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POLICY

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Korea - Republic of

Post: Seoul

Accreditation of Foreign Labs for GMO Testing

Report Categories:

Biotechnology and Other New Production

Technologies

Biotechnology - GE Plants and Animals

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Report Highlights:

This report contains an unofficial translation of the Korean Food & Drug Administration's (KFDA) recently-announced accreditation procedures and requirements for foreign laboratories interested in being approved to conduct GMO testing on food and other agricultural products for export to Korea. Shipments accompanied by test certificates from accredited laboratories will be exempt from mandatory arrival testing. The relevant KFDA points of contact are also included herein.

**Information on
Accreditation of Foreign Laboratory for
Genetically Modified Organisms (GMO)**

July 2011

**Korea Food and Drug Administration
Laboratory Audit and Policy Division**

□ Purpose

- To introduce procedures and standards regarding accreditation and onsite inspection of foreign laboratories for genetically modified organisms (GMO) and thereby enhance access and convenience.
 - Regulations on Accreditation Standards, Etc. for Foreign Laboratory (refer to KFDA Notice No. 2011-21 or Attachment 3)
 - Submission of lab report with regard to GMO labeling is limited to foreign laboratories accredited by KFDA (effective since January 1, 2012)

□ Eligibility Requirements for Foreign Laboratories

- Public laboratories established by the government of the exporting country (including local governments of the country) or laboratories officially accredited (including branches of the laboratory) by the government of the exporting country.
- Any laboratory established and operated overseas by a food sanitation laboratory accredited by KFDA.

* Foreign laboratories that have already been accredited may apply for modification (or addition) to the scope of subjects to test.

□ Applying for Accreditation of Foreign Laboratories (documents to be submitted)

- General laboratory information (function, history, organization, etc.)
- Testing experience in the relevant area (to be classified according to GMO test subjects)
- Status of major facilities and testing equipment of the laboratory
- Status of examiners and their individual testing experience (including training period)
- Details of accreditation given to the laboratory by the government (not applicable to laboratories operated directly by the government)
- Any documentation showing that the laboratory has participated in international programs evaluating testing capability (including evaluations made by the relevant government)

☞ The completed Application Form for Accreditation of Foreign Laboratory may be submitted directly or via the relevant government.

* Use [Form 3] of the Regulations on Accreditation Standards, Etc. for Foreign

Laboratory (Attachment 1).

□ **Accreditation Examination and Evaluation of Foreign Laboratories for GMO**

A. Document Review (Examination)

- Determine eligibility of the foreign laboratory by, among others, verifying whether or not it is a public entity established by the government of the exporting country or an entity accredited by the competent government.
- Review, among others, the functions, history, and structures of the organization capable of conducting GMO tests.
- Review the status of testing facilities and equipment necessary for GMO tests.
 - *Status of Testing Equipment Necessary for GMO Tests (refer to attached documents)
- Verify whether or not examiners skilled in the field of GMOs work at the laboratory.
- Review the appropriateness of the testing methodology applied by the laboratory in conducting GMO tests.
 - *Must check whether or not it is specified in the official compendium and accredited by KFDA.
- Review the results or experience of the laboratory in participating in international programs evaluating GMO testing capability.

B. Onsite Inspection

- Formulate an onsite inspection plan to evaluate testing capability (onsite evaluation) and inspect testing facilities.
 - Inspection team: 1 head of team (level-5 official), 1 manager-in-charge and 1 GMO expert
 - ※ 2-person team permitted if the manager-in-charge is a GMO expert
 - Inspection period: 2 days (may be extended by 1 day if necessary)
 - ※ Inspection schedule to be determined upon consultation with the applying laboratory
- Prior notice of onsite inspection schedule, etc. (visiting schedule, inspectors, etc.)
 - Pre-meeting of inspection team concerning evaluation areas for testing capability of the laboratory and level of evaluation
 - *Guideline on evaluation areas for laboratory testing capability and operations for GMOs (Attachment 1)

- Verify facility requirements and evaluate testing capability (based on areas to inspect).
 - Whether the laboratory has the facilities and equipment for GMO testing and whether these function properly
 - Verify status and testing experience of examiners for GMO testing
 - Inspect operational system of general laboratory functions (such as independence of testing function)
 - Evaluate testing capability such as expertise of examiners
 - *May evaluate testing process and outcome values using standard samples where necessary
- Hold meeting to deliberate (general assessment) on results of onsite inspection.
 - Evaluator comments on adequacy of testing equipment and facility requirements, etc.
 - Evaluator comments on overall laboratory operations
 - *General assessment shall be carried out at the site while the final decision will be made by the head of department upon return of the inspection team to Korea and relevant reporting procedures.
- Send notification of accreditation of foreign laboratories for GMO
 - Certificate of accreditation shall be issued to the foreign laboratory if it passes the document review and onsite inspection
 - *A minimum score of 80 on the onsite inspection for testing capability is considered a “pass.”
 - Public notification of foreign laboratory accreditation (for GMOs) made through the website of KFDA, etc.

□ Follow-up Management of Foreign Laboratories

- Conduct onsite inspection at least once every three years from the date of accreditation of the Foreign Laboratory (for GMOs).
 - If the laboratory has not carried out any testing, then its record of participation in international programs for evaluating testing capability may be submitted
- Notwithstanding, laboratories established overseas by food sanitation laboratories accredited by the Commissioner of KFDA shall be subject to onsite inspection at least once a year.

Attachments:

1. Evaluation Sheet for GMO Laboratory Testing Capability
2. Operation Guideline for Foreign GMO Laboratory
3. Regulations on Accreditation Standards, Etc. for Foreign Laboratory

(KFDA Notice No. 2011-21)

[Attachment 1]

Evaluation Sheet for GMO Laboratory Testing Capability

Name of Laboratory	
Representative	
Address	

Area of Evaluation	Evaluation Items	Score	
		0 2	1 3 N/A
Human Resources	Qualifications of chief engineer met		
	Qualifications of examiner and testing staff met		
	Regular education and training provided to examiner and testing staff		
Facility and Environment	Documentation relating to facility management and prevention of cross-contamination		
	Compliance with documented procedures		
	Division or designation of testing area		
	Proper storage and management of test materials such as reagents		
	Appropriate flow in moving reagents, consumables, equipment location, samples, DNA, etc.		
Equipment	Possession of proper equipment for GMO testing (electronic scale, centrifuge, cryorefrigerator, PCR, RT-PCR, etc.)		
	Procedures for proper maintenance and adjustment of equipment		
	Maintenance and verification of performance of critical equipment (PCR, etc.)		
Reagents and Consumables	Performance check and documentation of major reagents		
	Management and record-keeping of prepared reagents		
	Record-keeping on major reagents (primer, taq polymerase, etc.)		
	Possession of sequence information on primers and probes		
Management of Samples	Documentation on storage and extraction (representativeness) of samples		
	Compliance with documented procedures		
	Proper storage of samples		
	System for proper identification of samples		
Testing Method and Validity	Documentation of testing and examination methods		
	Appropriateness of testing and examination methods		
	Compliance with documented testing methods		
	Selection of pre-treatment method according to characteristics of sample		
	Possession of GM list available for testing		

	Adequacy of standard substances		
	(For qualitative tests)Policies on samples for qualitative testing and GM events		
	(For quantitative tests)Policies on samples for quantitative testing and GM events		
	Possession of materials verifying validity of kits, etc.		
Metrological Traceability	Possession of procedures on managing certified reference material		
	Proper storage and record-keeping of certified reference material		
	(For qualitative tests) Pre-set detection limit		
	(For quantitative tests) Pre-set standard curve and limit of quantitation		
	Relevance of comparative verification with standard substances other than those from national government entities		
Reporting of Results	Relevance of judgment criteria for testing and examination		
	Relevance of how testing and examination results are expressed		
	Relevance of preparing daily test log and lab report		
	Accurate judgment regarding test results		
Assurance of Test Results	Use of appropriate negative control group (non-GM)		
	Use of appropriate negative PCR control group (reagent blank)		
	Use of appropriate positive control group (GM)		
	Dual analysis on samples (repeated testing)		
	Use of correct primer for each GM event		
Proficiency Test	Participation in proficiency assessment programs at least once a year and results thereof		
	Documentation on corrections or improvements made upon proficiency test results		
	Total Score Possible		
	Total Points Earned by Laboratory		
Accuracy of Testing and Examination Results 1)	Relevance of testing and examination results using standard samples		Pass <input type="checkbox"/> Fail <input type="checkbox"/>
General Comments			

We hereby submit the above inspection report.

mm.dd.2011

Inspector: Organization

Position

Name

Inspector: Organization

Position

Name

*Exclude the maximum points for N/A items from the total score possible, and use the formula below to convert the applicant's score into a 100-point scale.

Converted score: {points earned/total score possible} x 100

- 1) If the test values of the applying laboratory in relation to the standard samples provided by KFDA are given a "fail" opinion, the final decision will be "fail" regardless of the points earned in the evaluation above.**

[Attachment 2]

Operation Guideline for Foreign GMO Laboratory

1. Human Resources

- 1) The testing laboratory shall have a chief engineer and at least one (1) examiner/testing staff with the knowledge and experience necessary for tests/examinations using polymerase chain reactors (PCR).
- 2) The chief engineer shall possess the following qualifications:
 - ① A bachelor's degree in relevant disciplines such as biology, microbiology, biochemistry, chemistry, molecular biology, genetic engineering, food engineering, etc. or equivalent qualification, and a minimum of three years of experience in related testing/examination; or
 - ② A minimum of 10 years of experience in related testing/examination work, when absent the qualifications mentioned above.
- 3) Examiner/testing staff
 - ① The examiner/testing staff shall complete in-house and external education and training programs on testing/examination using PCR.
 - ② The education and training programs shall include sample extraction, handling procedures, cross-contamination prevention, result handling, etc. together with testing/examination procedures.
 - ③ Records of education and training shall be maintained as verification of the capability to test/examine GMOs per event.

2. Facilities

- 1) At least four separate rooms or areas clearly designated for the purposes described below shall be available in order to minimize cross-contamination from DNAs, etc.:
 - ① Sample pre-treatment;
 - ② DNA extraction;
 - ③ Preparation of PCR reaction solution; and
 - ④ PCR product analysis (electrophoresis).
- 2) If the room or area for preparation of PCR reaction solution is located inside the DNA extraction room, means to strictly segregate the processes shall be in place at all times (eg. Class II Biological Safety Cabinet, etc.), and proper procedures and management policies for the prevention of cross-contamination must be adopted.
- 3) The area for detection of PCR products shall be strictly segregated from the areas for sample pre-treatment and DNA extraction.
- 4) The testing laboratory shall make available separate rooms or facilities for the following substances used in experiments:
 - ① Certified reference material;
 - ② GMO negative control group;
 - ③ GMO positive control group/plasmid;
 - ④ Samples;

⑤DNA extracts; and

⑥Extraction kit, reaction mixture, taq polymerizing factors, primers, probes, reagents, etc.

3. Equipment

- 1) The testing laboratory shall be equipped with PCR, real-time PCR, deep freezer, electronic scale, centrifuge, UV spectrometer, and other equipment necessary to carry out testing.
- 2) The laboratory must establish documented management procedures that include internal inspection methods and frequency of inspection for testing equipment such as electronic scale, UV spectrometer, PCR, real-time PCR, and deep freezer, and provide maintenance of the equipment based on such procedures.

4. Management of Certified Reference Materials and Reagents

- 1) Metrological traceability with regard to the certified reference material shall be maintained.
- 2) The certified reference material must be managed according to documented procedures while the extracted DNA shall be stored at a fixed concentration level and deterioration in its quality shall be minimized in order to keep it usable.
- 3) Performance checks on major reagents such as primers and taq polymerase shall be conducted.

5. Assurance of Testing and Results

- 1) If the testing laboratory does not use testing methods endorsed by the Commissioner of KFSA, then the laboratory shall carry out a validity assessment on the test method used and keep records of such data.
- 2) Any and all test methods used by the laboratory must be documented, and the examiner/testing staff shall conduct test/examinations in accordance with such documented procedures.
- 3) The examiner/testing staff shall carry out all tests for negative control group (non-GM), negative PCR control group (reagent blank), and positive control group (GM) to provide assurance to test results.
- 4) The testing laboratory must participate in external proficiency evaluations in order to maintain or upgrade the capabilities of the examiner/testing staff.

[Attachment 3]

Regulations on Accreditation Standards, Etc. for Foreign Laboratory

Ministry of Health and Welfare Notice No.1996- 44 (Apr. 18,1996)

Korea Food & Drug Administration Notice No.1998-7(Apr. 16, 1998)

Korea Food & Drug Administration Notice No.1998-118(Dec. 7, 1998)

Korea Food & Drug Administration Notice No.1999-26(Apr. 30, 1998)

Korea Food & Drug Administration Notice No.2004- 79(Oct. 12, 2004)

Korea Food & Drug Administration Notice No.2009-63(Aug. 12, 2009)

Korea Food & Drug Administration Notice No.2009-180(Dec.22,2009)

Korea Food & Drug Administration Notice No.2011-21(May 17, 2011)

Korea

Korea Food & Drug

Korea Food & Drug Administration

Korea Food & Drug Administration Notice

Korea Food & Drug Administration Notice No.2011-

Article 1 (Purpose)

This Notice aims to promote the efficiency of testing on imported foods, etc. by stipulating necessary matters regarding accreditation standards for foreign laboratories in accordance with Article 19 Paragraph 3 Subparagraph 2 of the Food Sanitation Act and Article 12 Paragraph 1 Subparagraph 1 of the Enforcement Rules of said Act.

Article 2 (Definitions)

For the purpose of this Notice:

1. "Foreign Laboratory" means a public laboratory established by the government (including local governments) of the exporting country, a laboratory officially accredited (including branches of the laboratory) by the government of the exporting country, or a laboratory established and operated overseas by a food sanitation laboratory accredited by the Commissioner of the Korea Food and Drug Administration (KFDA), all of which is recognized by the Commissioner of KFDA to have testing capability.
2. "Lab Report" means a report on the test results issued by the laboratory in a fixed form.
3. "Test Certificate" means the certificate of test results issued by the laboratory by completing Form 2 attached herein.
4. "Onsite Evaluation of Testing Capability" means the measurement and evaluation of testing capability using standard samples, conducted to secure reliability and accuracy of testing facilities and analytical techniques, etc. in the process of accrediting a foreign laboratory.
5. "Authorized Signatory" means any person authorized to sign on the "Lab Report" or "Test Certificate."

Article 3 (Laboratory Application and Accreditation, Etc.)

① Any entity seeking to be accredited as a Foreign Laboratory shall submit to the Commissioner of KFDA the Application Form for Accreditation of Foreign Laboratory (Form 1) attached herein together with documents described in each of the subparagraphs below. In such a case, the

Application Form may be submitted directly or via the government of the applying laboratory.

1. General laboratory information (function, history, organization, etc.);
2. Testing experience (past three-year experience in the area to be accredited, categorized into food, food additives, instrument, containers and packaging, and agro-products, forestry products, and fisheries products). Notwithstanding, laboratories established and operated overseas by food sanitation laboratories accredited by the KFDA Commissioner may submit the experience details of the food sanitation laboratory in Korea;
3. Status of major testing equipment;
4. Status of facilities;
5. Status of examiners (including training period);
6. Accreditation documents if laboratory obtained accreditation from the relevant government (not applicable to laboratories operated directly by the government); and
7. Copy of documentary evidence showing that the laboratory has been evaluated by the relevant government for its testing capability or has participated in international programs for verification of testing capability, where applicable.

② The Commissioner of KFDA shall conduct onsite inspection in order to verify testing capability and to ascertain whether the information submitted in the Application Form and supporting documents pursuant to Paragraph 1 are true and correct. Onsite Evaluation of Testing Capability may also be carried out at the same time when necessary. Notwithstanding, if the testing facilities and capability are deemed sufficient upon review of the documents in each of the subparagraphs of Paragraph 1 above, onsite inspection need not be carried out.

③ In the event onsite inspection is to be conducted in accordance with Paragraph 2, the inspection schedule, inspectors, areas of inspection, etc. shall be notified to the applicant at least one month prior to the date of inspection. Notwithstanding, in case of urgent and unavoidable circumstances, the notification may be made seven days prior to the date of inspection.

④ Where the KFDA Commissioner accredits a foreign laboratory upon review of the results of onsite inspection, etc., he must notify that laboratory and announce through the website the name and location of the laboratory, foods to be tested, and date of accreditation.

Article 4 Deleted <Oct. 12, 2004>

Article 5 (Accreditation Standards and Scope of Lab Report or Test Certificate) ①The foreign laboratory, when conducting tests on foods, etc., shall in principle do so in accordance with the 「Standards and Specifications for Food」, 「Standards and Specifications for Food Additives」, 「Standards and Specifications for Instruments, Containers, and Packaging」 and

「Standards and Specifications for Health Supplements」. Notwithstanding, the tests may be carried out pursuant to CODEX, AOAC, ISO, PAM, BAM, and NMKL. When test methods not stipulated herein are used, the validity of such methods must be presented.

② The Lab Report issued by the foreign laboratory may be in the form ordinarily used by the said laboratory, and the original copy must be submitted. In such a case, the test areas, methods, values, etc. shall be recorded on the form.

③ The Test Certificate issued by the foreign laboratory shall be in Form 2 attached herein, and its original copy must be submitted.

④ Where the Commissioner of the Regional KFDA confirms that the Lab Report in Paragraph 2 or Test Certificate in Paragraph 3 submitted by the importer conforms with Paragraph 1, further detailed testing on relevant test areas need not be carried out.

⑤ The Commissioner of the Regional KFDA shall not accredit the laboratory if and when the Lab Report or Test Certificate in Paragraph 2 or Paragraph 3:

1. Is deemed to pose potential risk to food sanitation, as a result of sensory tests conducted in accordance with Table 4 of the Enforcement Rules;
2. Is not submitted in its original copy; or
3. Was not based on test methods stipulated in Paragraph 1 or did not validate the test methods that were submitted.

Article 5-2 (Evaluation of Testing Capability, Etc.)

① The Commissioner of KFDA, where he has accredited a foreign laboratory pursuant to Article 3 Paragraph 4, shall evaluate the testing capability of the laboratory in terms of testing facilities and analytical techniques, by means of onsite inspection at least once every three years (at least once a year for laboratories established and operated overseas by a food sanitation laboratory) starting from the date of the first onsite inspection (the date of the first onsite inspection shall be the date of accreditation of the foreign laboratory). However, this shall not apply if the laboratory submits documentation showing that the government of said laboratory has evaluated its testing capability or documents showing that it has participated in international programs validating testing capability and thereby has been evaluated.

② Where onsite inspection is to be carried out in accordance with Paragraph 1 above, notification of the date of inspection, inspectors, areas of inspection, etc. shall be made to the relevant laboratory at least one month prior to the inspection. Notwithstanding, in case of urgent and unavoidable circumstances, the notification may be made seven days prior to the date of

inspection.

③ For a laboratory established and operated overseas by a food sanitation laboratory accredited by the KFDA Commissioner, relevant public officials may enter the office/inspection site or other similar locations of the laboratory and inspect the facilities, examiners, daily test log, records, etc., or browse through ledgers or documents related to the inspection when necessary.

Article 6 (Approval of Changes to the Accreditation Details, Etc.)

① If changes described in any of the following subparagraphs apply to a Foreign Laboratory, the laboratory must immediately notify such changes to the KFDA Commissioner by indicating such changes on Form 3 attached herein and obtain approval:

1. Changes have been made to matters accredited by the government of the exporting country;
2. Changes are sought with regard to foods to test, etc., as accredited by the KFDA Commissioner;
3. Changes have been made to the address or name of the Foreign Laboratory; or
4. Changes have been made to the representative of the Foreign Laboratory or to the Authorized Signatory for the Test Certificate or Lab Report.

② The Commissioner of KFDA shall approve the application for approval to changes described in Paragraph 1 above if no grounds for rejection are found upon document review or onsite inspection.

Article 7 (Cancellation of Accreditation, Etc.)

The KFDA Commissioner may cancel the accreditation of the Foreign Laboratory or order suspension or rectification of operations of the Foreign Laboratory for a pre-determined period of six months or less if any of the following applies:

1. The Foreign Laboratory has issued a false Lab Report or Test Certificate;
2. The results of evaluation of testing capability pursuant to Article 5-2 Paragraph 1 do not fully meet the standards of the evaluating agency;
3. The Foreign Laboratory failed to obtain approval from the KFDA Commissioner for the changes stated in each of the subparagraphs of Paragraph 1 under Article 6; or
4. Other obligations imposed by the KFDA Commissioner were not implemented.

Article 8 (Term of Validity)

Action on this Notice such as abolishment and amendment to be taken upon review of the changes in laws and conditions made after issuance of this Notice shall be implemented by May 16, 2014 in accordance with the 「Regulations on the Issuance and Management of Directives and

Administrative Rules, etc.] (Presidential Decree No. 248).

Addendum <April 18, 1996>

Article 1 (Date of Enforcement)

This Notice shall be enforced starting from April 25, 1996.

Article 2 (Exclusion of Application)

The laboratory officially accredited by the government of the exporting country for quarantine and sanitary inspection of solely livestock products and the quarantine certificate for livestock products issued by said laboratory shall be excluded.

Addendum <1998. 4. 16>

This Notice shall be enforced starting from the date it is announced.

Addendum <1998. 12. 7>

Article 1 (Date of Enforcement)

This Notice shall be enforced starting from the date of promulgation.

Article 2 (Interim Measures)

Cases in which the accreditation application is in progress prior to the date of enforcement of this Notice shall be governed by the previous Accreditation Standards and Procedures for Officially Endorsed Domestic and Foreign Laboratories and Test Certificates.

Addendum <April 30, 1999>

Article 1 (Date of Enforcement)

This Notice shall be enforced starting from the date of promulgation.

Article 2 (Interim Measures)

Cases in which the accreditation application is in progress prior to the date of enforcement of this Notice shall be governed by the previous Notice.

Addendum <October 12, 2004>

This Notice shall be enforced starting from the date it is announced.

Addendum <August 12, 2009>

This Notice shall be enforced starting from the date it is announced.

Addendum <December 22, 2009>

This Notice shall be enforced starting from the date it is announced.

Addendum <May 2011>

This Notice shall be enforced starting from the date it is announced.

[Form 1]

(Front)

Application Form for Accreditation of Foreign Laboratory		Required time for processing	
		60 days	
Applicant			
Name of Laboratory			
Address	Phone No.		
	FAX No.		
Foods to Test, Etc.			
<p>I hereby apply for accreditation as Foreign Laboratory in accordance with Article 3 of the 「Regulations on Accreditation Standards, Etc. for Foreign Laboratory」 .</p> <p style="text-align: center;">mm.dd.year</p> <p style="text-align: center;">Applicant: (signature)</p> <p>To: Commissioner of the Korea Food and Drug Administration</p>			
		Fee	
		None	

- Documents to submit:
 1. General laboratory information (function, history, organization, etc.)
 2. Testing experience (past three-year experience in the area to be accredited, categorized into food, food additives, instrument, containers and packaging, and agro-products, forestry products, and fisheries products). Notwithstanding, laboratories established and operated overseas by food sanitation laboratories accredited by the KFDA Commissioner may submit the experience details of the food sanitation laboratory in Korea
 3. Status of major testing equipment
 4. Status of facilities
 5. Status of examiners (including training period)
 6. Accreditation documents if laboratory obtained accreditation from the relevant government (not applicable to laboratories operated directly by the government)
 7. Copy of documentary evidence showing that the laboratory has participated in evaluations of testing capability, where applicable

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This Form is processed as follows: (back) Applicant	Processing Agency	
	Laboratory Audit and Policy Division of the Korea Food and Drug Administration	
<div style="border: 1px solid black; width: 300px; height: 60px; margin: 10px auto; text-align: center;">Completed Application Form</div>	<div style="border: 1px solid black; width: 180px; height: 60px; margin: 10px auto; text-align: center;">Registration</div>	
	↓	
	<div style="border: 1px solid black; width: 180px; height: 60px; margin: 10px auto; text-align: center;">Document Review</div>	
		↓
		<div style="border: 1px solid black; width: 180px; height: 60px; margin: 10px auto; text-align: center;">Onsite Inspection</div>

Certificate of Accreditation Issued



Approval



Notification



{Form 2}

Test Certificate				
Issue No.				Registration Date
Country of Laboratory Location				Test Date
Test Commissioned By	Name		Name of Company	
	Address(or location)			
	Phone No. and FAX No.			
Importer	Name		Name of Company	
	Address(or location)			
	Phone No. and FAX No.			
	Name of Product		Import Quantity (Total weight) kg	Packaging Unit
Port of Loading				Transport Method
Manufacturing No.				Manufacturing Date
Name of specimen (product)				Expiration Date
Region of Specimen Collection				Date of Specimen Collection
Area Tested	Test Method	Standard Test Value	Test Result Value	Remarks
<p>I hereby confirm that the information above is true and correct.</p> <p style="text-align: center;">mm.dd.year Address of Laboratory:</p> <p>Name of Laboratory :</p> <div style="float: right; border: 1px solid black; padding: 5px; margin-top: 20px;">Seal</div>				

Name of Head of Laboratory: (signature)

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[Form 3]

Application Form for Changes to Details of Accreditation of Foreign Laboratory		Required time for processing
		45 days
Name of Laboratory		
Accreditation No.		
Changes		
Item	Pre-Change	Post-Change
① Matters Accredited by Government of Exporting Country		
② Foods to Test		
③ Address or Name of Laboratory		
④ Representative (Authorized Signatory)		
Reason for Change(s)		
<p>I hereby apply for approval of changes to matters accredited in accordance with Article 6 of the 「Regulations on Accreditation Standards, Etc. for Foreign Laboratory」 .</p> <p>mm.dd.year</p> <p>Applicant: signature</p> <p>To: Commissioner of the Korea Food and Drug Administration</p>		
<p>○ Documents to submit:</p> <ol style="list-style-type: none">1. Documents showing accreditation by the government of the applying laboratory2. Status of facilities (only applicable to changes in address)3. Signature of successor		

210mm×297mm[regular paper 60g/m²(recycled)]

KFDA Points of Contact:

Interested labs seeking GMO testing accreditation are invited to send inquiries to KFDA's Laboratory Audits and Policy Division or the International Trade & Statistics Division. If emailing, please copy both Divisions to ensure the request is received.

Mr. Lee, Sang-Mok, Scientific Officer
Laboratory Audits and Policy Division
Korea Food & Drug Administration (KFDA)
Osong Health Technology Administration Complex
187 Osongsaengmyeong2-ro, Gangoe-myeon, Cheongwon-gun, Chungcheongbuk-do, Korea, 363-951
Phone) 82-43-719-1813
Fax) 82-43-719-1800
e-mail) slee@korea.kr

International Trade & Statistics Division
KFDA
Phone) 82-43-719-1554
Fax) 82-43-719-1550
e-mail) wtokfda@korea.kr