

# PROCEDURE FOR GRANTING, MAINTAINANCE, SUSPENSION, OR REFUSAL, REDUCING THE SCOPE OF CERTIFICATION, AND WITHDRAWAL OF CERTIFICATION

## 1.0 Purpose

To describe a procedure for granting, for maintenance, suspension or for refusal, for reducing the scope of accreditation; and for withdrawal certification.

## 1.1 About SABER SFDA COC

SABER is the consumer products certifications scheme in the Kingdom of Saudi Arabia. This scheme aims to ensure the safety of products and their compliance with Saudi requirements.

The conformity of regulated products is assessed by notified bodies that are approved by SASO, after assessment is complete the notified bodies are authorized to issue product certificate and shipment certificate for compliant products.

Compliance is verified by conducting conformity assessment according to the conformity assessment procedures mentioned in the applicable Technical Regulation of each product.

Consumer products under SABER certification scheme are categorized according to their level of risk on consumer into low, medium and high risk.

SASO issued Technical Regulation for medium and high-risk products. Each Technical Regulation is issued for a specific category of products.

## 1.2 About SFDA Certificate of Conformity for Food & Cosmetics

### 1.2.1 SFDA Food is a conformity assessment program developed by the Saudi Food and Drug Authority (SFDA) to ensure the quality and safety of food and beverage products imported into the Kingdom of Saudi Arabia.

Food and beverages products Certificate of Conformity (CoC) is mandatory from below countries and voluntary from others.

COUNTRY	FOOD CATEGORY
Egypt	• Frozen & proceed vegetables and fruits from approved establishments only.
	• Milks & Dairy products from approved establishments only.
	• Leafy Greens, Cow Beans (Black Eyes Beans), Cumin, Anise

Jordan	<ul style="list-style-type: none"> <li>• All food products of animal or plant origin</li> </ul>
	<ul style="list-style-type: none"> <li>• Fresh Vegetables &amp; Fruits</li> <li>• All agricultural crops and spices</li> </ul>
Sudan	<ul style="list-style-type: none"> <li>• Camels, Cows and Sheep meats</li> </ul>
Somalia	<ul style="list-style-type: none"> <li>• Camels, Cows and Sheep meats</li> </ul>
Sri Lanka	<ul style="list-style-type: none"> <li>• Tea</li> </ul>
India	<ul style="list-style-type: none"> <li>• Sheep and Buffalo meats</li> <li>• Proceed Vegetables and Fruits</li> <li>• Rice</li> <li>• Sesame and its products</li> </ul>
	<ul style="list-style-type: none"> <li>• Fresh Vegetables &amp; Fruits</li> <li>• All agricultural crops and spices</li> </ul>

Food and beverages products shall be in compliance with specific SFDA standards, per individual product. A Pre-Shipment Inspection compares the consignment with the shipping documents and verifies physical requirements / labelling requirements. Upon successful document evaluation, Pre-Shipment Inspection and successful testing from accredited lab, the Certificate of Conformity (CoC) will be issued.

**1.2.2** SFDA Cosmetics is a conformity assessment program developed by the Saudi Food and Drug Authority (SFDA) to ensure the quality and safety of cosmetic products imported into the Kingdom of Saudi Arabia.

A cosmetic product, regulated under the SFDA Cosmetics program, is defined as a product that contains one or more substance(s) intended to be used on the outer parts of the human body (such as for skin, hair, nails, lips, teeth etc.). The purpose of these products should be to perfume, protect, condition or change/improve the appearance and/or smell of the body.

Cosmetics Products must be registered and notified on the SFDA Electronic System "E-Cosma".

FASEH platform is a portal where importers will raise requests for Conformity Bodies (CBs), to issue them Certificates of Conformity (COCs) for Cosmetics, before shipping.

FASEH is linked to eCosma, as such, importers can use their eCosma user details (name and password) to login to FASEH.

Cosmetics Products shall be in compliance with specific SFDA Technical Regulation (testing and labeling). Upon successful document evaluation, and successful testing from accredited lab, the Certificate of Conformity (CoC) will be issued by FASEH platform.

## 2.0 Scope 范围

This procedure covers all types of product certification services provided by ASTC.

### **3.0 Responsibility**

**3.1 Certification Manager** is responsible for granting, for maintaining, for extending, or reducing the scope of accreditation. He is also responsible for suspending, withdrawing or for refusing certification. For all routine activities, he is supported by the support staff. He submits to the client the certificate for the product certified, after receipt of approval of the certificate by Managing Director.

**3.2 Managing Director** is responsible for approval / authorization of certificate of product.

### **4.0 Description of Activity**

#### **4.1 Product certificate: Conformity Assessment procedures**

##### **4.1.1 Type 1a Type Approval**

###### **Application documents:**

- Manufacturer name and address.
- Factory name and country of origin (Factory Industrial license).
- Instruction manual (if applicable).
- Representative specimens (if required) Further specimens maybe required if needed.
- Declaration of similarity in case of family of models.
- Technical documentation that should be adequate for assessing the Conformity of the product with the applicable Saudi Technical Regulation, they should suffice the process of risk analysis and conformity assessment, they include:
  - General description of the product.
  - Schematics (if required).
  - Explanations of the schematics (if required).
  - Test report.
  - List of critical components. (if required and in case it is not mentioned in test report)
  - In case the Saudi standards were not used then a technical description shall be provided to explain about fulfilling the applicable Saudi Technical Regulation.

##### **4.1.2 Product sample (in case samples are required)**

- Verify that sample is according to the technical documentation.
- Verify the need of examinations or re-testing when the applicable Saudi standard is applied.
- Verify the need of examinations or re-testing when the applicable Saudi standard is not applied.
- In case testing is decided, the location of testing shall be agreed on with the manufacturer.

##### **4.1.3 Factory Audit for (Type 3)**

Factory Audit is done for the purpose of evaluating the management system to ensure the compliance with the subsequent Production with the applicable regulation.

Necessity of factory audit is indicated in the corresponding technical regulation.

Factory Audit must be done annually.

**4.1.4** Based on review of evaluation records, decision is taken for issue of certificate for the product. If the product satisfies the applicable technical Saudi Regulations, the type approval certificate for the manufacturer is issued. The certificate is issued through SABER platform. The design and content of the certificate is the one set up on the platform. The certificate validity is one year.

**4.1.5** If the product does not satisfy the applicable technical Saudi regulation requirements, the certificate is rejected and not issued. Applicant is informed about the situation and the reasons of the refusal.

#### **4.1.6 Shipment Certificate**

Certification Body receive the Shipment Certificate application through SABER platform. As the conformity assessment was already done in the Product Certificate then it is only required to verify that the brand and model name in the commercial invoice is matching the brand and model name of the products which appears in the Product Certificate.

In case found identical, then the shipment application is approved through SABER platform and accordingly the shipment certificate is generated by SABER platform. This certificate can be only used for the purpose of Custom clearance in Saudi Arabia. It is the responsibility of the importer to ship the same product as in the product Certificate.

Note: The compliance of product in shipment with the applicable regulation is the responsibility of the importer. The importer declaration of compliance is one of the SABER shipment application steps and is done prior to sending application to notified body.

## **4.2 SFDA Conformity Assessment procedures for Food & Cosmetics**

### **4.2.1 Application documents:**

- Request for CoC application (RFC) for Food, and request from FASEH platform for Cosmetics.
- Final invoice and packing list.
- Clear label photos uploaded on FASEH by importer (for Cosmetics only)
- Valid test report from accredited lab complies with SFDA technical regulation on FASEH by importer (for Cosmetics only).
- Any other needed documents.

**4.2.2** Pre-Shipment physical inspection (for Food only), to take samples, attending containers loading and seal them.

Inspector shall take clear photos for labeling, sampling and all loading process.

Inspection shall be reported, check list and sampling form by inspector.

**4.2.3** Based on review of evaluation records, decision is taken for issue the certificate of conformity when the product satisfies the SFDA technical regulation.

Food CoC will be issued by ASTC system, and for Cosmetics CoC will be issued by FASEH platform.

**4.2.4** If the product does not comply with SFDA technical regulation, a Non-Conformity Certificate will be issued.

### **4.3 Receipt and review of Evaluation report**

**4.3.2** Evaluators team submits the evaluation documents / reports to the Certification Manager or technical expert, upon completion of evaluation.

**4.3.3** All such documents are reviewed by Certification Manager or technical expert for the completeness of the documents as well as signature of the evaluation team.

**4.3.4** Certification Manager or technical expert reviews the filled evaluation checklist / records and supportive documents submitted by evaluators (evaluation personnel).

**4.3.5** If required, he may consult Managing Director and other Technical Experts for such review.

### **4.4 Granting of product certificate**

**4.4.2** Based on review of evaluation records and after the manufacturer's application assessment carried out, ASTC will grant the requested certificate provided that all specified requirements are fulfilled.

**4.4.3** Based on the above 4.1.1 procedure, Certification Manager prepares certificate with all the relevant information related to the product.

**4.4.4** Upon completion of the certificate, the same is given to the Managing Director for approval.

**4.4.5** Product certificate (all the content as mentioned in clause no. 7.7 of Quality Manual) is issued to the client after approval of the Managing Director.

### **4.5 Maintenance of product certificate**

**4.5.1** For maintaining the certification of the product, periodic surveillance audit is conducted as per the details given in SP09 for periodic evaluation.

**4.5.2** Based on the successful periodic evaluation, the product certification remains maintained till the next periodic evaluation.

### **4.6 Suspension of certification**

- 4.6.1** This instruction covers suspension procedures of the certification.
- Grounds for action are brought to the attention of the Certification Manager, who reviews the information and decides whether to proceed.
  - If the Certification Manager decides to proceed, the certified client must reply to ASTC within fifteen days of receipt of letter.
  - If the Certification Manager determines that the action or position contained in the certified client reply is satisfactory, he issues a letter stating this, and mails it to the certified client via registered mail.
  - If actions are required, due dates must be set and Certification Manager must review the actions at those times to ensure that they are effectively completed in order to prevent suspension or withdrawal.
- 4.6.2** The following reasons are considered as grounds for suspension:
- Improper use of the certificate, symbol, or logo not remedied to the satisfaction of ASTC.
  - Certified client fails to meet financial obligations to ASTC.
  - Infringement by the certified client of any contractual conditions between the certified client and ASTC.
- 4.6.3** Subject to actions by the certified client, the following steps will be taken leading to possible suspension of the certified client's product certification:
- Unless a reply to the letter accompanying notification is received within 15 days, certification will be suspended, and a notification of suspension may be published at the discretion of ASTC.
  - The certified client's response to the accompanying letter will be reviewed and the proceedings may be put on hold while clarification is sought.
  - Where mutually agreed-upon corrective action is to be implemented, a time period for implementation will be specified and a review of the corrective action will be undertaken at the appointed time. This may be the subject of a special surveillance visit or of review of submitted objective evidence, at the discretion of ASTC. Should the corrective action not be considered adequate or not be completed by the appointed time, certification will be automatically suspended.
  - In the case of serious circumstances, ASTC may invoke suspension during the period pending the implementation of corrective action.
  - During suspension, suspension remark shall be placed in the register of certified clients.

## **4.7 Refusing certification**

- 4.7.1** Refusal of the certification is done in the following circumstances:
- Client fails to submit the corrective actions within 60 days time frame from the date of evaluation;
  - Corrective actions submitted by the client are not satisfactory considering the nonconformities / observations;
  - Client fails to pay the required fees in the given time frame;

- Client does not want to have certificate after completion of the assessment;
  - Objective evidence submitted during the evaluation is found fake.
- 4.7.2** All the above reasons will lead to refusal of product certification even after completion of the evaluation. Certification Manager takes decision on the refusal of certificate based on the above circumstances.
- 4.7.3** Details of refusal of the certificate are given to the client in the writing and a show-cause notice is issued to the client for such incidence.
- 4.7.4** Client is requested to reply in writing against the show-cause notice.
- 4.7.5** The details of refusal of certificate are maintained in the client file and then file is closed.
- 4.7.6** Certification Manager maintains the list of refusal of the certificates.

#### **4.8 Reducing the scope of certification**

- 4.8.1** Reduction in the scope of certification is possible in the below circumstances:
- Any of the product from the present certification may fail to comply with the relevant requirements;
  - Client requires voluntarily withdrawal of the product from the present certificate;
  - Due to some other unavoidable circumstances.
- 4.8.2** Based on above, decision for the scope reduction is taken and scope of certification is reduced by removal of the product (as identified), and the revised certificate is sent for the approval of Managing Director with the reason for the reduction in the scope of certification. Certificate is then issued to the client after approval of the Managing Director with the date of issue.

#### **4.9 Withdrawal of certificates**

- 4.9.1** This instruction covers withdrawal procedures.
- Grounds for action are brought to the attention of the Certification Manager, who reviews the information and decides whether to proceed.
  - If the certified client does not reply in fifteen days, if the reply is not satisfactory, or if the actions required are not effectively completed in the allowed time, the Certification Manager determines whether to suspend or withdrawal certification.
  - If the decision is made to withdrawal certification, the Managing Director is responsible for suspending the certified client or canceling the certified client from the Register of Certified Clients, advising the certified client by registered mail / courier, and publicizing the cancellation, if necessary.
- 4.9.2** The following reasons are considered as grounds for withdrawal:
- Major nonconformance(s) or effective corrective action not implemented within a specified time period.

- Certified client ceases to supply services of the certified quality for an extended period of time.
- Certified client persistently fails to meet any of the requirements for certification, including requirements for the effectiveness.
- Existence of a serious complaint, or a large number of second or third party complaints, which indicate that the system is not being maintained.
- Certified client is unable or unwilling to ensure conformance to revisions of standards.
- Certified client does not allow periodic evaluation to be conducted at the required frequency.

**4.9.3** Subject to actions by the certified client, the following steps will be taken leading to possible withdrawal of the certified client's product certification:

- Where suspension has been invoked, unless otherwise specified, the certified client must advise ASTC every 15 days of the current situation of corrective action. Failure to meet this requirement will result in withdrawal of the certified client's certification.
- Where suspension has been invoked due to failure to conduct periodic evaluation, the certified client shall give justification for failure and offer suitable date. An additional day shall be added to routine periodic days. The date shall not be later than 15 months from last evaluation. Failure to offer for evaluation within 15 months shall result in withdrawal of certification.
- Withdrawal of certification will be invoked where: following suspension of certification, the certified client fails to respond to ASTC communications within the 15 days grace period or fails to implement corrective action within the appointed time period.
- In extreme circumstances ASTC may invoke the withdrawal of certification with immediate effect without recourse to initial certification suspension.
- Withdrawal of certification will require the certified client to assume the status of non-approval and return all certification documentation to ASTC.
- Use of certification documents, symbols, or logos by the certified client following certification withdrawal may result in legal action being taken against the certified client.
- Re-approval after certification withdrawal will be on the same basis and follow the same process as that of initial application for a new certified client. This will require a full assessment with optional document review at the discretion of ASTC.
- The de-certification will be published as a separate list and will be available at the ASTC office upon request.
- The certified client has the right to appeal any decisions of ASTC and a copy of the appeals procedures will be made available upon request.
- Certification Manager shall remove from the register of certified



clients the company whose certificate has been withdrawn.

- For all withdrawal cases, the certified client's files shall be archived for a period of 3 months and then destroyed.

4.10 Certified client makes a formal request to terminate certification, Certification Manager shall remove from the register of certified clients the company whose certificate has been terminated.

4.11 Restoration of certificates

- When corrective action to resolve the problem(s) taken by the certified client has been verified, certification will be resumed. The period of certification will not be revised to cover the period of suspension.

4.12 The suspension, rejection withdrawal and restoration of certificates should also be notified to customers via F40.

## **5.0 Reference**

## **6.0 Formats / Exhibits**

F26 Certificate formats

F40 Notification of Certification Decision