

**STANDARDS & PROCEDURES FOR AUTHORIZATION OF DOMESTIC/FOREIGN  
OFFICIAL LABORATORIES AND FOR RECOGNITION OF  
INSPECTION CERTIFICATES OR CERTIFICATES OF  
LABORATORY TEST RESULTS**

**1999.5**

**KOREA FOOD AND DRUG ADMINISTRATION**

*Note: This publication has been prepared to help understanding of inspection procedures for food imported into **KOREA**. Since this is not an official translation, in case of divergence, the standards and procedures in Korean language shall prevail. Interested parties should refer to the original Korean texts when definitive information on legal requirements for application is needed.*

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*Notification of the **KFDA** No. 1999-26 May 7. 1999*

*Commissioner of Korea Food and Drug Administration*

**STANDARDS & PROCEDURES FOR AUTHORIZATION OF DOMESTIC/FOREIGN  
OFFICIAL LABORATORIES AND FOR RECOGNITION OF  
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OF LABORATORY TEST RESULTS**

**Article 1. Purpose.** The purpose of this notification is to enhance the efficiency of conducting inspection of imported foods by stipulating necessary conditions, standards, and procedures required for authorization of domestic/foreign official laboratories and for recognition of inspection certificates or certificates of laboratory test results issued by authorized official laboratories in accordance with Article 16 of the Food Sanitation Act and Article 11-1-5 of the Ministerial Ordinance of the food Sanitation Act.

**Article 2. Definitions.** Definitions of terms used in this notification shall be interpreted in accordance with terms defined in the Food Sanitation Act (hereinafter referred to as "the Act"), the Presidential Decree of the Food Sanitation Act (hereinafter referred to as "the Presidential Decree"), and the Ministerial Ordinance of the Food Sanitation Act (hereinafter referred to as "the Ministerial Ordinance").

**Article 3. Requirements for Application for Authorization, etc.** ① Laboratories can apply for authorization as an official laboratory according to procedures described in items 1 and 2 below.

1. A domestic official laboratory shall be designated as a food sanitation inspection laboratory by the Commissioner of the **KFDA** in accordance with Article 18 of the Act and Article 16 of the Ministerial Ordinance.

2. A foreign official laboratory shall be a laboratory operated by the government of the exporting country or a private laboratory approved or designated by the central or local government of the exporting country (hereinafter referred to as the "government of the exporting country").

② Domestic food sanitation inspection laboratory stipulated in provision 1.1 shall be recognized as a domestic official laboratory in accordance with this notification. The standards and procedures for authorization of domestic food sanitation inspection laboratories shall be in compliance with those defined in Article 18 of the Act and Article 16 of the Ministerial Ordinance.

**Article 4. Application and Authorization, etc.** ① In accordance with the provision of Article 3-1-2 of this notification, a party who wishes to be authorized as a foreign official laboratory shall submit an application form (Appendix 1) attached to accompanying documents. The application form can be submitted via the government of an exporting country or can be submitted directly to the Commissioner of the **KFDA**.

② To check the credibility of an application and documents submitted under provisions of Article 4-1, the Commissioner of the **KFDA** may conduct an on-site survey or ask an Embassy of Korea to do so. A foreign official laboratory which is operated by the government of the exporting country can be exempted from on-site survey.

③ When a foreign official laboratory is authorized, the Commissioner of the **KFDA** should refer details of the authorization to the relevant foreign official laboratory.

**Article 5. Standards and Criteria for Recognition of Inspection Certificates and Certificates of Laboratory Test Results, etc.** ① Principle test methods shall be the methods defined in the Korea Food Code and Korea Food Additives Code or in the methods and procedures listed in *CODEX*, *AOAC*, and *PAM*. If testing is conducted according to methods other than those listed above, such testing methods shall be documented in detail.

② Authorized official laboratories can issue certificates of laboratory test results using their own form; an original copy should be submitted. Test requirements, test methods, test results, etc., shall be included in a certificate of laboratory test results.

③ An inspection certificates by an authorized domestic/foreign official laboratory shall be issued in accordance with the form provided in Appendix ; the original copy should be submitted.

④ If an importer submits an inspection certificate or a certificate of laboratory test results issued by an authorized domestic/foreign official laboratory provided in Articles 5-2 or 5-3, the Commissioner of each regional **KFDA** or the director general of each National Quarantine Station (hereinafter referred to as "regional **KFDA** or quarantine station") can substitute it for a laboratory test or can adjust the testing requirements on the basis of the following principles.

1. If an inspection certificate or certificate of laboratory test results issued by an authorized inspection laboratory is submitted by the importer and meets the requirements of Article 5-1, it can be substituted for the laboratory test by the regional **KFDA** or quarantine station.

2. If the test is not conducted according to the testing method described in Article 5-1 or if the testing method submitted is not verified, the test requirements can be adjusted by the regional **KFDA** or quarantine station.

⑤ In the case where an inspection certificate and a certificate of laboratory test results falls under one of the following categories, the regional **KFDA** or quarantine station is permitted to refuse recognition of such inspection certificates and certificates of laboratory test results.

1. As the result of an on-the-spot inspection, in accordance with Appendix Table 6 of Article 11 of the Ministerial Ordinance of the shipment is considered to be a potential cause of food safety problems.

2. When an original copy of inspection certificate or certificates of laboratory test results is not submitted.

**Article 6. Approval of Changes in Details Authorized.** ① When any of the following changes are made by a foreign authorized official laboratory, the Commissioner of the **KFDA** shall immediately be requested to approve such changes.

1. In the case of a foreign private laboratory, when items recognized by the government of the exporting country have been changed.

2. When the kinds of foods subject to testing, as authorized by the Commissioner of the **KFDA**, have been changed.

② The Commissioner for the **KFDA** can check for changes as provided for in Article 6-1 by documentation or by an on-site survey.

**Article 7. Revocation of Authorization, etc.** The Commissioner of the KFDA can 1) revoke authorization of an official foreign laboratory, 2) suspend performance up to 6 months, or 3) require correction of existing documents if any of the following occur.

1. A false inspection certificate or certificate of laboratory test results has been issued.
2. The changes described in Article 6-1 have not been approved.
3. Other duties imposed by the Commissioner of the KFDA have not been implemented.

**Supplementary Provision**

*(Notification of the Ministry of Health and Welfare No. 1996-44, April 18, 1996)*

**Article 1. Date of Enforcement.** This notification shall be in force from April 25, 1996.

**Article 2. Exclusion of Application.** This notification shall not apply to an authorized inspection organization of an exporting country carrying out quarantine and sanitation inspection of livestock products and shall not apply to a quarantine certificate issued by such organization.

**Supplementary Provision**

*(Notification of the Korea Food and Drug Administration No. 1998-118, December 7, 1998)*

**Article 1. Date of Enforcement.** This notification shall be in force from the date of notification.

**Article 2. Measurement from Time of Previous Application.** An application for authorization that has been in progress since the time when former notification became effective will be handled by the former notification.

**Supplementary Provision**

*(Notification of the Korea Food and Drug Administration No. 1999-26, May 7, 1999)*

**Article 1. Date of Enforcement.** This notification shall be in force from the date of notification.

**Article 2. Measurement from Time of Previous Application.** An application for authorization that has been in progress since the time when former notification became effective will be handled by the former notification.

[Appendix 1]

| <b>The Application for Authorization of Foreign Official Laboratory</b>   |         |  | Period  |  |
|---|---------|--|---------|--|
|   |         |  | 60 days |  |
| Applicant   | Name    |  |         |  |
|   | Address |  |         |  |
| Name of Organization  |         |  |         |  |
| Location  | Tel     |  |         |  |
|   | Fax     |  |         |  |
| Food to be Tested and Test Items  |         |  |         |  |
| <p>I HEREBY FORMALLY APPLY FOR AUTHORIZATION AS AN OFFICIAL FOREIGN LABORATORY IN ACCORDANCE WITH ARTICLE 4-1 OF STANDARDS AND PROCEDURES FOR AUTHORIZATION OF FOREIGN OFFICIAL LABORATORIES AND FOR THE RECOGNITION OF INSPECTION CERTIFICATES OR TESTING RESULT CERTIFICATES.</p> <p>YEAR MONTH DATE</p> <p>APPLICANT SIGNATURE(SEAL)</p> <p><b>TO : THE COMMISSIONER, KOREA FOOD AND DRUG ADMINISTRATION</b></p>   |         |  |         |  |
|   |         |  | Fee     |  |
|   |         |  | Free    |  |
| <p><input type="radio"/> DOCUMENTS TO ACCOMPANY THE APPLICATION</p> <ol style="list-style-type: none"> <li>1. GENERAL STATUS(FUNCTIONS AND HISTORY)</li> <li>2. ORGANIZATION AND DIVISIONS (INCLUDING AN ORGANIZATION CHART)</li> <li>3. THE CONTENT OF MAIN BUSINESS</li> <li>4. LABORATORY TEST PERFORMANCES(SEPARATE, RECENT THREE-YEAR RECORD FOR FOOD, FOOD ADDITIVE, APPARATUS, CONTAINERS · PACKAGING, AGRICULTURAL · DAIRY · SEA FOOD)</li> <li>5. DESCRIPTION MAJOR ANALYTIC AND TEST EQUIPMENT STATUS</li> <li>6. DESCRIPTION OF LABORATORY FACILITY STATUS</li> <li>7. LABORATORY PERSONNEL STATUS(INCLUDING WORK EXPERIENCE OF INDIVIDUAL STAFF MEMBERS)</li> <li>8. DOCUMENTS APPROVED BY THE GOVERNMENT OF EXPORTING COUNTY REGARDING INSPECTION OF LABORATORIES(ONLY REQUIRED IF THE INSPECTION LABORATORY IF NOT OPERATED BY THE CENTRAL GOVERNMENT OF LOCAL GOVERNMENT)</li> </ol> |         |  |         |  |

[Appendix 2]

| INSPECTION CERTIFICATE  |                       |               |  |              |  |
|---|-----------------------|---------------|--|--------------|--|
| NO. OF ISSUANCE   |                       |               | DATE OF SUBMISSION                     |              |  |
| ISSUING COUNTRY   |                       |               | DATE OF INSPECTION                     |              |  |
| APPLICANT   | NAME                  |               | NAME OF COMPANY                        |              |  |
|   | ADDRESS(OR LOCATION)  |               |  |              |  |
|   | TEL NO AND FAX NO.    |               |  |              |  |
| IMPORTER  | ADDRESS (OR LOCATION) |               |  |              |  |
|   | TEL NO. AND FAX NO.   |               |  |              |  |
|   | NAME OF FOOD          |               | IMPORT QUANTITY (TOTAL QUANTITY)<br>Kg | PACKING UNIT |  |
| SHIPPING AREA BY AIR OR SEA   |                       |               | TRANSPORTATION METHOD                  |              |  |
| MANUFACTURING CODE  |                       |               | DATE OF MANUFACTURING                  |              |  |
| NAME OF PRODUCTS  |                       |               | SHELF LIFE                             |              |  |
| COLLECTING FOOD AREA  |                       |               | DATE OF COLLECTING FOOD                |              |  |
| TEST LIST   | TEST METHOD           | TEST STANDARD | TEST RESULT                            | REMARKS      |  |
|   |                       |               |  |              |  |
| <p>THIS IS TO CERTIFY THAT THE ABOVE STATEMENTS ARE TRUE.</p> <p>YEAR    MONTH    DATE</p> <p>ADDRESS OF OFFICIAL LABORATORY :</p> <p>NAME OF OFFICIAL LABORATORY :</p> <p>SEAL</p> <p>NAME OF REPRESENTATIVE OF OFFICIAL LABORATORIES :</p> <p>SIGNATURE</p> |                       |               |  |              |  |

**List of Foreign Official Laboratories  
Feb. 2002**

| Country   | No.  | Name  | Food items                              | Date     |
|-----------|--|---|---|----------|
| USA       | 1  | Export Service Center,<br>Department of Agriculture, Oregon                       | Foods,<br>Agricultural<br>Product, Etc. | '96.12.3 |
| THAILAND  | 2  | Bangkok Fish Inspection Center  | Fish & Fishery<br>Product               | '98.6.5  |
| THAILAND  | 3  | Songkhla Fish Inspection Center   |   |          |
| TAIWAN    | 4  | Bureau of Standard Inspection (BSMI),<br>6th Department                           | Fish & Fishery<br>Product               | '99.1.21 |
|           | 5  | BSMI, Keelung Branch  |   |          |
|           | 6  | BSMI, Tainan Branch   |   |          |
|           | 7  | BSMI, Kaohsiung Branch  |   |          |
| AUSTRALIA | 8  | Australian Government Analytical<br>Laboratories(AGAL), Victoria                  | Fish & Fishery<br>Product               | '99.1.21 |
|           | 9  | Australian Government Analytical<br>Laboratories (AGAL), New South Wales          |   |          |
|           | 10   | AWT Tasmaina  |   |          |
|           | 11   | Microserve Laboratory Pty Ltd   |   |          |
|           | 12   | Institute of Medical and Veterinary Science,<br>Food and Environmental Laboratory |   |          |
|           | 13   | Centre for Food Technology  |   |          |
|           | 14   | Queensland Health Scientific Services(QHSS)                                       |   |          |
|           | 15   | Dunn Son and Stone  |   |          |
|           | 16   | EML Consulting Services Pty   |   |          |
| 17        | East Laboratory Pty Ltd, Port Kembla,<br>New South Wales |   |   |          |
| FINLAND   | 18   | National Veterinary and Food Research<br>Institute                                | Foods, Fish &<br>Fishery Product        | '99.3.3  |
| USA       | 19   | OMIC USA Inc.   | Foods,<br>Agricultural Product          |          |
| GERMANY   | 20   | German Control Internationale Warenprufung  | Foods,<br>Agricultural Product          |          |

| Country   | No. | Name   | Food items                     | Date          |
|-----------|-----|--|--------------------------------|---------------|
| THAILAND  | 21  | Fish Inspection Center of Surat Thani  | Fish & Fishery<br>Product      | 2000.<br>8.25 |
|           | 22  | Fish Inspection Center of Samut sakorn   |                                |               |
|           | 23  | Division of Food - for - Export<br>Department of Medical Sciences<br>Ministry of Public Health | Foods                          | 2000.<br>8.25 |
|           | 24  | Regional Medical Sciences Center, Trang  |                                |               |
|           | 25  | Regional Medical Sciences Center, Songkhla   |                                |               |
|           | 26  | Regional Medical Sciences Center, Surat Thani  |                                |               |
|           | 27  | Regional Medical Sciences Center,<br>Samut Songkhram   |                                |               |
|           | 28  | Regional Medical Sciences Center, Chiang Mai   |                                |               |
| AUSTRALIA | 29  | Bernard Heath & Associates   | Agricultural<br>Product, Foods | 2000.<br>8.25 |
| VIETNAM   | 30  | NAFIQACEN(National Fisheries Inspection<br>and Quality Assurance Center) Branch I              | Fish & Fishery<br>Product      | 2001.<br>3.27 |
|           | 31  | NAFIQACEN - Branch II  |                                |               |
|           | 32  | NAFIQACEN - Branch III   |                                |               |
|           | 33  | NAFIQACEN - Branch IV  |                                |               |
|           | 34  | NAFIQACEN - Branch V   |                                |               |
|           | 35  | NAFIQACEN - Branch VI  |                                |               |