|  |  |
| --- | --- |
|  |  |
|  |  |
| **G/SPS/N/KOR/496** |
| 12 March 2015 |
| (15-1406) | Page: 1/2 |
| **Committee on Sanitary and Phytosanitary Measures** | Original: English |

NOTIFICATION

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Republic of KOREA **If applicable, name of local government involved:**   |
| **2.** | **Agency responsible:** Ministry of Food and Drug Safety  |
| **3.** | **Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Testing laboratories (food, livestock product, drug, traditional Korean medicinal substance, medical device, cosmetics) |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:****[****X] All trading partners**  **[** **] Specific regions or countries:**   |
| **5.** | **Title of the notified document:** Proposed amendments to the regulation of Food and Drugs Testing Laboratories Assessment  **Language(s):** Korean **Number of pages:** 52<http://members.wto.org/crnattachments/2015/SPS/KOR/15_1171_00_x.pdf> |
| **6.** | **Description of content:** a. Amend Annex 4 LAQAS (Laboratory Quality Assurance Standards) of the regulation of Food and Drugs Testing Laboratories Assessment to install testing record management system (such as Audit trail for instruments, using laboratory notebook for manual testing, etc).b. Amend the Certificate of Laboratory Testing to minimize fraud possibility.c. Establish requirements of re-operating laboratory after service suspension due to testing ability. |
| **7.** | **Objective and rationale: [****X] food safety, [** **] animal health, [** **] plant protection, [** **] protect humans from animal/plant pest or disease, [** **] protect territory from other damage from pests.**   |
| **8.** | **Is there a relevant international standard? If so, identify the standard:****[** **] Codex Alimentarius Commission *(e.g.  title or serial number of Codex standard or related text)***  **[** **] World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)***  **[** **] International Plant Protection Convention *(e.g. ISPM number)***  **[****X] None**  |
|  | **Does this proposed regulation conform to the relevant international standard?** **[** **] Yes [** **] No****If no, describe, whenever possible, how and why it deviates from the international standard:**   |
| **9.** | **Other relevant documents and language(s) in which these are available:** Testing and Inspection of Food and Drugs Act, Enforcement Regulation of Testing and Inspection of Food and Drugs Act (available in Korean)  |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** To be determined.**Proposed date of publication *(dd/mm/yy)*:** To be determined. |
| **11.** | **Proposed date of entry into force: [****X] Six months from date of publication**, **and/or** ***(dd/mm/yy)*:**  **[** **] Trade facilitating measure**   |
| **12.** | **Final date for comments: [** **] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 14 April 2015**Agency or authority designated to handle comments: [** **] National Notification Authority, [****X] National Enquiry Point. Address, fax number and e‑mail address (if available) of other body:** International Cooperation OfficeMinistry of Food and Drug Safety#187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do363-700, KoreaTel: +(82 43) 719 1554Fax: +(82 43) 719 1550E-mail: wtokfda@korea.kr |
| **13.** | **Text(s) available from: [** **] National Notification Authority, [****X] National Enquiry Point. Address, fax number and e‑mail address (if available) of other body:** Documents are available from the Korea Ministry of Government Legislation website at: <http://www.law.go.kr>Also available from:International Cooperation OfficeMinistry of Food and Drug Safety #187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do363-700, KoreaTel: +(82 43) 719 1554Fax: +(82 43) 719 1550E-mail: wtokfda@korea.kr |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |  |
| --- | --- |
| **世界贸易组织** | **G/SPS/N/KOR/496****分发日期：**2015-03-12(15-1406) |
| 卫生及植物卫生措施委员会  | 原文: 英文 |

**通 报**

|  |  |
| --- | --- |
| **1.** | **通报成员:** **韩国**适用时，列出涉及的地方政府名称:  |
| **2.** | **负责机构:** 食品和药物安全部 |
| **3.** | **所覆盖产品(提供在WTO备案的国家目录中指定的关税条目号；如可能，可另提供国际商品系统编号(ICS)):** 测试实验室(食品、畜产品、药物、韩国传统药用物质、医疗器械、化妆品) |
| **4.** | **只要相关或可行，可能受影响的地区或国家：****[** X **]所有贸易伙伴，或 [ ]特定地区或国家：** |
| **5.** | 通报文件的标题、语言及页数：食品和药物测试实验室评估法规拟定修改案韩文52页 http://members.wto.org/crnattachments/2015/SPS/KOR/15\_1171\_00\_x.pdf |
| **6.** | **内容简述:** a.修改食品和药物测试实验室评估法规的附件4LAQAS(实验室质量保证标准)，以建立测试记录管理系统(如利用实验室人工测试等记录簿对仪器审计跟踪)。b.修改实验室测试证书，以将欺诈的可能性降到最低。c.制定因测试能力而暂停服务后实验室重新运转的要求。 |
| **7.** | **目标与理由: [ X ]食品安全，[ ]动物健康，[ ]植物保护，[ ]保护人类免受动/植物有害生物的危害，[ ]保护国家免受有害生物的其它危害:** [ ] |
| **8.** | **是否有相关国际标准？如有，指出标准:****[ ] 食品法典委员会(例如：食品法典委员会标准或相关文件的名称或序号)****[ ] 世界动物卫生组织(OIE)(例如：陆生或水生动物卫生法典，章节号)****[ ] 国际植物保护公约(例如：ISPM N*°*)[ X ] 无该法规草案是否符合相关国际标准？****[ ]是 [ ]否 如不符，请尽量说明与国际标准不符之处与原因:**  |
| **9.** | **可提供的相关文件及文件语种:** 食品和药物法案的测试和检验、食品药物法案测试和检验执行法规(提供韩文) |
| **10.** | **拟批准日期(年/月/日):** 待定 **拟公布日期(年/月/日):** 待定 |
| **11.** | **拟生效日期: [ X ]通报日后6个月，及/或(年月日)：**  **[ ]贸易促进措施**  |
| **12.** | **意见反馈截止日期：[ ]通报发布日起60天，及/或(年/月/日) :** 2015年4月14日**负责处理反馈意见的机构: [ ]国家通报机构，[ X ]国家咨询点 ，或其他机构的联系地址、传真及电子邮件地址(如能提供):** InternationalCooperationOfficeMinistryofFoodandDrugSafety#187Osongsaengmyeong2-ro,Osong-eup,Heungdoek-guCheongju-si,Chungcheongbuk-do363-700,KoreaTel:+(8243)7191554Fax:+(8243)7191550E-mail:wtokfda@korea.kr |
| **13.** | **文本可从以下机构得到: [ ]国家通报机构，[ X ]国家咨询点，或其它机构的联系地址、传真及电子邮件地址(如能提供):** 韩国政府立法部网站提供相关文件:http://www.law.go.kr另有以下单位提供文件：InternationalCooperationOfficeMinistryofFoodandDrugSafety#187Osongsaengmyeong2-ro,Osong-eup,Heungdoek-guCheongju-si,Chungcheongbuk-do363-700,KoreaTel:+(8243)7191554Fax:+(8243)7191550E-mail:wtokfda@korea.kr |

 |
|  |