreement is to establish a bilateral cooperative mechanism regarding food and feed safety. Such a mechanism may include current and future registration and certification systems. The mechanism aims to provide the Parties with information to use in judging whether an imported product meets the requirements of the importing country.

Article II

Definitions

For purposes of this Agreement, the following definitions shall apply.

1. "Covered Products" means food and feed under the jurisdiction of both Parties.
2. "Designated Covered Product" means a Covered Product that has been designated for inclusion in any phase of the cooperative mechanism regarding food and feed safety. Designated Covered Products are listed in the Annex.
3. "Feed" means articles under the jurisdiction of both Parties that are used for food or drink for animals other than humans, including articles used for components of such article and including vitamins or herbs meant to supplement the diet not regulated as drugs. Feed includes feed ingredients, feed additives, and feed that contains veterinary drugs, whether processed, semi-processed, or raw.
4. "Firm" means any business in either the customs territory of China or the United States that is engaged in the manufacture, production, growing,

processing, packing, testing, holding, transporting, distribution, or export of food or feed.

5. "Food" means articles under the jurisdiction of both Parties that are used for food or drink for humans, including articles used for components of any such article.
6. "HHS/FDA Requirement" means any U.S. law, regulation or other requirement, including any amendment adopted after the date of entry into force of this Agreement, concerning food or feed that is administered or enforced by HHS/FDA.
7. "AQSIQ/CNCA Requirement" means any Chinese law, regulation or other requirement, including any amendment adopted after the date of entry into force of this Agreement, concerning food or feed that is administered or enforced by AQSIQ or the Certification and Accreditation Administration ("AQSIQ/CNCA").
8. "AQSIQ/CNCA Registered Establishment" means an Establishment that AQSIQ/CNCA has registered meets Chinese relevant registration Laws/regulations and HHS/FDA Requirements pursuant to the Annex.
9. "HHS/FDA Registered Establishment" means an Establishment that has registered with HHS/FDA pursuant to the U.S. Federal Food, Drug, and Cosmetic Act under 21 U.S.C. 350d.
10. "Establishment" means any Firm's site or facility within the customs territory of China or in the United States that is engaged in the manufacture, producing, growing, processing, packing, testing, holding, transporting, distribution, or export of food or feed.

Article III

General Principles

1. The Parties shall engage in regulatory cooperation regarding the export of Covered Products from the customs territory of China to the United States and Covered Products produced in the United States and exported to the customs territory of China as set out in Article V and as further defined in Work Plans to be agreed upon by the Parties.
2. Each Party shall engage in information-sharing as set out in Article IV to improve its understanding of, and to gain greater confidence in, the other Party's regulatory system and as further defined in Work Plans to be agreed upon by the Parties. As specified in Article IV, each Party shall share relevant information with the other Party, including on laws, regulations, areas of jurisdiction, and public health and safety.
3. The Parties shall engage in regulatory cooperation regarding improving the safety of food and feed as set out in Articles IV and V and as further defined in Work Plans to be agreed upon by the Parties.
4. The Parties shall hold annual meetings between HHS/FDA and AQSIQ leaders to discuss and evaluate progress under this Agreement, among other things.

Article IV

Information Sharing

The Parties shall exchange information on their regulatory systems and other public-health matters concerning Covered Products as follows:

1. A Party may provide information to the other Party in the English or the Chinese language.
2. The Parties shall exchange copies of, and other relevant information concerning, their respective laws and regulations relating to food and feed safety.

3. Each Party shall immediately notify the other Party 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 with regard to Covered Products. Such notification shall occur within two (2) calendar days of the discovery of the significant risk to public health or gross deception of consumers. Each Party shall promptly respond to requests from the other Party for information concerning any such notification, including contact information for the Establishments or other entities concerned. Such response shall normally occur within five (5) calendar days of the request from the other Party unless otherwise specified in the Work Plan. The Work Plan shall include specific commitments to ensure the timeliness of any such notification or response.

Article V

Regulatory Cooperation

The Parties shall:

1. Develop and set out in the Work Plan strategies to control the transshipment of potentially unsafe Covered Products.
2. Develop appropriate regulatory cooperative activities, including training programs and scientific discussions or cooperation, intended to support the long-term stability and effectiveness of the registration and certification programs for Covered Products. For each training program or other cooperative activity that requires travel or other organizational costs, each Party shall bear its own costs of participation. Appropriate regulatory cooperative activities may include the following:

a. development of laboratory and risk-assessment methodologies, including performing analyses on request by the other Party;

b. work on identifying and discussing significant differences in maximum residue levels (MRLs) of veterinary drugs used in food-producing animals;

c. exchange of scientific, technical, and regulatory information about compliance and enforcement programs of each Party;

d. identification of, and work on the mitigation and elimination of, significant human-health and animal-health concerns associated with the incidental or intentional chemical, radiologic, or microbiological contamination of human and animal foods (for example contamination with copper sulfate, dioxin or polychlorinated biphenyls);

e. identification of any substitution or addition of a substance to an ingredient in food or feed or to a food or feed product that reduces the quality of the ingredient or the product, or makes it appear of greater value than it is, when the substitution or addition has not been clearly revealed to the recipient; and

f. exchange of information regarding mandatory, pre-market review/approval processes for food ingredients.

3. Report any science and technology cooperation to the Joint Commission on Scientific and Technological Cooperation established under the Agreement Between the Government of the United States of America and the Government of the People's Republic of China on Cooperation in Science and Technology, signed at Washington January 31, 1979.

4. Develop a streamlined process for facilitating (e.g., issuing a letter of invitation), no later than five (5) calendar days after receipt of a request from a Party, inspections of Establishments by the requesting Party. Such inspection may be conducted with or without providing advance notice (as specified in the request) to the Establishment concerned.

5. Exchange their respective web links that identify requirements for import into their respective customs territories for Covered Products. Each Party shall post the web link of the other Party on its website within thirty (30) calendar days of receipt of the web link.

Article VI

Rights

1. For the purpose of using AQSIQ/CNCA registration and/or certification to inform decision-making regarding the admissibility of Covered Products for entry into the United States, both Parties shall endeavor to agree on all criteria and procedures that AQSIQ/CNCA uses to implement the registration and certification provisions of this Agreement. For greater certainty, all Covered Products offered for import into the United States shall be subject to HHS/FDA Requirements and all other relevant U.S. laws and regulations.
2. Both Parties shall endeavor to agree on all criteria and procedures that HHS/FDA uses to implement the registration obligations under this Agreement. For greater certainty, all Covered Products exported to the customs territory of China shall be subject to AQSIQ Requirements and all other relevant Chinese laws and regulations.
3. For greater certainty, nothing in this Agreement shall be construed to require a Party or any other relevant Government official to base any decisions on admission of any Covered Product on any list or other information the other Party may provide.

Article VII

Administration

1. Within fifteen (15) calendar days of the date of entry into force of this Agreement, each Party shall notify the other Party in writing of its primary points of contact for coordinating all bilateral activities under this Agreement, including coordinating meetings, exchanging information, and sending and receiving notifications.
2. The Parties hereby establish a Working Group. Within thirty (30) calendar days of the date of entry into force of this Agreement, each Party shall identify

relevant policy and technical experts of each Party to serve on the Working Group.

3. Within sixty (60) calendar days of the date of entry into force of this Agreement, the Working Group shall hold its first meeting to develop a Work Plan that:

a. further details the specific activities each Party shall perform pursuant to this Agreement within the first 12-month period following the date of entry into force of this Agreement and time lines for completion of each such activity; and

b. includes, as appropriate, performance measures to evaluate the success of each activity.

4. Within 120 calendar days of the date of entry into force of this Agreement, the Working Group shall finalize the Work Plan for the first 12-month period following the date of entry into force of this Agreement. The Parties shall assess the Work Plan at the conclusion of the 12-month period.

5. For each subsequent 12-month period, the Working Group shall meet to develop a Work Plan that further details specific activities that each Party shall perform pursuant to this Agreement within that period and, as appropriate, includes performance measures to evaluate the success of each such activity. The Parties shall assess each such Work Plan at the conclusion of the relevant period.

6. The Work Plan for each 12-month period, when adopted by the Parties, shall include binding commitments for the effective and timely implementation of this Agreement. Each Party shall make the Work Plan for the first twelve (12) months, and each subsequent year, publicly available on its respective website.

7. Within 180 calendar days of the date of entry into force of this Agreement, high level representatives of the Parties shall meet to discuss the implementation of and review progress under this Agreement and related matters.

8. Thereafter, the high level representatives of the Parties shall meet on an annual basis to discuss and review the implementation of and progress under this Agreement and related matters. Unless the Parties otherwise agree, the location of these annual meetings shall alternate between the United States and China. The Parties may convene additional technical or program-level meetings on an as-needed basis in any mutually agreeable location.

Article VIII

Performance Measures

1. The Parties shall collaboratively evaluate and discuss progress under this Agreement on an annual basis, including the effectiveness of the program, pursuant to the Annex.
2. HHS may base its evaluation of such progress on, among other things, the following:

a. the rate of refusal by HHS/FDA of Designated Covered Products exported from the customs territory of China and offered for import into the United States, as compared to the overall rate of refusal in calendar year 2007 or other relevant period by HHS/FDA of Designated Covered Products exported from the customs territory of China and offered for import into the United States;

b. the overall percentage of Designated Covered Products exported from the customs territory of China and offered for import into the United States that do not come from AQSIQ/CNCA Registered Establishments or are not certified; and

c. the volume, frequency and significance in terms of public health hazard of recalls of Designated Covered Products in the United States, including counterfeit Covered Products, exported from the customs territory of China and offered for import into the United States as compared to the volume, frequency and significance of such recalls in 2007 or other relevant period.

3. AQSIQ may base its evaluation of such progress on, among other things, the following:

a. the rate of refusal by AQSIQ of Designated Covered Products exported from the United States and offered for import into the customs territory of China, as compared to the overall rate of refusal in calendar year 2007 or other relevant period by AQSIQ of Designated Covered Products exported from the United States and offered for import into the customs territory of China;

b. the overall percentage of Designated Covered Products exported from the United States and offered for import into the customs territory of China that do not come from HHS/FDA Registered Establishments; and

c. the volume, frequency and significance in terms of public health hazard of recalls of Designated Covered Products in the customs territory of China, including counterfeit Covered Products, exported from the United States and offered for import into the customs territory of China as compared to the volume, frequency and significance of such recalls in 2007 or other relevant period.

Article IX

Final Provisions

1. Nothing in this Agreement precludes the Government of the United States or the Government of China from taking any measure to protect the public health of the citizens of its respective country. Each Party affirms that it shall work with its country's national, state/provincial, or municipal bodies, as appropriate, to implement this Agreement fully.

2. Nothing in this Agreement shall be construed to affect the rights or obligations of the United States or China under any other agreement in force between the United States and China.

3. The Parties shall endeavor to resolve any dispute regarding the implementation or interpretation of this Agreement through timely consultations.

4. This Agreement shall enter into force upon signature by both Parties and shall remain in force for a period of five (5) years, unless terminated by either Party. On the last day of the five-year period, and of each subsequent five-year period, the Agreement shall automatically be renewed for another five-year period, unless either Party notifies the other Party that it wishes to terminate the Agreement at least sixty (60) calendar days prior to the last day of the relevant five year period. In addition, either Party may terminate the Agreement upon sixty (60) calendar days' written notice to the other Party. The Parties may amend the Agreement at any time, by mutual written agreement of the Parties.
5. All Annex provisions are incorporated in, and integral to, this Agreement. Each Party shall undertake all activities under this Agreement in accordance with its country's laws and regulations.

Done at Beijing, this 11th day of December, 2007, in duplicate in the English and Chinese languages, each text being equally authentic.

For
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF

THE UNITED STATES

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

ANNEX

Section I. Determination of Designated Covered Products

Work under this Agreement will be implemented in a phased approach, beginning with an initial defined list of Designated Covered Products. The Parties shall conduct a formal evaluation of the outcomes of these programs for the initial Designated Covered Products. Based on the determination of the success of this first phase, the defined list of Designated Covered Products will be expanded to include additional Covered Products.

A. Factors

After consulting with each other, the Parties shall designate which Covered Products to include on the list of Designated Covered Products in each phase as appropriate based on the following factors:

a. potential or actual, direct or indirect risk to the public health associated with the product, based on testing, inspection results or other information both Parties deem relevant;

b. the rate of refusal by one Party of admission of the Covered Products into its territory or of problems associated with the Covered Products before, during or after entering the domestic commerce of the importing country, including product recalls, safety alerts, and enforcement actions;

c. fraudulent or deceptive labeling or indications of any substitution or additions of a substance to a Covered Product or an ingredient of a Covered Product that reduces the quality of the ingredient or product or makes it appear of greater value than it is, without clearly revealing such substitution or addition to the recipient in the importing country; and

d. the feasibility of implementing an effective and timely Work Plan with respect to the product.

B. First Phase - Designated Covered Products

1. The Parties agree that the following Covered Products, for which there are high import refusal rates and associated risk, shall be included in the first phase:

a. Low-acid canned products or acidified food;

b. Pet food/pet treats of plant origin or animal origin;

c. Ingredients of food and feed, i.e., wheat gluten and rice protein; and

d. All aquaculture farming products other than molluscan shellfish.

Details about these product categories will be further defined through the Work Plan agreed by the Parties.

2. Upon agreement, the Parties may designate additional Designated Covered Products for inclusion in any subsequent phase of the registration and certification programs. This process shall be detailed in the Work Plan.

Section II. Controls for Exports

1. The Parties acknowledge the successes of the AQSIQ/CNCA registration and certification programs in China, (e.g., in restoring confidence and improving the safety of ceramic ware imported from the customs territory of China). The Parties desire to build upon these successes of these long established programs to help ensure the safety of other food and feed imported from China.

2. Based on the success of the registration and certification programs, detailed below, HHS/FDA will use registration and certification information provided to it by AQSIQ to inform HHS/FDA import entry decisions, which may include a reduction in the rate of examination of Designated Covered Products that are part of the registration and/or certification program.

A. **General**

1. With respect to Covered Products that have been designated in accordance with Section I. A. of this Annex, AQSIQ/CNCA has already established and shall continue:

a. a registration program that requires all Establishments of Designated Covered Products for export from the customs territory of China to the United States to register with AQSIQ/CNCA; and

b. a certification program that is expanded to cover Designated Covered Products for export from the customs territory of China to the United States that provides for such products to be certified by AQSIQ as meeting HHS/FDA Requirements.

2. The Parties shall consult regarding the development of the registration and certification programs. These programs shall be implemented in phases and for the first phase shall cover the Designated Covered Products set forth in Section I.B.1 of this Annex and for subsequent phases shall cover the Covered Products as designated in accordance with Section I.A. of this Annex. The program shall expand to other products for subsequent phases contingent on the success of the preceding phase. In addition, based on the success of the preceding phase, the Parties may agree that with respect to a later phase that this Agreement shall be modified to include limitations on the export of any shipment of Designated Covered Products from the customs territory of China to the United States that AQSIQ has not certified as meeting HHS/FDA Requirements. 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.

3. HHS/FDA shall provide AQSIQ with copies of all relevant HHS/FDA Requirements, updated as appropriate, with respect to Designated Covered Products.

4. HHS/FDA shall promptly notify ASQIQ/CNCA about Designated Covered Products refused entry into the United States. Details for this notification system, including the timing and the mechanism, will be further defined in the Work Plan.
5. HHS/FDA commits to explore finding a mechanism to notify AQSIQ/CNCA about Designated Covered Products not accompanied by an AQSIQ/CIQ certificate.
6. Details for this notification system, including the timing and the mechanism, will be further defined in the Work Plan.
7. In the event that an Establishment shipping Designated Covered Products to the United States does not have an AQSIQ/CIQ certificate or in the event that a shipment of Designated Covered Product offered for import into the United States is not accompanied by an AQSIQ/CIQ certificate, and HHS/FDA deems that Establishment or shipment meets HHS/FDA Requirements, HHS/FDA shall notify AQSIQ and the Parties shall discuss the situation, as warranted.

B. Registration

1. With regard to Designated Covered Products for shipment to the United States, AQSIQ/CNCA shall:

a. ensure it registers only Establishments that meet HHS/FDA Requirements;
b. monitor each AQSIQ/CNCA Registered Establishment to ensure that it continues to meet HHS/FDA Requirements; and
c. ensure each AQSIQ/CNCA Registered Establishment is informed of all applicable HHS/FDA Requirements.

2. Pursuant to the program maintained in accordance with Section I.A.1 of this Annex, AQSIQ shall require that all Establishments of Designated Covered Products for export to the United States register with AQSIQ/CNCA. Each registration shall include the following:

a. the name and address of the Establishment;

b. a list of all Designated Covered Products associated with the Establishment; and

c. the name and contact information (including phone number) of the owner, manager, or other senior official responsible at the Establishment.

3. AQSIQ/CNCA shall require AQSIQ/CNCA Registered Establishments to inform ASQIQ/CNCA upon any changes in the information provided in its registration and to provide updated information.

4. AQSIQ/CNCA shall conduct annual inspections of all AQSIQ/CNCA Registered Establishments to ensure each AQSIQ/CNCA Registered Establishment meets HHS/FDA Requirements. AQSIQ/CNCA shall inspect each AQSIQ/CNCA Registered Establishment within 180 calendar days of the date of registration as a baseline for annual inspections thereafter. AQSIQ/CNCA shall revoke or suspend the registration of any Establishment that it determines, as a result of an inspection or otherwise, does not meet HHS/FDA Requirements.

5. AQSIQ/CNCA shall provide HHS/FDA a list of all AQSIQ/CNCA Registered Establishments, and the Designated Covered Products of each such Establishment ("List of AQSIQ/CNCA Registered Establishments"), via a secure electronic system. AQSIQ/CNCA shall provide HHS/FDA the first List of AQSIQ/CNCA Registered Establishments within thirty (30) calendar days of the date of entry into force of this Agreement, and shall update the list every ninety (90) calendar days from the date it provides the first List of AQSIQ/CNCA Registered Establishments.

6. Within fifteen (15) calendar days of receiving the List of AQSIQ/CNCA Registered Establishments or any updates, HHS/FDA shall publish it on its website.

7. HHS/FDA shall provide AQSIQ/CNCA a list of all Establishments registered with HHS/FDA. HHS/FDA shall provide this list to AQISQ/CNCA, via a secure electronic system, within thirty (30) calendar days of the date of entry

into force of this Agreement, and shall update the list every ninety (90) calendar days from the date it provides the first list of AQSIQ/CNCA Registered Establishments.

8. AQSIQ/CNCA shall notify HHS/FDA in writing of all AQSIQ/CNCA Registered Establishments that have failed inspection or whose registration AQSIQ/CNCA has suspended, revoked or denied and the reasons therefor. AQSIQ/CNCA shall provide HHS/FDA this information, including a description of the problems identified, within two (2) calendar days of the failure, denial, revocation, or suspension, via secure electronic transmission.
9. AQSIQ/CNCA shall require AQSIQ/CNCA Registered Establishments to notify AQSIQ/CNCA within three (3) calendar days of detection of any failure to meet HHS/FDA Requirements or of any contamination, major defect, or any other safety concern with regard to a Covered Product for export to the United States. AQSIQ/CNCA shall transmit any such notification to HHS/FDA within three (3) calendar days of the time AQSIQ/CNCA receives it. HHS/FDA shall transmit such notification to the U.S. Department of Homeland Security's Customs and Border Protection as appropriate.
10. AQSIQ shall ensure it has and uses a system to enable the tracing of Designated Covered Products from the source of production or manufacture to exportation to assist in containing and resolving safety problems. AQSIQ shall cooperate with HHS/FDA to ensure that AQSIQ's system is effective. The Work Plan shall further specify the forms or specific types of cooperation to be undertaken.
11. AQSIQ/CNCA shall maintain documents on file related to reviews, inspections, testing, recalls, compliance, and any other assessment of a AQSIQ/CNCA Registered Establishment. AQSIQ/CNCA shall make such records available to HHS/FDA within five (5) calendar days of an HHS/FDA request.

12. Upon agreement by both Parties, AQSIQ shall facilitate periodic audits or reviews of the AQSIQ/CNCA registration program by HHS/FDA.

C. Certification

1. If the China Entry-Exit Inspection and Quarantine Bureau ("AQSIQ/CIQ") determines a shipment meets HHS/FDA Requirements, it shall issue a certificate that contains a unique identifying number and attests that the shipment meets HHS/FDA Requirements. AQSIQ/CIQ shall issue a certificate for a shipment of Designated Covered Products for export to the United States only if such shipment meets HHS/FDA Requirements.
2. To avoid counterfeiting of certificates or the falsification of information, within sixty (60) calendar days of the date of entry into force of this Agreement, AQSIQ and HHS/FDA shall designate technical experts to work together to develop the technological capabilities to implement a secure electronic system or other secure means to transmit certificate and to receive information.
3. Once the secure electronic system is established, AQSIQ/CIQ shall provide HHS/FDA a copy of each certificate issued pursuant to the certification program maintained pursuant to Section II.A.1.b. of this Annex via a secure electronic transmission within three (3) calendar days of the issuance of the certificate. AQSIQ should notify the exporter of the shipment for which AQSIQ issued the certificate that it should provide the certificate's unique identifying number to the importer of record in the United States, or to any intermediate party responsible for transmitting entry filing information to the importer of record in the United States. AQSIQ should notify the exporter or intermediate party that it should provide the unique identifying number electronically to the United States customs authorities along with the entry filing for each shipment.

4. AQSIQ shall immediately revoke a certificate of any shipment of Designated Covered Products for export to the United States if it determines that a shipment does not meet HHS/FDA Requirements. AQSIQ may base a revocation of a certificate on inspection or testing results or any other information that comes to the attention of Chinese or United States authorities to indicate that the product does not meet HHS/FDA Requirements. AQSIQ shall notify HHS/FDA of any revocation with three (3) calendar days of the revocation.
5. Upon agreement by both Parties, AQSIQ shall facilitate periodic audits or reviews of the AQSIQ certification program by HHS/FDA.
6. AQSIQ shall monitor the safety of Designated Covered Products by conducting a testing program that provides, as determined by HHS/FDA, a high level of statistical confidence in the quality of such products offered for import into the United States.

D. Additional Provisions

1. HHS/FDA may request AQSIQ to conduct an investigation regarding any Covered Products exported from the customs territory of China that HHS/FDA has reason to believe may pose a health or safety risk to public health or safety of U.S. citizens. AQSIQ shall respond to HHS/FDA within three (3) calendar days of receipt of the request and shall promptly conduct a thorough investigation. With regard to AQSIQ/CNCA Registered Establishments, AQSIQ shall notify HHS/FDA within fifteen (15) calendar days of an inspection request of:
   a. information relating to the source of the health or safety risk;
   b. the steps taken to remedy the risk; and
   c. the outcome of any remediation.

   With regard to non-AQSIQ/CNCA Registered Establishments, AQSIQ shall notify HHS/FDA of the above information as soon as it becomes available.

2. AQSIQ shall inform HHS/FDA of the results of its investigation within three (3) calendar days of completing its investigation. The Work Plan shall further detail requirements and performance measures related to requested investigations.
3. Upon the agreement of AQSIQ/CNCA, HHS/FDA may participate fully in any annual or other AQSIQ inspection of any AQSIQ/CNCA Registered Establishment.
4. HHS/FDA will consult with AQSIQ/CNCA, and shall be permitted to conduct an inspection of any AQSIQ/CNCA Registered Establishment within five (5) calendar days of notifying AQSIQ. AQSIQ shall facilitate HHS/FDA's inspection, including by ensuring, at HHS/FDA's request, that such inspections are conducted without providing advance notice to the AQSIQ/CNCA Registered Establishment.
5. Upon the agreement of HHS/FDA, AQSIQ/CNCA may conduct an audit of any refusal of a Covered Product within five (5) calendar days of notifying HHS/FDA. HHS/FDA shall facilitate AQSIQ/CNCA's audit including by providing relevant information at AQSIQ/CNCA's request (e.g., the test methods and procedures as well as test results.)
6. To the extent possible, HHS/FDA shall notify AQSIQ/CNCA of significant potential negative impact, based on scientific investigation, on human or animal health relating to food and feed imported from the customs territory of China as soon as HHS/FDA becomes aware that there may be a link with a product imported from the customs territory of China. The Parties shall discuss the data in an effort to better understand the situation.
7. For any shipment of Covered Products for export to the United States that AQSIQ determines does not meet, or appears not to meet, HHS/FDA Requirements, or if AQSIQ obtains information or has other reason to believe that a shipment poses a risk to public health, AQSIQ shall notify HHS/FDA in writing, including the reasons therefor and other information that may assist in

HHS/FDA in identifying the shipment and the supplier, within three (3) calendar days of its determination.

8. In addition to other provisions of this Agreement, AQSIQ shall not permit the export to the United States of any Covered Product that it has evidence is unsafe.

9. Except in extraordinary circumstances, each Party shall observe the following procedures: Each Party shall publish on its website and in the relevant government publication (i.e., HHS/FDA, the Federal Register; AQSIQ, the Ministry of Commerce of People's Republic of China (MOFCOM) Gazette), all proposed regulations and other measures related to Designated Covered Products and allow a reasonable period of time for all interested parties to submit comments. Each Party shall consider such comments and, at the time it adopts final regulations, address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision made to the proposed regulations. Each Party shall also publish on its website, and in the relevant government publication, all final regulations, and measures related to Designated Covered Products and allow a reasonable amount of time before implementation and enforcement.

美利坚合众国卫生与人类服务部
与
中华人民共和国国家质量监督检验检疫总局
关于食品和饲料安全的协议

美利坚合众国（简称美国）卫生与人类服务部（以下简称HHS）与中华人民共和国（简称中国）国家质量监督检验检疫总局（以下简称AQSIQ）（以下简称双方）：

了解到在食品及饲料安全领域开展双边合作与交流，有利于保护双方的公众健康；

珍惜美国卫生与人类服务部食品药品管理局（HHS/FDA）与中国国家质量监督检验检疫总局（AQSIQ）的长期协作关系，以及AQSIQ注册登记与出证体系的历史；

期望继续合作，防止、干预并反馈一国向另一国出口食品及饲料时出现的任何相关安全问题，保护美国和中国关税区内消费者、动物的安全与健康；

认识到此项合作可以促进美中两国人民健康水平的提高并增强彼此向对方出口食品及饲料安全的信心；

协议如下：

第一条
目的

本协议旨在建立食品和饲料安全的双边合作机制，为双方判定

某一进口产品是否符合进口国要求提供相关信息。这种机制可以包括现行或今后实行的注册登记与出证制度。

第二条

定义

为达到本协议的目的，特定义如下：

1. 相关产品：指属于双方监管范畴内的食品及饲料。

2. 指定相关产品：指在食品及饲料安全合作机制任何阶段被指定包括在内的“相关产品”。指定相关产品名录见附件。

3. 饲料：用于动物而非人类食用或饮用的、属于双方监管范畴内的物质及其成分，包括不作为药品管理的维生素或草药等膳食补充剂。饲料包括饲料成分、饲料添加剂以及含兽药的加工、半加工饲料及原料。

4. 公司：中国关税区内或美国境内从事食品及饲料制造、生产、种植、加工、包装、检测、储藏、运输、配送或出口的企业。

5. 食品：双方管理权限范围内供人类食用或饮用的物质及其成分。

6. HHS/FDA 的要求：指由 HHS/FDA 管理和实施的有关食品、饲料的美国法律、法规或其他要求，包括本协议生效之后被采用的有关修订条款。

7. AQSIQ/CNCA 要求：指与 AQSIQ 或中国国家认证认可监督管理委员会（CNCA）管理和实施的有关食品、饲料的中国法律、法规或其他要求，包括本协议生效之后被采用的有关修订条款。

8. AQSIQ/CNCA 注册企业：经过 AQSIQ/CNCA 注册的、符合中国相

关注册法规以及附件所列 HHS/FDA 要求的企业。

9.HHS/FDA 注册企业：经过 HHS/FDA 注册、符合美国法典第 21 条第 350d 款的《联邦食品、药品和化妆品法》要求的企业。

10. 企业：在中国关税区或美国境内制造、生产、种植养殖、加工、包装、检测、储存、运输、配送、出口食品或饲料的公司场所或设备。

第三条

总则

1、双方应根据本协议第五条及双方将要共同制定的工作计划要求，针对从中国关税区出口美国的相关产品以及在美国生产并出口中国关税区的相关产品，开展监管层面的合作。

2、各方应根据本协议第四条及双方将要共同制定的工作计划，努力推进信息共享，以增进对双方管理体系的理解和更大的信心。根据本协议第四条，一方应与另一方分享法律、法规、管辖范围以及公共健康与安全方面的信息。

3、双方应根据本协议第四条、第五条及双方共同制定的工作计划要求，针对如何提高食品和饲料安全，开展监管层面的合作。

4、双方应举办 HHS/FDA 和 AQSIQ 领导人年会，讨论并评估本协议取得的有关进展及其他事宜。

第四条

信息共享

双方应就与食品或饲料有关的管理体制及指定产品的其他公共

健康问题交换信息，具体如下：

1、一方可以英文或中文向另一方提供信息。

2、 双方应交换各自关于食品及饲料安全的法律法规文本及其它相关信息。

3、 一方应立即向对方通报给公共健康带来重大风险并与产品安全、生产条件、产品召回有关的事件、其它紧急或显著危害健康的事件，以及与相关产品有关涉及消费者的重大欺诈行为。此类通报应自发现对公共健康危胁或涉及消费者的重大欺诈行为起2日(历日)内开始。一方应迅速反馈对方关于了解上述通报相关信息的要求，包括相关企业或实体的联系方式。此类信息反馈通常应在接到对方要求后5日(历日)内开始，除非本工作计划中另外规定。在本工作计划中应为保证此类通报及信息反馈的及时性做出特别承诺。

第五条

监管层面的合作

双方应：

1.制订并在工作计划中明确控制存在安全隐患的相关产品转运的战略。

2.开展适当的监管合作活动，包括举办培训项目、开展科学研讨与合作等，以确保相关产品注册登记及出证制度的长期稳定性和有效性。对于需要旅行或其他组织经费的培训项目或其他活动，双方应各自承担己方的参与费用。适当的监管合作活动可以包括以下方面内容：

a. 开发实验及风险评估方法，包括应对方要求所做的分析；

b. 确认和讨论两国用于食品生产动物的兽药最高残留限量(MRL)之间的显著差异；

c. 交换双方符合性项目和执法项目的科学、技术及监管方面的信息；

d. 合作以确认、降低或消除由于食品或饲料受到偶然或蓄意的化学、辐射或微生物污染（例如硫酸铜、二恶英或多氯联苯污染）而引起的对重大人类或动物健康问题的担忧；

e. 确认那些在未明确告知收货人的情况下，在食品、饲料或其成分中使用替代物或添加物，导致产品或其成分质量下降或者使其看起来比实际更优质的行为；

f. 交换关于上市前食品成份强制性审查/批准程序信息。

3.任何科技合作都应向美中科技合作联委会报告。该委员会是依据1979年1月31日美中两国政府在华盛顿签署的科技协议成立的。

4.一方应在接到对方请求5日(历日)内，制定有效安排程序以便利对方对企业实体的考察（例如发出邀请函）。此类考察可能提前或不提前通知相关企业（根据具体要求明确）。

5. 一方应向另一方提供允许相关产品进口到本国关税区内的要求的网络链接。另一方在接到对方提供的网址后30天内在自己的网站上建立起链接。

第六条

权利

1．为达到将AQSIQ/CNCA的登记注册/出证作为输美相关产品批

准决策依据的目的，双方应努力就本协议规定的AQSIQ/CNCA实行的登记注册及出证全部标准及程序达成一致。为更加明确，所有输美相关产品都应符合HHS/FDA要求及美国其它相关法律法规。

2．双方应努力就本协议规定的HHS/FDA用以登记注册的全部标准及程序达成一致。为更加明确，所有输华的相关产品都应符合AQSIQ要求及中国其它相关法律法规。

3．为更加明确，本协议无任何条款可被理解为要求一方或任何其他有关政府官员以另一方提供的任何列表或其他信息为基础就对另一方相关产品准入问题进行决策。

第七条

协议的实施

1．本协议生效后15天(历日)内，双方应以书面形式向对方通报负责协调本协议框架下双边活动的联系人，包括协调会议、交换信息、收发通报等。

2．双方据此成立工作组。各方应在本协议生效后30天(历日)内确定工作组的相关政策及技术专家。

3．本协议生效后60天(历日)内，工作组应举行首次会议，制定工作计划：

a. 进一步细化协议生效后12个月内各方应开展的具体活动及每项活动的完成时间表；

b. 在适当的情况下，形成活动成效评价标准。

4．本协议生效后120天(历日)内，工作组应完成第一个工作年度（本协议生效后的12个月）的工作计划，并在第一个工作年度

结束后评估该工作计划。

5. 对此后每 12 个月的活动，工作组应开会制定工作计划，明确各方在此期间根据本协议应开展的活动，并（依据情况）对各项活动制定活动成效的评估标准。每一阶段结束后，双方应对该阶段的工作计划作出评估。

6. 此后经双方确认的每 12 个月的工作计划均应包括及时、有效实施本协议的约束性承诺。双方均应每年在各自的网站上公布首个 12 个月工作计划，随后每年公布。

7. 本协议生效后 180 天(历日)内，双方高级代表应会晤讨论本协议的实施情况、取得的进展及其他事宜。

8. 此后，双方高级代表应每年会晤一次，就协议实施、进展情况及相关事宜进行磋商。若无另外约定，年会轮流在美中两国召开。根据需要，双方可协商临时召开技术性或项目层的会议，地点由双方协商确定。

第八条

绩效评估

1、双方每年均应共同评估并讨论本协议的进展状况，包括依据附件对项目进行的有效性评估。

2、HHS 将从如下方面对进展状况进行评估：

a. 中国关税区输美或产自中国的指定相关产品被 HHS/FDA 退货比例与 2007 年度或其他 HHS/FDA 指定时段的中国关税区输美或产自中国的指定相关产品被退货比例的对比；

b. 中国关税区输美或产自中国的指定相关产品，来自非

AQSIQ/CNCA 注册企业或者无卫生证书（certified）的总体比例；及

c. 因公共卫生危害而被召回的中国关税区输美或产自中国的指定相关产品（包括假冒产品）的数量、召回频率及危害大小与 2007 年度或其他时段此类情况的比较；

3．AQSIQ 将从如下方面对进展状况进行评估：

a. 美国输华或产自美国被 AQSIQ 退货的指定相关产品比例与 2007 年度或其他时段的对比；

b. 美国输华或产自美国的指定相关产品，来自非 HHD/FDA 注册企业的总体比例；及

c.因公共卫生危害而召回的美国输华或产自美国的指定相关产品（包括假冒产品）的数量、召回频率及危害大小与 2007 年度或其他时段此类情况的比较。

第九条

最终条款

1．本协议任何条款均不能阻止美中两国政府为保护各自公众健康而采取有关措施。每方确认将与各自国内有关的国家、州/省、市级有关部门共同全面贯彻落实本协议。

2.本协议任何条款均不应影响美中之间现行其他协议规定的美中两国的权利和义务。

3．双方应及时磋商努力解决本协议实施或理解中存在的争议。

4．本协议在双方签署后生效，除非一方终止，有效期五年。如果任何一方在协议期满 60 天(历日)以前均未提出终止要求，则该协议在期满最后一天自动延长五年。此外，在协议期满 60 天(历日)以

前，双方均有权利以书面形式通告对方要求中止协议。双方可通过书面协定的形式随时修订本协议。

5. 所有附件条款都作为本协议的必要组成部分。双方在本协议框架下开展的任何活动均应符合各自国家法律法规的要求。

本协议于2007年12月11日在北京签署，一式两份，以英中文书就，两种文本同等作准。

美利坚合众国
卫生与人类服务部
代　表

中华人民共和国
国家质量监督检验检疫总局
代　表

附 件

第一部分 指定相关产品的确定：

本协议有关工作将分阶段实施，首先从初步确定的指定相关产品名单开始。双方应对第一阶段与指定相关产品有关的活动成效作出正式评估，并在此第一阶段的成功基础上，将该指定相关名单扩展至其他相关产品。

A. 条件

经相互协商后，双方应当根据下列条件指定每一阶段应包括在指定相关产品名单上的相关产品：

1．根据检测、检验结果或双方获得的其他相关信息，有关产品对公众健康存在潜在或现实的、直接或间接的风险；

2．相关产品被一方拒绝入境的比率，或相关产品进入进口国前或在进口过程中及进口后出现问题的比例，包括产品召回、安全警示及被采取强制性措施的情况；

3．欺骗、伪造标签情况，或在未明确告知进口方收货人情况下，将替代物或添加剂加入到相关产品或其成分，导致产品或其成分质量下降，或者使其看起来比实际更优质；

4．与相关产品有关的工作计划是否能得到及时有效地执行。

B. 第一阶段指定相关产品

1．双方同意将下列退货率较高、风险较大的产品列为第一阶段的指定相关产品：

a. 低酸罐头产品或酸化食品；

b. 动植物源性宠物食品或宠物零食；

c. 食品或饲料成分（如麦粉和米蛋白粉）；及

d. 除软体贝类之外的其他养殖水产品。

上述产品的详细目录由双方在工作计划中确定。

2、经对方同意，双方可在任一后续阶段中扩大适用于登记注册及出证制度的指定相关产品种类。具体的程序在工作计划中列明。

第二部分 出口监管

1. 双方承认 AQSIQ/CNCA 的注册和出证制度项目在中国的成功实施（例如，恢复了对从中国关税区进口的陶器制品的信心，并提高了产品的安全性）。双方期望以该长期以来建立的制度的成功经验，帮助确保从中国进口的其他食品和饲料的安全。

2. 基于此项注册和出证分阶段项目的成功（具体情况如下所示），HHS/FDA 可能采用 AQSIQ/CNCA 为其提供的相关信息作为进口准入决策的依据，可包括降低属于登记注册和出证制度的指定相关产品的查验比例。

A. 概述

1、对于根据本附件第一部分A条款指定的相关产品，AQSIQ/CNCA 已经建立并应继续实施：

a. 注册制度，要求所有中国关税区输美指定相关产品的企业向 AQSIQ/CNCA 注册；

b. 将出证制度扩大至包括中国关税区输美指定相关产品，这些

产品必须由 AQSIQ 出具证书，证明其满足 HHS/FDA 的要求。

2. 双方应就开展注册和出证项目进行磋商。这一项目应分阶段实施，第一阶段应涵盖附件第一部分 B/1 条款的指定相关产品，后续阶段应涵盖附件第一部分 A 指定的相关产品。此制度应在前阶段成效的基础上扩展到在后续阶段包括其他产品。另外，基于对前阶段成功，双方可同意在后续阶段修改本协议，以包括限制未经 AQSIQ 出证证明符合 HHS/FDA 要求的产品从中国关税区向美国出口。将来双方可讨论修改本协议以反映经双方认可的第三方检验和出证制度在促进产品安全方面的作用。

3. HHS/FDA 应向 AQSIQ 提供所有 HHS/FDA 对指定相关产品的相关要求，包括新近更新的要求。

4. 对被拒绝进入美国的指定相关产品，HHS/FDA 应迅速通知 AQSIQ/CNCA。关于通报系统的详细信息，包括通报时间和机制，将在工作计划中做进一步规定。

5. HHS/FDA 承诺将建立未附 AQSIQ/CNCA 证书的指定相关产品的通报机制。

6.该通报机制的详细信息，包括时间和机制将在工作计划中具体确定。

7. 如果 HHS/FDA 认为一个向美国出口产品的企业或一批来自中国的未附有 AQSIQ/CIQ 证书的指定相关产品符合 HHS/FDA 要求，HHS/FDA 应通知 AQSIQ，双方应就此进行讨论。

B. 注册

1、对于出口到美国的指定相关产品，AQSIQ/CNCA 应：

a. 确保仅注册满足 HHS/FDA 要求的企业；

b. 对每一家 AQSIQ/CNCA 注册企业进行监管须使之始终满足 HHS/FDA 要求；

c. 应保证向每一家 AQSIQ/CNCA 注册企业详细告知 HHS/FDA 采用的要求；

2. 基于本附件第一部分 A/1 标准，AQSIQ/CNCA 应要求所有输美指定相关产品企业在 AQSIQ/CNCA 注册。注册均应包含如下内容：

a. 企业的名称和地址；

b. 企业的指定相关产品名录；

c. 企业所有者、经理或者高层管理人员的姓名及联系方式（包括电话号码）。

3. AQSIQ/CNCA 应要求 AQSIQ/CNCA 注册企业对任何注册信息的变更都通知 AQSIQ/CNCA 并提供更新信息。

4. AQSIQ/CNCA 应对所有 AQSIQ/CNCA 注册企业实体进行年检，以保证每家 AQSIQ/CNCA 注册企业都符合 HHS/FDA 的要求。AQSIQ/CNCA 应在企业向 AQSIQ/CNCA 注册后 180 天(历日)内检查企业，并以此时间作为以后年检的基准。当 AQSIQ/CNCA 经过检查或在其他情况下认为企业不能满足 HHS/FDA 要求时，应取消或暂停其注册资格。

5. AQSIQ/CNCA 应通过安全的电子系统向 HHS/FDA 提供所有 AQSIQ/CNCA 注册企业及每家 AQSIQ/CNCA 企业的指定相关产品的名单（“AQSIQ/CNCA 注册企业名单”）。AQSIQ/CNCA 应在本协议生效后 30 天(历日)内向 HHS/FDA 提供首份 AQSIQ/CNCA 注册企业名单，此后每 90 天(历日)更新一次。

6. HHS/FDA 应在收到 AQSIQ/CNCA 注册企业名单或更新名单后

15 天(历日)内将其公布在 HHS/FDA 网上。

7. HHS/FDA 应向 AQSIQ/CNCA 提供所有经过 HHS/FDA 注册的企业名单。HHS/FDA 应在本协议生效后 30 天(历日)内通过安全的电子系统向 AQSIQ/CNCA 提供首份名单，此后每 90 天(历日)更新一次。

8.AQSIQ/CNCA 应以书面形式向 HHS/FDA 通报未通过检查、注册资格被中止、撤销或否定的 AQSIQ/CNCA 企业及其原因。AQSIQ/CNCA 应在 2 天（历日）之内通过安全可靠的电子途径将上述信息提供给 HHS/FDA。

9. AQSIQ/CNCA 应要求 AQSIQ/CNCA 注册企业在 3 天(历日)内将输美指定相关产品不符合 HHS/FDA 要求、发生污染、具有重大问题或其他安全隐患的情况通知 AQSIQ/CNCA。AQSIQ/CNCA 应在收到通报后 3 天(历日)内向 HHS/FDA 转告有关信息。HHS/FDA 应视情况转告美国国土安全部海关和边境保护局。

10. AQSIQ 应确保拥有并使用一个能确保对指定相关产品从生产加工源头到出口的可进行追溯的系统，以协助遏制、解决有关安全问题。AQSIQ 应与 HHS/FDA 合作以确保该系统的有效。工作计划将对此类合作的方式和具体类型进行说明。

11. AQSIQ 应保存对 AQSIQ/CNCA 注册企业进行考察、检查、检测、实施召回、企业执行情况及其他评估活动的记录。应 HHS/FDA 要求，AQSIQ 应在 5 天(历日)内提供上述记录。

12. 经双方同意，AQSIQ 应为 HHS/FDA 对 AQSIQ/CNCA 注册系统的阶段性审核和评估提供便利。

C. 出证

1．若中国国家质量监督检验检疫总局/中国出入境检验检疫机构（AQSIQ/CIQ）确认一批货物符合 HHS/FDA 的要求，AQSIQ/CIQ 应签发具有唯一识别号的证书，注明符合 HHS/FDA 的要求。只有当输美指定相关产品符合 HHS/FDA 要求时，AQSIQ 才能为其签发证书。

2．为避免伪造证书或虚假信息的产生，AQSIQ 和 HHS/FDA 应在本协议生效后 60 天(历日)内指定技术专家共同工作开发技术支持以建立安全的电子传输系统或其他安全手段，用以传送证书、接收信息。

3．一旦建立了安全电子系统，AQSIQ/CIQ 应在每份证书签发后 3 天(历日)内通过安全电子传输系统向 HHS/FDA 提供符合本附件第二部分 A/1/b 所述要求的出证项目之要求的证书副本。AQSIQ 应通知出口商将证书的唯一识别号提供给美国备案进口商，或负责进境单证信息传送的中介方。AQSIQ 应告知出口商或中介方将唯一识别号及每批货物的进境单证以电子传输方式提交给美国海关部门。

4.当 AQSIQ 认为相关指定产品不符合 HHS/FDA 要求，应立即取消已签发的证书。AQSIQ 可根据查验、检测结果或中美主管部门获得的其他证据做出取消证书的决定。AQSIQ 应在取消证书后 3 天(历日)内将此情况通报 HHS/FDA。

5．经双方同意，AQSIQ 应为 HHS/FDA 对 AQSIQ 出证制度进行的定期检查或评估活动提供便利。

6．AQSIQ 应通过实施出口检测计划对指定相关产品的安全性进行检测，以使输美产品质量达到高统计信心水平，该指标由 HHS/FDA 确定。

D. 其他条款

1．若 HHS/FDA 有理由认为中国关税区输美的任何相关产品会给美国公民带来健康或安全风险，HHS/FDA 可以要求 AQSIQ 对其进行调查。AQSIQ 应在收到 HHS/FDA 要求后 3 天(历日)内予以反馈并迅速进行彻底调查。对于注册企业，AQSIQ 应在收到要求的 15 天(历日)内将如下信息通报 HHS/FDA:

a. 有关健康或安全风险来源的信息;

b. 采取应对风险的补救措施;和

c. 补救结果.

对于非注册企业，AQSIQ/CNCA 应在得知上述信息后尽快通知 HHS/FDA。

2．AQSIQ 将在完成调查后的 3 日内将调查结果通报 HHS/FDA。此类调查的要求和评估标准将在工作计划进一步明确。

3．经 AQSIQ/CNCA 同意，HHS/FDA 可以参与 AQSIQ 对任何 AQSIQ/CNCA 注册企业的年度检查或其它检查工作。

4．经协商，AQSIQ/CNCA 应在得到通知后 5 日内允许 HHS/FDA 对任何 AQSIQ/CNCA 注册企业进行检查。AQSIQ/CNCA 应协助 HHS/FDA 的检查工作，其中包括在 HHS/FDA 的要求下保证不提前通知有关 AQSIQ/CNCA 注册企业。

5．经 HHS/FDA 同意，AQSIQ/CNCA 可在通知 HHS/FDA 后 5 日内对被拒绝入境的相关产品进行核查。HHS/FDA 应协助 AQSIQ/CNCA 的核查工作。其中包括应 AQSIQ/CNCA 的要求提供相关信息(如检测方法、程序以及检测结果)。

6．如果可能，基于科学的调查，一旦 HHS/FDA 意识到可能与中国关税区进口产品有关时，HHS/FDA 应通知 AQSIQ/CNCA 与从中国关税区进口的食品和饲料有关的对人类和动物健康的巨大、潜在的负面影响。双方应讨论相关数据以努力使双方对事情的整体情况有更好的理解。

7．若 AQSIQ 确定输美相关产品不符合或看似不符合 HHS/FDA 要求，或者 AQSIQ 得到相关信息或有其它理由认为该批货物会对公共健康带来风险，AQSIQ 应在确认后 3 天内将其原因或其他信息以书面形式通知 HHS/FDA，以协助 HHS/FDA 确认该批货物及其供应商。

8.另外，即使本协议未作出有关规定，AQSIQ 也不应允许任何有证据表明不安全的指定相关产品出口美国。

9．极端情况除外，各方均应尽量遵循以下程序：各方应提前在网站上或在相关政府出版物（例如，HHS/FDA 网站、美国联邦公报、AQSIQ 和 CNCA 网站、中国商务部公报）上公布所有与指定相关产品相关的规章制度和其它措施，并给予所有利益方合理的时间来发表评论。双方应考虑这些评论，在形成最终规章时以书面形式反馈重要的具有实质性意义的评论，并对规章中任何实质性的修改作出解释。对于最终的规章和指定相关产品有关的措施，双方也应在网站上或相关政府出版物上公布，并在实施前给予合理的过渡期限。