Board of Governors of the Federal Reserve System, July 22, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–19190 Filed 7–27–99; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Nutritional Biochemistry Cooperative Agreements for Innovative Technology Development Grant for Detection and Monitoring of Diabetic Hypoglycemia by Non- or Minimally-Invasive Techniques

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Nutritional Biochemistry Cooperative Agreements for Innovative Technology Development Grant for Detection and Monitoring of Diabetic Hypoglycemia by Non-or Minimally-Invasive Techniques, Program Announcement #99151.

Times and Dates: 8:30 a.m.–9 a.m., August 12, 1999 (Open); 9 a.m.–5 p.m., August 12, 1999 (Closed); 9 a.m.–4 p.m., August 13, 1999 (Closed).

Place: Atlanta Marriott North Central, 2000 Century Boulevard NE, Atlanta, Ga. 30345–3377. Telephone 404/325–0000.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #99151.

Contact Person for More Information: Dayton T. Miller, Ph.D., Chief, Nutritional Biochemistry Branch, NCEH, CDC, 4770 Buford Hwy., m/s F18, Atlanta, Ga. 30341–3724. Telephone 770/488–4579, e-mail dtm1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 22, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–19235 Filed 7–27–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–8000]

Memorandum of Understanding Between the Food and Drug Administration and People's Republic of China

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and People's Republic of China. The purpose of the MOU is to establish a certification system that will increase the likelihood that daily-use ceramicware manufactured in the People's Republic of China and offered for import into the United States will comply with U.S. law.

DATES: The agreement became effective May 20, 1999.

FOR FURTHER INFORMATION CONTACT: Frank M. MacKeith, Center for Food Safety and Applied Nutrition (HFS–585), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4045.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 20, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

BILLING CODE 4160–01–F

225-99-8000

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

AND THE

STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA

COVERING CERAMICWARE INTENDED FOR USE IN THE PREPARATION, SERVING OR STORAGE OF FOOD OR DRINK AND OFFERED FOR EXPORT TO THE UNITED STATES OF AMERICA

PREAMBLE

The Parties to this Memorandum of Understanding (MOU), the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America, and the State Administration of Entry-Exit Inspection and Quarantine of the People's Republic of China (SAIQ), hereinafter referred to as the "Parties,"

RECOGNIZING that SAIQ is the government agency in charge of unified supervision and administration of the China's export and import commodity inspections,

RECOGNIZING that the China Import and Export Commodity Inspection Bureaus (CCIB), under the authority of SAIQ, are authorized by SAIQ to conduct the inspections, and collect and examine representative samples of all exports of ceramicware from China to ensure that qualified daily-use ceramicware from SAIQ/CCIB certified factories intended for export to the United States is safe for use in the preparation, serving, or storage of food or drink, and

RECOGNIZING that the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America is charged with the enforcement of, among other laws, the Federal Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act,

AGREE as follows:

I. PURPOSE

The mutual goals of FDA and SAIQ, in entering into this MOU, are to:

A. Establish a certification system that will increase the likelihood that daily-use ceramicware manufactured in the People's Republic of China and offered for import into the United States will comply with United States law. To that end, this MOU sets forth the Criteria for Certification (the Criteria) of: 1) ceramicware to be exported directly from the People's Republic of China or from the People's Republic of China via Hong Kong to the United States, as indicated by those involved in the trade (ceramicware manufacturers or importers/exporters), and intended for use in the preparation, serving, or storage of food; and 2) firms in the People's Republic of China manufacturing such ceramicware.

B. Enable the FDA to reduce the frequency of its sampling of daily-use ceramicware from factories in the People's Republic of China certified by the China Import and Export Commodity Inspection Bureaus (CCIBs) of SAIQ and offered for import into the United States, in accordance with FDA's confidence in the effectiveness of the SAIQ/CCIB factory certification system.

C. Provide for the cooperative exchange of scientific and regulatory information, technical assistance, and research to help ensure the safety, quality, and proper labeling of ceramicware exported from the People's Republic of China and offered for entry into the United States, under the terms of this MOU.

II. DEFINITIONS

For the purposes of this MOU, both Parties agree to the following definitions:

A. Action Level - means the concentration of an adulterant in or on a commodity at which FDA may take regulatory action against the commodity. The action level is non-discriminatory, applies without distinction to domestic and imported products, and reflects FDA's current thinking on the concentration of the adulterant in or on the commodity at which regulatory action is appropriate.

B. Audit Sample - means a sample collected to verify analytical results provided through a certification system or private laboratory analysis that purports to show that a product complies with the Food, Drug, and Cosmetic Act and/or regulations.

C. Certified Delivery Lot - means a quantity of ceramicware offered for entry into the United States at one time, that is produced by a factory certified by a CCIB, and is in compliance with the CRITERIA FOR CERTIFICATION FOR EXPORT OF CERAMICWARE set forth in Attachment B this MOU (Criteria). A certified delivery lot may consist of one or

more factory lots or production lots. All shipping cartons and retail cartons in the lot are identified by a CCIB sticker/logo that is imprinted with the standardized factory code of the CCIB-certified factory.

D. Daily Use Ceramicware - means ceramic dinnerware intended for use in the preparation, serving, or storage of food or drink that usually are inexpensive, more durable items that have the expectation of being commonly used by the consumer.

E. Detention Without Physical Examination - means FDA's administrative act of detaining an import entry of a specified article without physical examination on the basis of information regarding its past history of violation of the Food, Drug, and Cosmetic Act or other information whereby there is an appearance that the product may be violative.

F. Electronic Entry Processing System - means an automated FDA import entry processing system which allows for a pre-determined percentage of import entries to be cleared by electronic means for entry into commerce in the United States. The pre-determined percentage of such cleared entries, referred to as a "may proceed rate," depends upon, among other things, the demonstrated degree of compliance of the commodity/country/firm combination with the laws enforced by FDA and their implementing regulations, and FDA's level of confidence that the commodity/country/firm combination will comply with such laws and regulations.

G. Factory Code - means an alpha-numeric code consisting of three parts with a total of six characters (five figures and one letter) for a particular plant. The first two figures represent the province or city, followed by the letter "T" for ceramicware, and followed by a set of three figures that SAIQ/CCIB uses to designate the factory number within each province or city.

H. Factory Lot or Production Lot - means a unit of ceramicware that is uniform and that represents ceramicware from no more than one homogeneously milled slip from the same materials. The factory lot or production lot must be uniform in the time and temperature of firing and the composition and application of the decorations and glazes.

I. Factory Lot Number or Production Lot Number - means a number assigned by the factory that relates to both the date and period of manufacture and denotes a distinct group of conditions (manufacturing date, kiln conditions, materials, patterns, etc.) that may affect the quality of the ceramicware.

J. Flatware - means ceramic articles that have an internal depth, as measured from the lowest point to the horizontal plane passing through the upper rim, that does not exceed 25 millimeters.

K. Hollowware - means ceramic articles having an internal depth, as measured from the

lowest point to the horizontal plane passing through the upper rim, greater than 25 millimeters. The two categories of hollowware and their sub-categories are:

1. Large hollowware - Ceramic articles with a capacity of 1.1 liter or more.

   a. Pitchers - Large ceramic hollowware vessels (sometimes known as jugs) commonly used for storage and dispensing of fruit and vegetables juices or other acidic beverages at or below room temperature. Pitchers are generally manufactured without a lid but with a handle and lip spout. Creamers, coffeepots and teapots are not considered to be pitchers. Depending upon capacity, creamers, coffeepots and teapots will be considered small or large hollowware.

   b. Other (not including pitchers) - Ceramic vessels with a capacity of 1.1 liter or more. (Note that different action levels apply to pitchers than to large hollowware other than pitchers under the Criteria.)

2. Small hollowware - Ceramic articles with a capacity of less than 1.1 liter.

   a. Cups and Mugs - Small ceramic hollowware vessels commonly used for consumption of beverages, for example, coffee or tea, at or above room temperature. Cups and mugs usually, but not exclusively, have a capacity of about 240 milliliters (240 mL) or 8 fluid ounces (8 fl. oz.) and are manufactured with a handle. Cups generally have a base and curved sides while a mug has cylindrical sides.

   b. Other (not including cups and mugs) - Ceramic vessels with a capacity of less than 1.1 liter. (Note that different action levels apply to cups and mugs than to small hollowware other than cups and mugs under the Criteria.)

L. May Proceed Rate - means the rate of import entries entered into domestic commerce without FDA physical examination or sampling that varies from a high near 100% for commodity/country/firm combinations for which FDA has a high confidence of compliance (e.g., particular firms have demonstrated a good compliance history and are certified by a foreign government), to a low of 0% for commodity/country/firm combinations for which FDA has a low confidence of compliance (e.g., firms with a history of noncompliance with the Food, Drug, and Cosmetic Act).

M. Sample - means portion of a certified delivery lot being offered for entry into the United States that is intended to be representative of that lot. It will consist of a number of units or subsamples, collected as specified in Article V, governing SAMPLE COLLECTION.

N. Shipping Carton - means a box that contains one or more retail cartons of daily-use

ceramicware produced by a CCIB-certified factory, has the CCIB sticker/logo with the CCIB factory code imprinted on it, and has the factory name and code, the year of production of the factory lot and the factory lot number printed on its exterior surface.

O. Traditional Ceramicware - means the ceramic dinnerware, spoons and other ware that might be used to contain or store foods and beverages. Such items are usually porcelain items, hand-painted with soft lead-containing enamels, and highly decorated with vivid colors and intricate patterns, which have been found to leach unacceptable levels of lead. The patterns are of red, yellow, and green, and referred to as "Longevity," "Flowers on Black," and "One Thousand Flowers," for example.

III. BASIC OBLIGATIONS

A. THE STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA

SAIQ shall ensure that daily-use ceramicware products that are intended for export to the United States comply with the provisions of this MOU. SAIQ agrees to direct the CCIBs to inspect and certify factories, and inspect and analyze samples, to ensure that ceramicware intended to be exported to the United States complies with these requirements and provisions.

To carry out its responsibilities, SAIQ agrees to:

1. Implement and oversee a daily-use ceramicware factory certification system;

2. a. Provide, on a continuing basis, FDA's Center for Food Safety and Applied Nutrition with a nationally standardized listing of factory names, addresses and codes of CCIB-certified daily-use ceramicware factories that export such daily-use ceramicware to the United States;

   b. Authorize the export of qualified daily-use ceramicware to the United States only from CCIB-certified factories;

3. a. Affix to each shipping carton and retail carton containing daily-use ceramicware that meets the Criteria a CCIB "H" (for Health) sticker/logo that is imprinted with the factory code of the CCIB-certified factory;

   b. Require that the factory lot or production lot number be on each shipping carton of the daily-use ceramicware that is to be exported to the United States;

4. Inspect and analyze factory lots or production lots of daily-use ceramicware to be

exported to the United States at a rate commensurate with the compliance history of the CCIB-certified factory and sufficient to provide a high degree of confidence that the daily-use ceramicware exported to the United States is in compliance with the Criteria;

5. Ensure that the CCIB laboratories that test daily-use ceramicware to determine its compliance with the Criteria follow the analytical procedures as described in the ANALYTICAL METHODOLOGY set forth in Attachment A;

6. Authorize the export of and issue export certificates for daily-use ceramicware intended for export to the United States, as indicated by either directly or transshipped through Hong Kong or other countries either by the manufacturer or by the importer/exporter, only for those delivery lots that are in compliance with the Criteria;

7. Require that all shipments of daily-use ceramicware intended to be exported to the United States via Hong Kong or other countries, as indicated by either the daily-use ceramicware manufacturer or the importer/exporter, be sealed by the CCIBs in such a way as to help prevent opening during transit;

8. a. Work with manufacturers and CCIBs to find solutions to any problems found when daily-use ceramicware from a CCIB-certified factory and covered by this MOU are determined by FDA not to meet the Criteria;

   b. Conduct an investigation if a daily-use ceramicware product from a CCIB-certified factory is detained by FDA because of an analytical finding of excessive levels of leachable lead or cadmium, to determine the cause of the technical defect that led to the violation and how it was remedied. SAIQ will provide FDA with a full report, in English, within three months of notification, on the findings of the investigation and the corrective measures taken to ensure future compliance;

9. Furnish FDA, upon request, with a copy, in both Chinese and English, of the current procedures and regulations relevant to daily-use ceramicware production/export and of the procedures/quality control plans used to ensure that each production lot of daily-use ceramicware is in compliance with United States FDA requirements;

10. Encourage the development and use of lead-free and cadmium-free decals, glazes and pigments in daily-use ceramicware and Chinese traditional ceramicware production; and,

11. Prevent, to the extent practicable, the export to the United States of ceramicware

which is not produced in a CCIB-certified factory, such as Chinese traditional ceramicware.

It is recognized by FDA and SAIQ that a period of four (4) months from date of signature will be necessary for SAIQ to complete certification procedures and logistical arrangements for all ceramicware factories which qualify for participation under the terms of this MOU. Therefore, SAIQ will provide FDA will the names, addresses and codes, as specified in Section III, A., as they are certified by SAIQ during the initial four-month implementation period.

B. THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

FDA intends to:

1. Sample and analyze certified delivery lots of daily-use ceramicware produced in CCIB-certified factories, and offered for entry into the United States to ensure that such lots exported from the People's Republic of China and offered for entry into the United States comply with the laws of the United States administered by the FDA;

2. Adjust its electronic entry processing system and conduct surveillance monitoring of daily-use ceramicware from CCIB-certified factories at a rate consistent with the Agency's confidence in the effectiveness of the SAIQ/CCIB factory certification system, so that the may proceed rate can be substantially higher for daily-use ceramicware firms identified/certified by SAIQ/CCIB as consistently producing and exporting daily-use ceramicware in accordance with this MOU than the may proceed rate for other Chinese daily-use ceramicware firms not so identified and certified;

3. Sample and analyze delivery lots of daily-use ceramicware from manufacturers not on the list of factories certified by the CCIB at a relatively high review and sampling rate consistent with the FDA's concern about possible lead and cadmium contamination of daily-use ceramicware from these uncertified factories, and place such firms on detention without physical examination when it appears that the firms do not meet FDA's requirements;

4. Detain, at FDA discretion, without physical examination, subsequent delivery lots of daily-use ceramicware from a CCIB-certified factory whose products appear to be, through previous analysis, in violation of the United States laws administered by the FDA. All daily-use ceramicware from a CCIB-certified factory that produces violative daily-use ceramicware may remain subject to detention without physical examination until such time as the SAIQ provides assurance to FDA's satisfaction that appropriate corrective actions have been implemented, and that

future daily-use ceramicware products from that factory will be in compliance with the Criteria. This assurance includes the report of Section III., A., 8., b., above. FDA may then resume review of ceramicware from the CCIB-certified factory, consistent with the provisions in III.B.2, above;

5. Promptly notify SAIQ and the First Secretary (Commercial) of the Embassy of the People's Republic of China in the United States of any delivery lot or portion thereof of ceramicware covered by this MOU that is detained for failure to comply with United States law. This notification, by the International Activities Staff of FDA's Center for Food Safety and Applied Nutrition, should include:

   a. The CCIB-certified factory number;

   b. A copy of the accompanying CCIB certificate or certificate number;

   c. Production Lot number;

   d. Quantity of daily-use ceramicware detained;

   e. Commodity or the name of the product and the style number or pattern name;

   f. FDA's sample number;

   g. Date sample collected;

   h. Reason for detention, including the technical defect, e.g., defective color in decal, if known;

   i. Date of detention;

   j. FDA's District Office that detained the product and Port of Entry;

   k. Manufacturer/shipper name (Factory code, name and address); and

6. Provide advice to SAIQ concerning approaches or actions that may be taken by the manufacturer/shipper of the detained product to help ensure that subsequent shipments will not be detained.

7. On an annual basis, provide SAIQ with results of any FDA analyses of daily-use and other ceramicware offered for import into the United States from the People's Republic of China.

IV. TECHNICAL INFORMATION EXCHANGE

The Parties agree to share expertise, provide assistance, and exchange information. Such mutual cooperation may include, but shall not be limited to:

A. Sharing current, new, and improved methods of sampling and testing of daily-use ceramicware for lead and cadmium;

B. Sharing current, proposed, or modified regulations or legislation related to daily-use ceramicware;

C. As resources permit, the exchange of administrative, regulatory, and scientific personnel knowledgeable about daily-use ceramicware;

D. The exchange of information about daily-use ceramicware quality control operations, plans, and procedures, including summaries of inspections, samples and analytical results; and

E. The exchange of data and research related to major food-caused health concerns that may be attributed to lead and cadmium.

V. SAMPLE COLLECTION

Whenever practicable, FDA intends to use the same representative sample to determine adherence with the Criteria. A representative sample will generally consist of:

Six (6) units of identical size, shape, color, decoration, and glaze collected from each sampled delivery lot.

VI. ADMINISTRATIVE PROCEDURES

The Parties shall mutually agree on the ways and means of giving instruction and guidance for the practical implementation and application of this MOU. All travel and per diem expenses incurred by one of the Parties in the course of providing technical assistance or other non-regulatory activities requested by the other Party in accordance with this MOU will be borne by the requesting Party, upon receipt from the providing party of an itemized statement of account.

The Parties shall designate points of contact under this MOU. The Parties shall notify each other of the points of contact by letter.

VII. PERIOD OF AGREEMENT AND TEXTUAL VERSIONS

This MOU will enter into force upon signature by both Parties and will continue for five (5) years. The Parties agree to evaluate the MOU during the five-year period. It may be extended or amended by written consent of the Parties. It may be terminated by either Party upon 30-days written notice to the other.

This MOU is done in duplicate, in the Chinese and English languages, both being equally authentic.

Signed at:

WASHINGTON, DISTRICT OF COLUMBIA

ON May 20, 1999

FOR THE STATE ADMINISTRATION OF ENTRY-EXIT INSPECTION AND QUARANTINE OF THE PEOPLE'S REPUBLIC OF CHINA:

Shi Jianxin
Minister-Counselor (Commercial)
Embassy of the People's Republic of China

and

WASHINGTON, DISTRICT OF COLUMBIA

ON May 20, 1999

FOR THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA:

Sharon S. Holston
Deputy Commissioner for International and Constituent Relations

ATTACHMENT A

ANALYTICAL METHODOLOGY

Compliance with the Criteria in Attachment B will be determined by using the analytical method Standard Method for Lead and Cadmium Extracted from Glazed Ceramic Surfaces described in the latest edition of *Annual Book of ASTM Standards*, of the American Society for Testing and Materials (ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959), currently volume 15.02 (1996), designation C738-94.

The method also appears in the March 1996 Supplement to the 16th Edition of *Official Methods of Analysis* (AOAC International, 481 N. Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417). Method 973.32 is used for high levels, Method 973.82 is used for low levels.

The levels of lead and cadmium are to be determined by analyzing each unit at the same time, individually, according to the above cited method.

ATTACHMENT B

CRITERIA FOR CERTIFICATION FOR EXPORT OF DAILY-USE CERAMICWARE

SAIQ agrees not to certify ceramicware factories that produce daily-use ceramicware for export to the United States that contain levels of lead or cadmium that exceed the following United States Food and Drug Administration guidance that is non-discriminatory, and applies without distinction to domestic and imported products:

A. LEAD

Category	Action Basis	Maximum Level* micrograms/mL
Flatware	Average of 6 units	3.0
Small Hollowware other than cups, mugs and pitchers	Any one of 6 units	2.0
Cups and mugs	Any one of 6 units	0.5
Large Hollowware other than pitchers	Any one of 6 units	1.0
Pitchers	Any one of 6 units	0.5

B. CADMIUM

Category	Action Basis	Maximum Level* micrograms/mL
Flatware	Average of 6 units	0.5
Small Hollowware	Any one of 6 units	0.5
Large Hollowware	Any one of 6 units	0.25

* Micrograms of element per milliliter of four percent (4%) acetic acid leaching solution as per cited analytical method.

[FR Doc. 99–19106 Filed 7–17–99; 8:45 am]
BILLING CODE 4160–01–C

美利坚合众国卫生和人类服务部食品药物管理局
与
中华人民共和国国家出入境检验检疫局
关于对美出口的调制、盛放或贮存食品和饮料的陶瓷器皿
问题谅解备忘录

序言

本备忘录涉及的双方，美利坚合众国卫生和人类服务部食品药物管理局(FDA)和中华人民共和国国家出入境检验检疫局(SAIQ)，以下简称双方，

认识到SAIQ是中华人民共和国负责统一监督管理全国进出口商品检验工作的政府机构，

认识到SAIQ所属的CCIB经SAIQ授权负责从事中华人民共和国各种出口陶瓷的检验、有代表性的试样抽取和检测工作以确保来自SAIQ/CCIB认证工厂的对美出口的合格日用陶瓷安全地用于调制、盛放或贮存食品和饮料。

认识到FDA负责执行联邦《食品、药品和化妆品法》、《良好包装和标签法》以及美国其他相关法规，

同意以下内容:

目的

美利坚合众国卫生和人类服务部食品药物管理局(FDA)和中华人民共和国国家出入境检验检疫局(SAIQ)，达成本《谅解备忘录》的共同目的是:

A. 建立认证体系以便增加在中华人民共和国制造的准备进入美国的日用陶瓷完全符合美国法律的可能性。为此，本备忘录阐明的是: 1).直接从中华人民共和国出口到美国或者贸易关系人(陶瓷生产厂或者进/出口商)声明经香港转运出口到美国供调制、盛放或贮存食品的陶瓷器皿，以及2).中华人民共和国生产这些陶瓷器皿的加工厂的认证准则。

B. 根据 FDA 对 SAIQ/CCIB 工厂认证体系的有效性的信任,使美国减少其对来自经中国进出口商品检验局(CCIBs)认证的中华人民共和国内工厂的输美日用陶瓷器皿的抽查频率。

C. 在本备忘录项下，为科学信息及管理规章信息的合作交流提供技术帮助和研究，以助于确保中华人民共和国出口到美国的陶瓷器皿的安全、优质和标识正确无误。

二、定义

双方同意本备忘录如下定义:

A. 行动水平: 系指某商品中或商品上污染物的浓度所处的食品药物管理局可按规章对该商品采取行动的水平。行动水平是非歧视性的，无差别地适用于国内产品和进口产品，反映了 FDA 对该商品中或该商品上污染物浓度的一般想法,处于该限量水平时即可按章采取行动。

B. 审查样品: 系指抽取的用以核实某认证体系或私人实验室所提供的分析结果的样品,目的旨在表明某产品符合食品、药物和化妆品法律或法规。

C. 认证交货批: 系指经中国商检局认证的工厂生产的、符合本备忘录附件《出口陶瓷认证准则》的、一次出口至美国的陶瓷器皿的数量单位。一个认证交货批可以由一个或多个工厂批或生产批组成。该交货批的每一运输纸箱和零售纸箱均用 CCIB 的标签/标识加以识别，其上印有 CCIB 认证工厂的标准化的厂代号。

D. 日用陶瓷: 系指用于调制、盛放或贮存食品或饮料的陶瓷餐具,通常是廉价的、较为耐用的、有望为消费者普遍使用的陶瓷餐具。

E. 不经实际检验即行扣留: 系指食品药物管理局无需实际检验,凭其以往有违反《食品、药物和化妆品法》的前科或者有显现该产品可能违章的其他信息即可对某一进口商品实行扣留的管理行为。

F. 电子报关处理系统：系指自动的 FDA 进口报关处理系统。该系统供以电子手段按进口报关的预定百分率结关，以便进入美国市场。除了其他因素,自动结关的预定百分率，即“可通关率”取决于该商品/国家/企业的综合因素与 FDA 强制执行的法律及其实施细则相符合的表现的优劣以及FDA对该商品/国家/企业的综合因素同这些法律法规符合的信任程度。

G. 工厂代号：系指某一特定工厂的由三部分共6个字符（5个数字和一个字母）所组成的一组字母数字代码。前2位数字代表所在省市,字母“T”代表陶瓷器皿，最后3位数字是SAIQ/CCIB用以表示各省市内的工厂的代码。

H. 工厂批或生产批：系指陶瓷器皿的统一数量单位,它表明该批陶瓷器皿是由均匀研磨而成的同一种泥釉制作的。同一工厂批或生产批在烧制时间和温度、成分、装饰花型、瓷釉等方面必须一致。

I. 工厂批号或生产批号：系指工厂指定的既与生产日、生产期间有关，又指示出可能会影响陶瓷器皿质量的一组特定条件（生产日期、窑的条件、材料、图案等）的号码。

J. 扁平器皿:系指从最低点至口边缘水平面之间的内深不超过25毫米的陶瓷器皿.

K. 空心器皿:系指从最低点至口边缘水平面之间的内深大于25毫米的陶瓷器皿。空心器皿的两大分类及其子分类是:

1. 大空心器皿：容量大于或等于1.1升的陶瓷器皿。

a. 罐：大陶瓷空心器皿（有时称作壶),通常用于在室温或室温以下贮存、调制果蔬汁或其他酸性饮料。罐一般没有盖子，但有手柄和唇状嘴。奶油罐、咖啡壶、茶壶不视为罐类。奶油罐、咖啡壶、茶壶依其容量可视为小空心器皿或大空心器皿。

b. 其他大空心器皿（不包括罐)：容量大于或等于1.1升的陶瓷器皿。

注:在准则中,用于罐类的行动水平与除了罐类外的其他

大空心器皿不同。

2. 小空心器皿：容量小于 1.1 升的陶瓷器皿。

a. 杯和大杯：小陶瓷空心器皿通常用于在室温或室温以上饮用饮料，如咖啡或茶。杯和大杯的容量通常为(但不全是)240 毫升或 8 液盎司，带有把柄。杯通常有底座和弯曲的侧面，而大杯则是圆柱形的侧面。

b. 其他小空心器皿(不包括杯和大杯)：容量小于 1.1 升的小陶瓷空心器皿。

注：在准则中,用于杯和大杯的行动水平与除了杯和大杯外的其他小空心器皿不同。

L. 可通关率：系指进口报关未经 FDA 实际检查或取样就进入美国国内市場的比率。可通关率的高低视情况而定，对 FDA 符合信任程度高的商品/企业/国家/来说(例如，对记录表明好的符合要求的历史并获得外国政府认证的特定企业)，可通关率可高达近 100%；对 FDA 符合信任程度低的商品/企业/国家/来说(例如，对有不符合食品、药物和化妆品法前科的企业)，可通关率可低至 0%。

M. 样品：拟用来代表输美认证交货批的部分产品,由按第五章“取样”条款来采取的几组样品单元或子样组成。

N. 运输包装箱：系指盛放经 CCIB 认证的工厂生产的日用陶瓷的箱子,里面可能有一个或多个零售包装箱,其上贴着印有 CCIB 工厂代号的 CCIB 标签/标识,印有工厂名称和代号,该工厂批的生产年份和工厂批号。

O. 传统陶瓷：系指那些有可能用于盛装或存放食品和饮料的陶瓷餐具和汤匙器皿，通常为瓷器,用含铅软釉料手绘，用鲜艳的彩色和复杂的图案来装饰，已经发现其可溶出铅含量达到了难以接受水平。例如，红、黄、绿颜色的“万寿无疆”、“黑地万花”、“万花”等图案。

三、基本义务

A. 中华人民共和国国家出入境检验检疫局

SAIQ 保证出口到美国的日用陶瓷产品符合本备忘录之

规定。SAIQ 同意指导 CCIB 对工厂进行检查和认证，并对样品进行检验和分析,以保证输美陶瓷器皿符合上述要求和规定。

SAIQ 为履行其职责,同意做到:

1.实施和监督日用陶瓷厂认证体系。

2.a.连续地向 FDA 的食品安全和应用营养中心提供 CCIB 认证的输美日用陶瓷工厂的名称、地址和代号的国家标准化清单;

b.只批准经 CCIB 认证工厂的合格日用陶瓷器皿输往美国。

3.a.对装有符合准则的日用陶瓷器皿的每一运输包装箱和零售包装箱,均要加贴印有 CCIB 认证工厂代号的 CCIB "H" (卫生)标签/标识。

b. 要求输美日用陶瓷器皿的每一运输包装箱上均要有工厂批号或生产批号。

4.按与 CCIB 认证工厂以往符合史相称的且足以提供高度相信该输美日用陶瓷是符合准则的比例去检测和分析输美日用陶瓷的工厂批或生产批。

5. 保证进行日用陶瓷检测的 CCIB 实验室为确定要按本备忘录附件 A《分析方法》中详述的分析程序进行检测,以确定输美日用陶瓷符合准则。

6. 只批准符合准则的日用陶瓷交货批出口到美国并出具出口证书，无论该交货批是直接出口还是厂商或是进/出口商声明经香港或其他国家转运到美国。

7.要求所有由陶瓷生产厂或由进/出口商声明经香港或其他国家转运到美国的日用陶瓷货物都要由CCIB加以封识,以帮助于防止在转运中开箱。

8.a.如 FDA 认定来自 CCIB 认证工厂的并为本备忘录涵盖的日用陶瓷器皿不符合准则,与生产厂和CCIB一同寻求解决问题的办法;

b.若来自 CCIB 认证工厂的日用陶瓷产品经分析发现其铅/镉溶出量超过行动水平而被 FDA 扣留,进行调查,以确

定导致问题发生的技术缺陷的原因和缺陷的补救办法,SAIQ应在扣留通知后三个月内向 FDA 提交一份有关调查结果和为保证以后符合规定准则所采取的纠偏措施的英文报告。

9.应 FDA 要求，向 FDA 提供有关日用陶瓷生产/出口现行程序和规定的中英文本和用以保证每一日用陶瓷生产批都符合美国 FDA 要求的程序/质量控制计划的中英文本。

10.鼓励在日用陶瓷和中国传统瓷生产中开发和采用无铅无镉移画印花纸、釉料和颜料。

11.在可行的范围内,防止非 CCIB 认证工厂生产的陶瓷器皿,如“传统陶瓷”，出口到美国。

FDA 和 SAIQ 承认,SAIQ 完成本备忘录项下所有合格陶瓷厂的认证程序和后勤准备工作在备忘录签署后需4个月的时间。因此,在实施期的最初 4 个月,SAIQ 将按第三章 A 款的要求向 FDA 提供其所认证的工厂名称、地址和代号。

B、美利坚合众国食品药物管理局

FDA 拟:

1.对 CCIB 认证工厂生产的输美陶瓷交货批抽取样品,并加以分析以确保已获 CCIB 认证厂生产的由中华人民共和国出口到美国的日用陶瓷交货批符合 FDA 强制执行的美国法律要求。

2.调整其电子报关处理系统并对来自 CCIB 认证工厂日用陶瓷进行监督检查。调整和监督检查的比例将与该机构对 SAIQ/CCIB 工厂认证体系的有效性的信任程度相一致。因此，经 SAIQ/CCIB 认定/认证为按本备忘录要求连续生产并向美国出口日用陶瓷器的企业的“可通关率”实际上要高于未获得此种认定/认证的中国日用陶瓷企业的“可通关率”。

3.保留对未列入 CCIB 认证工厂名单的生产厂的日用陶瓷交货批以相对较高的比例进行审查和取样的权力,该比例与 FDA 对来自这些非认证工厂日用陶瓷铅镉污染物关注的程度相一致,如发现这些企业不符合 FDA 的要求,不经实际检验即将这些企业列入自动扣留。

4.对某一 CCIB 认证工厂的日用陶瓷交货批，若此前经

分析表明，该厂产品曾违反 FDA 执行的美国法律的话，由 FDA 判断，不经实际检验即可随意扣留。凡来自曾生产过违法日用陶瓷的 CCIB 认证工厂的所有日用陶瓷器皿均维持自动扣留，直至 SAIQ 提供已采取了相应的整改措施及今后来自该CCIB认证工厂的日用陶瓷产品将符合准则的令FDA满意的保证时为止。该保证包括前面第三章 A 款第 8 条 b 项的报告内容，而后 FDA 方可恢复对来自该 CCIB 认证工厂的陶瓷器皿的正常检查，与前面第三章 B 款第 2 条的规定相一致。

5.本备忘录所涉及陶瓷器的任何交货批或其中一部分，一经因不符合美国法律而被扣留，将立即通知 SAIQ 和中华人民共和国驻美国大使馆一等秘书(商务)。由 FDA 食品安全和应用营养中心国际事务部发出的这份通知内容应包括:

a.CCIB 认证工厂代号;

b.随附的 CCIB 商检证书复印件或证书编号;

c.生产批号;

d.被扣日用陶瓷器皿数量;

e.商品或产品名称以及式样号或型号;

f.FDA 的样品号;

g.取样日期;

h.扣留原因,包括技术缺陷，如移画印花的颜色缺陷,如果知道的话;

i.扣留日期;

j.扣留产品的 FDA 地区机构和进口港;

k.生产厂/发货人名称(工厂代号、名称和地址);

6.就有关被扣产品的生产厂/发货人可以采取的方法和措施等向 SAIQ 提供建议，以有助于保证今后货物不被扣留。

7.将 FDA 对中华人民共和国输美日用的和其他陶瓷的分析结果按年提供给 SAIQ。

四、技术信息交流

双方同意分享专有技术、提供协作、交流信息。这种互相合作可以包括，但不限于:

A.分享现行的、新的和改进的日用陶瓷铅镉取样和测定方法;

B. 分享现行的、提议的或修订的有关日用陶瓷器皿的规定或法规;

C.当财力允许时，进行有关日用陶瓷管理人员、规章制定人员和学有专长的科技人员的交流;

D.有关日用陶瓷质量控制操作、计划和程序，包括检验、取样和分析结果摘要方面的信息交流;

E.交换有关可能由铅镉造成的由食品引起的重大健康问题的数据和研究结果。

五、取样

只要可能，FDA 准备使用同一的代表性样品来判定是否符合《准则》,进行测定。代表性样品通常包含: 从每一个被抽样的交货批中抽取的尺寸、形状、颜色、装饰和釉面完全相同的六件产品。

六、管理程序

双方需共同商定为实施和适用本备忘录而发布指令和指南的方式方法。协议一方应另一方要求，提供技术协作或其他非监管活动时，所产生的全部旅费和各项费用根据本备忘录均应由请求方负担，提供帮助的一方需提交逐项花费的收据。

双方将在本备忘录下指定联络点，并通过信函通知对方。

七、协议期限和文本

本备忘录的各项条款经双方签字后生效，有效期 5 年。双方同意在 5 年有效期内对本备忘录进行评价。经书面协商同意可延长或修改本备忘录。一方可提前 30 天书面通知对方终止本备忘录。

本备忘录一式两份，以中、英文书就，两种文本具有同等效力。

签署地点
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签署日期
一九九九年五月二十日

美利坚合众国
卫生和人类服务部
食品药物管理局

中华人民共和国
国家出入境检验检疫局

附件 A

分析方法

为确定铅、镉溶出量符合附件 B 准则规定的限量，采用的分析方法为：美国试验与材料协会(ASTM，位于 100 BARR HARBOR DRIVE，WEST CONSHOHOCKEN，PA 19428-2959)之最新版“ASTM 标准年鉴”中所述“上釉陶瓷表面溶出的铅、镉标准方法”，现行 15.02 卷(1996)，代号 C738-94 的方法。

该方法另见于 1996 年 3 月“官方分析方法”第 16 版增刊（AOAC INTERNATIONAL，481 N. FREDERICK AVENUE，SUITE 500，GAITHERSBURG，MD 20877-2417）。973.32 用于高的水平,973.82 用于低的水平。

铅隔溶出量是按上述方法对每一样品分别同时进行分析来确定的。

附件 B

出口日用陶瓷认证准则

SAIQ 同意输美陶瓷铅或镉溶出量超过下述美国食品药物管理局规定限量的陶瓷工厂不予认证。该限定限量是非歧视性的，无差别地适用于国内产品和进口产品：

A、铅

类　　型	运算基数	最高限量 * (微克/毫升)
扁平器皿	六件平均	3.0
除杯、大杯和罐以外的小空心器皿	六件中的任何一件	2.0
杯和大杯	六件中的任何一件	0.5
除罐以外的大空心器皿	六件中的任何一件	1.0
罐	六件中的任何一件	0.5

B、镉

类　　型	运算基数	最高限量 * (微克/毫升)
扁平器皿	六件平均	0.5
小空心器皿	六件中的任何一件	0.5
大空心器皿	六件中的任何一件	0.25

*按引用分析方法，每毫升 4%醋酸溶出液中含元素的微克数。