

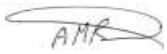
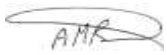
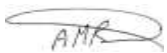


## SP09 PROCEDURE FOR EVALUATION

Document No.	Revision No	Date	Prepared	Approved
SP09	03	Jan 01, 2025		
This Manual may not be circulated outside ASTAC without permission of the Quality Manager				

## Amendment Record Sheet

Clause No.	Date of amendment	Present Rev. No.	Amended Rev. No.	Nature of change Brief description of change	Signature
All	Aug 4, 2024	/	00	Initial Release	
All	Oct 20, 2024	00	01	Updated Annex A according to the latest evaluation report form	
All	Dec 01, 2024	01	02	According to the requirements of personnel functions, add the person in charge of the step.	

## **1.0 Purpose**

The purpose of this document is to describe a procedure for planning and conducting the evaluation of product, preparation of reports, and submitting the reports.

## **2.0 Scope**

This procedure covers evaluation planning, conducting evaluation, and reporting the results of evaluations, as listed below;

- Evaluation planning
- Conducting the evaluation
- Periodic evaluation
- Re-evaluation before expiry of present certificate

## **3.0 Responsibility**

3.1 **Certification Manager** is responsible for planning the evaluation and ensuring that the evaluation reports are received timely in the office. He is also responsible for review of the evaluation reports.

3.2 **Technical reviewers** are responsible for review of the evaluation reports.

3.3 **Evaluators (Evaluation personnel)** are responsible for conducting evaluation against the specific requirements, and preparation and submission of evaluation reports.

## **4.0 Description of Activity**

### **4.1 Introduction**

The objective is to provide consistent service delivery. Evaluators (evaluation personnel) are responsible for ensuring the objectives of their assigned evaluations are fully met. The various activities needed to be carried out are as below.

### **4.2 Service agreement**

ASTC sent the Service agreement with the quotation and RFC to the client to fill and sign.

### **4.3 Technical documentation**

4.2.1 The Applicant is responsible to establish the Technical Documentation in order to prove the conformity of products to the relevant requirements.

4.2.2 The Technical Documentation must specify the applicable requirements and must contain at least the documents included in the RFC application form for the product under consideration.

## **4.4 Evaluation procedure**

### **4.4.1 Application Reviewing**

The application reviewer should:

- Check the adequacy of the product applied for and the received documents from the manufacturer (i.e. invoice, PL, BoL,..., etc.)
- Check if the establishment is registered with the SFDA Authority
- Fill in the Application Review form
- Opens a new job through using the Job Order Form (F45)
- Schedules the Inspection using the Request Inspection Form (F 22-7) and send this form to the inspector.

### **4.4.2 Inspection**

#### **A. Sampling**

"Sampling must be conducted by the conformity assessment body for testing, in accordance with the technical regulations approved by SFDA and ensure that the sample is tracked, so that it represents the consignment, provided that the consignment for which the conformity certificate is required to be issued is seized to ensure that the products in the consignment are not changed and stamped with the seal of the conformity verification office on the lock of the container and/or means and/or batch of transport".

#### **B. List of testing to be passed by product:**

According to the food testing list, the minimum acceptable level of food testing for consignment certificates of conformity as shown in the attached file.



SFDA-food testing.pdf (Command Line)

#### **D. ASTC must:**

- Conform the documents based on the clearance conditions and requirements.
- Ensure that the product conforms to the regulations and standards mentioned in the clearance conditions for each product.
- Ensure that the consignments conform to the clearance conditions and requirements for the products subject to the SFDA's supervision.
- Inspect and ensure the safety and conformity of the means of transport and containers to the SFDA's requirements and that they are stamped with the seal of the ASTAC on the lock of the container and/or means and/or batch of transport. Inspect for the purpose of sampling for testing.

An appointment shall be scheduled between the inspector and the applicant to conduct the inspection at the manufacturer's premises or the product storage location.

During the inspection, the inspector shall:

- Review the products and verify their conformity with the invoice included in the application file.
- Ensure the products correspond to the submitted technical documentation.
- Take documentary photographs of the products and their labeling through conducting the inspection in accordance to the ISF11 Inspection Checklists form by taking Sampling photos, Product Marking Photos, Carton Marking Photos, Container Photos (before, during & after loading) and Sealing photos and then sealed the container.
- Collect a sample of the product and send it to an accredited laboratory for the required testing.
- Upon completion of the inspection, the inspector shall issue an official inspection report (F-42-2) and submit it with the report and photos to the evaluator for further review of the application.

#### **4.4.3 Evaluation**

The evaluator should do the following:

- Check ingredients against SFDA standard requirement
- Check inspection photos and Inspection report
- Check labels to be comply with SFDA regulation
- Check the test report issued by accredited lab
- Check CoC draft with RFC, Invoice, Packing list and shipment itself
- Prepare the evaluation report (ER) through using F30-4 & F30-5
- Send the evaluation report to final reviewing and decision making

#### **4.4.4 Reviewing**

On the basis of the evaluation report for the stated product and considering all the documents related with the certification file, the technical reviewer declared the result of the technical review is positive or negative and assigns the final decision to the decision maker.

#### **4.5 Decision Making**

4.5.1 The decision maker reviews the filled evaluation report and supportive documents submitted by evaluators.

4.5.2 Based on review of the evaluation records, and in case the product satisfies the applicable SFDA requirements, the decision maker decided to issue the shipment CoC for Food through ASTAC internal system, and to issue the shipment CoC for Cosmetics through FASEH platform.

4.5.3 In the event of the shipment products does not satisfy the SFDA requirememnts, ASTAC will refuse to issue the shipment CoC and will inform the applicant accordingly, giving detailed reasons for its refusal.

4.5.4 Accreditations required to carry out these activities  
ISO/IEC 17020 for consignment inspections and sampling for testing.  
ISO/IEC 17025 for testing and sampling analysis.  
ISO/IEC 17065 for certification processes.

**5.0 Formats / Exhibits**

F24-6 Application Review for Cosmetics CoC

F30-5 Evaluation Report for Cosmetics CoC

F30-4 Evaluation Report for Food CoC

F30-5 Evaluation Report for Cosmetics CoC

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## **Annex A Requirements and Standards**

The food product must meet all the requirements and supplementary references referred to in the technical regulations approved by SFDA, including the regulations shown below, in addition to the circulars published on the SFDA's website:

1. SFDA.FD/GSO 323 General Requirements for Transportation and Storage of Chilled and Frozen Foods.
2. GSO 9 Labeling of Prepackaged Food Stuffs.
3. SFDA.FD/GSO 2106:2021 Infants Formula, Follow on Formula and Formulas for special medical purposes.
4. SFDA.FD/GSO 150-1 Expiration Dates for Food Products -Part 1: Mandatory Expiration Dates.
5. SFDA.FD/GSO 150-2 Expiration Dates for Food Products - Part 2: Voluntary Expiration Dates.
6. SFDA.FD/GSO 2500 Additives Permitted for Use in Food Stuffs.
7. SFDA.FD 2233 Requirements of Nutritional Labeling.
8. SFDA.FD 2333 Requirements for Nutrition and Health Claim in The Food. SFDA.FD 1016 Microbiological Criteria for Foodstuffs.
9. SFDA.FD 382 Maximum Limits of Pesticide Residues in Agricultural and Food Products.
10. SFDA.FD/GSO 2055-1 HALAL FOOD - Part 1: General Requirements.
11. SFDA.FD/GSO 2481 Maximum Residues Limits (Mrls) Of Veterinary Drugs in Food.
12. SFDA.FD/GSO 2359 Extraction Solvents and its Residue Limits in The Production Foodstuffs and Food Ingredients.
13. SFDA.FD CAC 193 Contaminants and Toxins in Food and Feed.
14. SFDA.FD/GSO 1366 General Requirements for Handling of Foods for Special Medical Purposes.

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## **Annex B Requirements and Standards**

The product must be in conformity with the technical regulations below, in addition to the specified product standard and any other requirements that are communicated via circulars and announcements of the Saudi Food and Drug Authority:

1. Executive regulation of cosmetic products law (here).
2. SFDA.CO/GSO 1943.
3. SFDA.CO/GSO 2528.
4. ISO/IEC 22716 – Good Manufacturing Practices for Cosmetics.
5. Lists of banned and restricted cosmetic ingredients, colorants, preservatives, and UV filters (here).
6. Circulars published on the SFDA's website (here).
7. Conditions for clearing cosmetic products and the raw materials used in their manufacture.

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## Annex c

### 4. Consignment conformity certificates for cosmetic products

#### Requirements and Standards

The product must be in conformity with the technical regulations below, in addition to the specified product standard and any other requirements that are communicated via circulars and announcements of the Saudi Food and Drug Authority:

1. Executive regulation of cosmetic products law (here).
2. SFDA.CO/GSO 1943.
3. SFDA.CO/GSO 2528.
4. ISO/IEC 22716 – Good Manufacturing Practices for Cosmetics.
5. Lists of banned and restricted cosmetic ingredients, colorants, preservatives, and UV filters (here).
6. Circulars published on the SFDA's website (here).
7. Conditions for clearing cosmetic products and the raw materials used in their manufacture.

#### Processes to be inspected

Required Activities	Inspection	The conformity body must:
		<ol style="list-style-type: none"><li>1. Ensure that the product is registered in the SFDA's systems.</li><li>2. Ensure that the product conforms to the actual import.</li><li>3. Ensure the physical integrity of the product.</li><li>4. Conform documents based on the clearance conditions and requirements.</li><li>5. Ensure that the product conforms to the regulations and standards set forth in the clearance conditions for each product.</li><li>6. Ensure that the consignments conform to the clearance conditions and requirements for the products subject to the SFDA's supervision.</li><li>7. Inspect and ensure the safety and conformity of the means of transport and containers to the requirements of SFDA and stamped with the seal of the conformity verification office on the lock of the container and/or means of transport and/or batch.</li><li>8. Inspect for the purpose of sampling for testing.</li></ol>

#### Sampling and Frequency

Sampling must be conducted by the conformity assessment body for testing and ensure that the sample is tracked, so that it is similar to the consignment sent, in accordance with the mechanism approved by SFDA for sampling and risk criteria.

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## List of testing to be passed by product

Unless SFDA issues a provision of the regulation that are required to be applied to the products for which a conformity certificate is to be issued and the required analyses, the testing must be conducted in accordance with (list of cosmetic testing). The conformity body has the right to add what it deems appropriate to verify the conformity of the products to the technical regulations, standards, and circulars issued by SFDA.

## Accreditations required to carry out these activities

ISO/IEC 17020 / ISO/IEC 17025 for sampling and analysis.  
ISO/IEC 17065 for certification processes.

## Required competence of technical staff of conformity assessment body

A bachelor's degree in one of the following majors or equivalent: pharmacy, pharmaceutical sciences, pharmaceutical care, epidemiology, preventive health, chemistry, biochemistry, toxicology, pharmacology, health promotion, health security, virology, preventive medicine and public health, and microbiology.

## Information required for certificate of conformity

Trader name, commercial register number, invoice number, container number, exporter, country of export, product details (product date, expiration date, batch number, weight, quantity, country of manufacture and product name), listing reference number, inspector's name and signature, certificate number and date, production sites and/or assessments carried out, reference of the accreditation or recognition status of the conformity assessment body, and these requirements as a minimum.

## Registration and listing

The conformity body must verify that:  
The product is listed in the SFDA's electronic systems, according to the approved laws, regulations, standards, and circulars issued by SFDA.

## Acknowledgments required from the establishment

An acknowledgment by the customer not to be relieved from product obligations and responsibilities after being registered/listed.  
An acknowledgment by the customer of the validity of all information submitted to the conformity body.

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## Conditions required for clearance

Meeting and applying the clearance conditions published on the SFDA's website at the following link: <https://www.sfda.gov.sa/sites/default/files/2022-03/SFDA-Cosmetic.pdf> to products that will be granted a conformity certificate, while keeping records documenting the conformity audit of such requirements by SFDA and submitting them to the conformity body.

**Responsibility for reviewing assessment results and issuing certificate**

Conformity assessment body.

**Scope of certificates**

For imported products.

**Certificate validity period**

Expires once the consignment is cleared at the port.