

**Memorandum of Understanding between
Food and Drug Administration
Department of Health and Human Services of the United States of America
and
Certification and Accreditation Administration of the People's Republic of China
Regarding
Registration of U.S. Food Manufacturers Exporting to China**

PREAMBLE

The Participants in this Memorandum of Understanding (MOU), the Food and Drug Administration (FDA), Department of Health and Human Services (HHS) of the United States of America, and the Certification and Accreditation Administration of the People's Republic of China (CNCA), hereinafter referred to as the "Participants,"

Recognizing that the Food Safety Law of the People's Republic of China and Decree 145 of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) require overseas manufacturers of certain food products offered for entry into China to be under the effective control and supervision of foreign competent authorities;

Recognizing that under Decree 145 overseas manufacturers of certain food products offered for entry into China are to be certified by the foreign competent authority exercising control and supervision over such manufacturers to be in compliance with the relevant laws and regulations of China, with respect to the food product categories identified in AQSIQ-related notices;

Recognizing that FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, pursuant to the FD&C Act, is charged with protecting public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled,

Recognizing that U.S. based food manufacturers of certain food products offered for entry into China must be certified to be in compliance with the laws and regulations of China for food product categories identified in AQSIQ-related notices, and such certification is available only from third parties; and

Recognizing that the differences between the U.S. and Chinese regulatory systems as they apply to food manufacturers necessitate clarification of the registration processes in order for U.S. food manufacturers to be able to comply with AQSIQ Decree 145;

Have reached the following understandings:

I. PURPOSE

The mutual goals of FDA and CNCA, in signing this MOU, are to:

- A. Establish a registration process that provides assurances to CNCA that U.S. food manufacturers subject to AQSIQ Decree 145, and their food products subject to AQSIQ Decree 145 that the manufacturers offer for entry into China, are in compliance with the relevant standards, laws and regulations of China, as specified in AQSIQ Decree 145;
- B. Outline roles and responsibilities of each participant within this process so that each may operate according to the laws and regulations of their respective country;
- C. Clarify that the third party certification bodies acknowledged by Participants are to serve the purpose of auditing manufacturers who offer food products subject to AQSIQ Decree 145 for entry into China according to the relevant standards, laws, and regulations of China;
- D. Provide greater clarity and certainty for all those offering food products subject to AQSIQ Decree 145 for entry into China regarding applicable processes for ensuring that the manufacturing facility and product meet the relevant food safety requirements of China; and
- E. Provide for the cooperative exchange of scientific and regulatory information, technical assistance, and research to ensure an effective registration process of food products subject to AQSIQ Decree 145 and exported from the United States and offered for entry into the People's Republic of China.

II. AREAS OF COOPERATION AND TYPES OF ACTIVITIES

A. CNCA

CNCA intends to:

1. Provide a list of third-party certification bodies for each food product category under the scope of AQSIQ Decree 145 as updates to the Annexes to this Memorandum;
2. Confirm that the third-party certification bodies have relevant technical capacity and conditions to conduct China Hazard Analysis and Critical Control Point (HACCP) certification audits;
3. Update the list of third-party certification bodies within the appropriate Annex as needed or as requested by the United States;
4. Accept facility certification from one of the third-party certification bodies identified in Annexes to this document;
5. Allow third-party certification bodies to attest, as indicated in Annex 1, that the U.S. manufacturer and its food products offered for entry into China, subject to AQSIQ Decree 145, meet the relevant standards, laws and regulations of China;
6. Approve the manufacturers which meet the registration requirements according to AQSIQ Decree 145 and publish online an updated list of registered manufacturers after receipt of the list of manufacturers from FDA;
7. Stipulate that registered manufacturers shall accept at least one audit every two years by the third-party certification body listed in the appropriate Annex;

8. Conduct evaluations of the U.S. regulatory procedures for listing food manufacturers and the recommended registration process according to CNCA's work plan, as needed;
9. Evaluate acknowledged third-party certification body's audit activities and inspect U.S. food manufacturers that have been registered with CNCA; and
10. Request that all U.S. food manufacturers registered in China at the time this MOU is signed receive an audit against the standards, laws and regulations of China and obtain a certification from the third-party certification body listed in the appropriate Annex within two years from the date of signature of this MOU.

B. FDA

FDA intends to:

1. Acknowledge the list of third-party certification bodies for each food product subject to the AQSIQ Decree 145 which is provided by CNCA as updates to the Annexes to this Memorandum;
2. Issue a Competent Authority Statement to CNCA when a manufacturer and its food products that are subject to the AQSIQ Decree 145 are certified by a third-party certification body as being in compliance with the standards, laws and regulations of China according to relevant requirement specified in AQSIQ Decree 145 (for template refer to Annex 1);
3. Evaluate relevant manufacturers' regulatory standing with FDA through a review of regulatory compliance, inspection history and any pending regulatory action;
4. Upon completion of the third-party certification body's review, receive certification from the third-party body and, if certified by the third-party body to be in compliance with the standards, laws and regulations of China according to relevant requirements specified in AQSIQ Decree 145, and if found by FDA to be in good regulatory standing, include the manufacturer on FDA's internal list of manufacturers and food products;
5. Every quarter, or as otherwise decided between the Participants, provide CNCA with a list of manufacturers that would facilitate registration by CNCA, including any changes to previous lists of manufacturers;
6. Provide an attestation, as indicated in Annex 1, along with the list of manufacturers and any changes to previous lists, that the manufacturer and its food products are in good regulatory standing and have received a confirmation from a third-party certification body that the manufacturer and its food products are in compliance with the standards, laws, and regulations of China according to the relevant requirements specified in the AQSIQ Decree 145;
7. Notify CNCA of changes FDA is making to its list of manufacturers or their products when FDA is made aware of manufacturers and their products not being in compliance with the laws and regulations of China; and
8. Issue a Competent Authority Statement to CNCA to confirm the list of registered manufacturers already registered with CNCA before this MOU is signed once those

manufacturers have successfully received the attestation referenced in Annex 1 from acknowledged third-party certification bodies.

III. ADMINISTRATIVE PROCEDURES

The Participants intend that this MOU not provide for the sharing of any proprietary or confidential business information between Participants.

The Participants intend to designate points of contact under this MOU. The Participants are expected to notify each other or the points of contact in writing.

The Participants intend that nothing in this MOU affect the acceptance of U.S. government-issued export health certificates by AQSIQ.

The Participants intend to resolve any dispute regarding the implementation or interpretation of this MOU through timely consultations.

All activities carried out pursuant to this MOU are to be conducted in accordance with the laws and regulations of the United States of America and the People's Republic of China and are subject to the availability of personnel, resources, and available funds. This MOU is not intended to create any binding obligations under international or domestic law.


IV. PERIOD OF UNDERSTANDING

The activities under this MOU may commence upon signature by both Participants and are expected to continue indefinitely until the MOU is modified or discontinued. The Participants intend to evaluate the MOU every five (5) years. The MOU may be modified by mutual written consent of the Participants and may be discontinued by either Participant upon 30 days' written notice to the other.

Signed in duplicate in the English and Chinese languages, both texts being equally valid.

FOR THE U.S. FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH AND HUMAN SERVICES OF
THE UNITED STATES OF AMERICA

FOR THE CERTIFICATION AND
ACCREDITATION ADMINISTRATION OF
THE PEOPLE'S REPUBLIC OF CHINA


Stephen Ostroff, M.D.
Deputy Commissioner
For Foods and Veterinary Medicine


Liu Weijun
Deputy Chief Administrator

Date: June 15, 2017

Date: June 15, 2017

Place: College Park, MD

Place: College Park, MD

Annex 1 – Attestations

By the Third-Party Certification Body upon transmittal of a facility and product certification:

“It is hereby certified, relating to the requirements of AQSIQ Decree 145, that the manufacturer and the identified food products exported to China meet the relevant standards, laws, and regulations of China.”

By FDA, upon transmittal of the manufacturer list to CNCA:

“It is hereby certified, relating to the requirements of AQSIQ Decree 145, that the manufacturers on this list are subject to the jurisdiction of the Federal Food, Drug, and Cosmetic Act and relevant FDA regulations, that each manufacturer on the list has been found by FDA to be in good regulatory standing and during the most recent facility inspection to be in substantial compliance with all applicable FDA regulations, including current good manufacturing practice requirements, and that each manufacturer and identified food products, as applicable, have been certified by an acknowledged third-party certification body to meet the relevant standards, laws, and regulations of China.”

**Annex 2 – Acknowledged Third-Party Certification Bodies
for Dairy and Infant Formula Products**

序号 No.	名称 Name	地址 Address	联系电话 Tel
1	Agricultural Marketing Service, United States Department of Agriculture	1400 Independence Ave SW, Washington DC, 20250,	+1 202-720- 4392
2	中国质量认证中心 China Quality Certification Centre (CQC)	北京市丰台区南四环西路 188 号 9 区 Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu (West Road), Beijing, China	+86 10- 83886666
3	方圆标志认证集团有限公司 China Quality Mark Certification Group Co., Ltd	北京市海淀区增光路 33 号 No.33, Zengguang Road, Haidian District, Beijing, China	+86 10- 68477287
4	北京中大华远认证中心 Beijing Zhongda Huayuan Certification Center (ZDHY)	北京市东城区阜外大街乙 22 号 415 室 B22, Fuwai Street, West District, Beijing	+86 10- 68396415
5	北京五洲恒通认证有限公司 Beijing Continental Hengtong Certification Co., Ltd(CHTC)	北京市丰台区角门 18 号枫竹苑二区 1 号楼 3 层 303 室 Room 303,Mingliuweilai Mansion, No.18 in Jiaomen, Fengtai District, Beijing, China	+86 10- 63180681
6	上海天祥质量技术服务有限公司 Intertek Testing Services Ltd., Shanghai	上海市徐汇区宜山路 889 号齐来工业城 2 号楼 6 楼 6/F., Building 2, Comalong Industrial Park, No.889,Yishan Road, Shanghai	+86 21- 61194005

Annex 3 – Acknowledged Third-Party Certification Bodies for Seafood Products

序号 No.	名称 Name	地址 Address	联系电话 Tel
1	National Marine Fisheries Service, National Oceanic and Atmospheric Administration, United States Department of Commerce	1315 East West Highway, Silver Spring, MD 20910	+1 301-427-8300
2	中国质量认证中心 China Quality Certification Centre (CQC)	北京市丰台区南四环西路 188 号 9 区 Section 9, No.188, Nansihuan (the South Fourth Ring Road) Xilu (West Road), Beijing, China	+86 10-83886666
3	方圆标志认证集团有限公司 China Quality Mark Certification Group Co., Ltd	北京市海淀区增光路 33 号 No.33, Zengguang Road, Haidian District, Beijing, China	+86 10-68708523
4	上海质量体系审核中心 Shanghai Audit Center of Quality System (SAC)	上海市长宁区武夷路 258 号 No.258 Wuyi Road Shanghai	+86 21-52387700 (总机 Operator), 52389950
5	广东中鉴认证有限责任公司 Guangdong Certification Co., Ltd	广东省广州市越秀区广州大道中路 227 号 4 楼 No.227, Middle Road, Guangzhou Avenue, Yuexiu District, Guangzhou, Guangdong Province	+86 20-87369002/9003/9001
6	东北认证有限公司 Northeast Audit CO., LTD.(NAC)	沈阳市沈河区文艺路 21-1 号 No. 21-1, Wenyi Road, Shenhe District, Shenyang, Liaoning	+86 24-83961668
7	杭州万泰认证有限公司 HANGZHOU WIT ASSESSMENT CO LTD	杭州市滨江区江虹路 1750 号信雅达国际创意中心 1 幢 1301-1308、1401-1402、1405-1408 室 13-14 Floor, Sunyard International, No.1750 Jianghong Road, Binjiang District, Hangzhou, China	+86 571-87901296, 87711527

序号 No.	名称 Name	地址 Address	联系电话 Tel
8	北京新世纪检验认证股份有限公司 Beijing New Century Inspection & Certification Co., Ltd. (BCC)	北京市西城区国英园 1 号楼 11 层 1101 室 11/FI, Guoying Yihao, Nanxiaojie, Xizhimen'nei, Xicheng District, Beijing	+86 10-58561802
9	北京中大华远认证中心 Beijing Zhongda Huayuan Certification Center (ZDHY)	北京市东城区阜外大街乙 22 号 415 室 B22, Fuwai Street, West District, Beijing	+86 10-68396633, 68396647
10	华夏认证中心有限公司 China Certification Center	北京市海淀区卧虎桥甲六号 No.6 Wohuqiao, Haidian District, Beijing	+86 10-62335102
11	深圳市环通认证中心有限公司 Universal Certification Centre Co., Ltd. (UCC)	广东省深圳市福田区侨香路裕和大厦六层全层 6TH FLOOR, Yuhe Building, Qiaoxiang Road, Futian District, Shenzhen	+86 755-83355888
12	北京中安质环认证中心 ZhongAn Authentication Center	北京市朝阳区东三环南路 58 号富顿中心 1 号楼 22 层 Fulton Center, No.58, East Sanhuan Road, Chaoyang District, Beijing	+86 10-58673519; 18311490788
12	兴原认证中心有限公司 Xingyuan Quality Certification Center (XQCC)	北京市海淀区上地三街 9 号金隅嘉华大厦 C 座 711 室 Room 711, Building C, Jinyu Jiahua Plaza, No. 9, Shangdi San Avenue, Handian District, Beijing	+86 10-62981683, 62981193
13	北京世标认证中心有限公司 World Standards For Certification Center (WSF)	北京市海淀区德胜门西大街 15 号远洋风景家园 8 栋 2 单元 701、702 室 Room 701 and 702, Unit 2, Building 8, Yuanyangfengjing, No.15, Deshengmen West Avenue,	+86 10-82291199

序号 No.	名称 Name	地址 Address	联系电话 Tel
		Haidian District, Beijing	
14	北京埃尔维质量认证中心 Ever Win Quality Certification Center (EWC)	北京市西城区车公庄大街甲 4 号 物华大厦 A1007 室 Room A1007, Wuhua Plaza, Chegongzhuang Avenue, Xicheng District, Beijing	+86 10-68001010
15	北京大陆航星质量认证中心股份有限公司 Beijing Daluhangxing Quality Certification Center Co., Ltd. (HXQC)	北京市海淀区玉泉路甲 12 号七层 7/F, No.jia 12 Yuquan Road, Haidian District, Beijing	+86 10-88266093
16	上海挪亚检测认证集团有限公司 NOA Test & Certification (NOA)	中国（上海）自由贸易试验区锦 绣东路 2777 弄 26 号 3 层 Building 26 No.2777 East Jinxu Road, China (Shanghai) Pilot Free Trade Zone, Shanghai	+86 21-50430897
17	北京恩格威认证中心有限公司 Beijing NGV Certification Center (NGV)	北京市东城区建国门内大街 7 号 701 Room 701, No.7, Jianguomen Inner Street, Dongcheng District, Beijing	+86 10-64802303- 08
18	凯新认证（北京）有限公司 Kaixin Certification (Beijing) Co.,Ltd (KCB)	北京东城区新中西街 2 号新中大 厦 7 层 706 室 Room 706, Xinzhong Building, Xinzhong West Street, Dongcheng District, Beijing	+86 10- 65535910/1/2/3
19	福建东南标准认证中心 Southeast Standard Certification Center (SEC)	福州市鼓楼区西门外山头角 121 号 No.121, Ximenwaishantoujiao, Gulou District, Fuzhou, Fujian Province	+86 591-83762036 , 83732144

序号 No.	名称 Name	地址 Address	联系电话 Tel
20	中环联合（北京）认证中心有限公司 China Environmental United Certification Center Co., Ltd	北京市朝阳区育慧南路 1 号 No. 1 Yuhuananlu, Chaoyang District, Beijing	+86 10-59205880
21	山东世通质量认证有限公司 Seatone Certification	青岛市竹园路 2 号 No.2 Zhuyuan Road, Qingdao, Shandong	+86 532-85730069
22	北京东方纵横认证中心有限公司 Beijing East Allreach Certification Center Co., Ltd(EACC)	北京市通州区中关村科技园区通州园金桥科技产业基地景盛南四街 17 号 121 号楼一层 Building 121 Floor 1, Nov. 17, Jingsheng South four Avenue, Jinqiao Technology Industry Base, Tongzhou Park of the Zhongguancun Technology Park, Tongzhou district, Beijing	+86 10-56495881
23	北京五洲恒通认证有限公司 Beijing Continental Hengtong Certification Co.,Ltd(CHTC)	北京市丰台区角门 18 号枫竹苑二区 1 号楼 3 层 303 室 Room 303, Mingliuweilai Mansion, No.18 in Jiaomen, Fengtai District, Beijing, China	+86 10-63180681
24	上海英格尔认证有限公司 ICAS Certification Center	上海市徐汇区中山西路 2368 号华鼎大厦 801 室 Huading Tower, No.2368, West Zhongshan Rd., Xuhui District, Shanghai	+86 21-51114700 , 54253540
25	北京五岳华夏管理技术中心 Beijing WuYue HuaXia Management & Technique Center (CHC)	北京市宣武区广安门南滨河路 2 3 号立恒大厦 1 号楼 5 0 2 室 Room 502, No. 1 Building, Lihengmingyuan, No.23, South Binhe Road, Guanganmen, Xicheng District, Beijing	+86 10-63310558

序号 No.	名称 Name	地址 Address	联系电话 Tel
26	南京国环有机产品认证中心 Organic Food Development and Certification Center of China (OFDC)	南京市玄武区蒋王庙 8 号 8 Jiang-Wang-Miao Street, Nanjing	+86 25-85287233/85287118
27	北京华测食农认证服务有限公司 Beijing CTI Food and Agriculture Certification Service Co., Ltd.	北京市朝阳区东三环北路 30 号 (住宅) 楼 2-11A No. 2-11A, No. 30 North Road of East 3 rd Ring Road, Chaoyang District, Beijing	+86 10-85967093
28	华中国际认证检验集团有限公司 Huazhong International Certification Inspection Group Co., Ltd.	江西省南昌市西湖区站前路 96 号天集大厦 2206 室 Room 2206, Tianji Plaza, No. 96, Zhanqian Road, Xihu District, Nanchang, Jiangxi	+86 791-86121595
29	山东国鉴认证有限公司 Shandong Guojian Certification Co., Ltd.	山东省济南市市中区舜耕路 217 号九城尚都办公楼 801 室 Room 801, Jiuchengshangdu, No.217, Shungeng Road, Shizhong District, Jinan, Shandong Province	+86 531-67618299
30	通标标准技术服务有限公司 SGS-CSTC Standards Technical Services Co., Ltd.	北京市海淀区阜城路 73 号世纪裕惠大厦 16 层 16F Century YuHui Mansion, No. 73 Fucheng Road, Beijing	+86 10-68456699
31	上海天祥质量技术服务有限公司 Intertek Testing Services Ltd., Shanghai	上海市徐汇区宜山路 889 号齐来工业城 2 号楼 6 楼 6/F., Building 2, Comalong Industrial Park, No.889, Yishan Road, Shanghai	+86 21-61194005
32	劳氏质量认证 (上海) 有限公司 Lloyd's Register Quality Assurance - LRQA	上海市黄浦区延安东路 550 号海洋大厦 2017-18、2001-02 室 Ocean Masion, No.550 Yanan East Road, Shanghai	+86 21-51585700

序号 No.	名称 Name	地址 Address	联系电话 Tel
33	上海挪华威认证有限公司 DNV	上海市虹口区虹桥路 1591 号 9 号楼 BLD No.9, No.1591 Hongqiao Road, Hongqiao District, Shanghai	+86 21-32084518