Saudi Food and Drug Authority (SFDA) Product Certification Scheme

1. Introduction

This procedure aims to describe the steps followed by RACS as Certification Body authorized by Saudi Food & Drug Authority (SFDA) for the Conformity Assessment Certification Program to assure that products intended for certification with SFDA are complying the relevant mandatory schemes and applicable Standards.

1.1 Responsibilities

It is responsibility of RACS Quality Certificates Issuing Services as an Authorized Certification Body to issue Certificate of Conformity (COC) to export in Kingdom of Saudi Arabia and assure all steps of compliance verification are applied in this regard. RACS is responsible for the correctness of all information specified in the Certificate of Conformity (COC) and establish and maintain the appropriate system to satisfy both SFDA and client's requirements in accordance with the certification system mandated by SFDA.

It is the responsibility of SFDA clients and RACS clients to provide all needed requirements as per SFDA Certification system to ensure their products compliance to the applicable schemes and standards.

2. Definitions

- **SFDA:** Saudi Food and Drug Authority
- **RACS**: RACS Quality Certificates Issuing Services
- **Certification**: Third-party attestation related to products, processes, systems or persons.
- **Authorized Certification Body**: A Conformity Assessment Body (CAB) authorized and designated by the related authority to conduct conformity assessment process on products and processes on behalf of the authority in accordance with related schemes/standards/regulations mandated by this body
- **Certificate of Conformity (C.O.C)**: Formal document issued by RACS stating that compliance verification has been completed for the products in accordance with applicable scheme/standards as per SFDA Requirements.
- **CM**: Conformity Manager
- **QAM**: Quality Assurance Manager
- **RACS assigned Personnel:** Inspector, Evaluator, Auditor or any other assigned person by RACS to perform the compliance verification procedure.
- **CE**: Conformity Engineer
- **MOCI:** Ministry of Commerce and Industry
- **IAF:** Initial Assessment Form
- **RFC:** Registration for Certification
- **IJO:** Inspection Job Order

3. Certification Procedures

Based on its role as SFDA authorized body, Procedure will be performed as follows:

3.1 SFDA Process Flow Diagram

RACS-SFDA-REC01-Rev00 SFDA Process

3.2 SFDA Certification Process Flow

RACS-SFDA-REC02-Rev00 SFDA Certifica

4. Procedures:

Procedure of issuance SFDA COC consists of the following steps:

4.1 Application:

- The Client shall submit the completed RFC Template. Please refer to RACS/SFDA/REC/03 - RFC in below related form table.

4.2 Legal Agreements:

RACS/Ag/10 – General Conditions for Certification Services (client will sign only 1 time)

4.3 Fees as detailed in RACS Schedule of Fees (RACS/REC/46)

4.4 Preparatory Steps

4.4.1 Application Form shall be submitted by applicant in SFDA platform

4.4.2 Sales and Marketing Executive/Administrative assistant will review it to check documents availability on a primary basis

4.4.3 A quotation will be sent to applicant by Sales and Marketing; containing the scope of certification and fees related to each step of the certification process.

4.4.4 Payment shall be done by applicant.

4.5 Application Review

4.5.1 Upon acceptance of quotation by client, client is requested to sign the General Conditions for Certification Services (RACS/Ag/10), this agreement to be signed one time from the client regardless of number of applications.

4.5.2 Application along with related supporting documents will be received by RACS CM and do the application review by filling out the RACS/REC/103 Application Review form and shall assign one of RACS technical team members (CE (Evaluator or Auditor)).

4.6 Application Evaluation

4.6.1 CE (Evaluator or Auditor) shall perform conformity assessment (Evaluation) steps related to the certification schemes types:

- Detailed documents review for all the documents
- Document review includes the check up for Test Reports parameters and results (1 year validity), done by third party Laboratory according to the specific technical regulations and applicable standards.
- Evaluation of product the eligibility of the Product for certification to assure compliance according to applicable schemes and standards.

Note: No of Samples to be selected for testing is defined by the specific technical requirements and as per scheme owner

4.6.2 Evaluation Outcome results:

- Evaluation includes Product Safety Verification through test reports provided on all safety Test parameters requested by applicable scheme/standards, test reports shall be issued by third party accredited Laboratory sub-contracted according to the approved Standards and applicable technical requirements.

- CE (Evaluator or Auditor) shall fill-in the IAF (RACS/SFDA/REC/04) and provide the initial evaluation accordingly based on the initial documents provided. If there are pending, missing, invalid documents or other needed information are required to complete the evaluation, additional supporting documents will be requested from Applicant. During Supporting Documents Evaluation, Conformity Engineer will assess product conformity based on the following criteria:

  - **Acceptable**: if full compliance to the standard/s and Technical Regulation is readily fulfilled;

  - Conditional: if partial requirements are fulfilled and/or if discrepancy is found on the result, then additional requirements will be mentioned on the IAF;

  - Rejected: if supporting documents are not acceptable, then the corresponding requirements will be provided in the IAF.

- For Incomplete documents and test reports, RACS to request further missing documentations. Testing details such as test parameters, test lab to test, etc. shall be agreed upon with the applicant, in this case, applicant will receive a notice from RACS regarding the missing documentations. Applicant shall initiate the provision of a representative product sample, its preferred lab, tests to be performed. Such information shall be coordinated with RACS at all times.

- 'Reports/Study' on alternative solutions applied by the applicant is not sufficient evidence for compliance – RACS may require further supporting documents of the subject item as per relevant SASO standard.

- Evaluation will be repeated upon applicant re-submission of needed documents/information.

4.7 Physical Inspections

4.7.1 General information

Physical Inspection is necessary for product identification and to gain confidence that the requirements not covered by the testing (e.g. marking, labelling, packaging) are fulfilled.

It is to be expected that the IJO be supplemented with instructions from the Conformity Team on a per product basis in order to verify full compliance with standards and other technical regulations. These instructions should take into consideration critical safety hazards, and typical visual, as well as functional criteria which confirm the quality and performance of the product to be inspected.

Inspection can be arranged upon receipt of the following:

- Completed RFC
- Pro-forma or Final Invoice
- Packing List (if available)
- Copy of the Test Certificates (if available)
- Statement of Registration (if available)
- SFDA Warehouse license and
- Product registration in SFDA electronic system **(Final E-Cosma Listing Number)**

Important Note:

As a rule, Inspection Centre will schedule inspection only after receiving confirmation from Conformity Team on compliance of the documents submitted together with RFC and instructions for verification during inspection (reception of the IAF). However, there may be cases where the client requests the inspection with urgency and the affiliate has yet received the IAF.

4.8 Decision of Certification

Upon submission of this information, and as per the result of documents review and completing product evaluation process.

- **Recommendation of approval of Product certification**: Product evaluation shows full compliance with applicable schemes/standards:
  - Granting the issuance of CoC
- **Recommendation of rejection of Product certification**: Product evaluation shows non-compliance with applicable schemes/standards, due to any reason preventing product from Certification:
  - RACS will inform client by an official rejection statement (Letter of certification status) by e- mail stating the reason of rejection

5. Scope of certified products and applicable schemes by RACS Certification Body:

This document cover certifies below list of **Scopes** with details of Sector, scope of certified products, products categories, and applicable type of certification:

Sector	Scope of Certification	Product categories	Type of Certification
Chemical	**Cosmetics and Personal Care Products**	1. Creams, emulsions, lotions, gels and oils for skin (hand, face, feet, etc.)	**Certificate of Conformity (COC)**
		2. Face masks (with the exception of peeling products)	
		3. Tinted bases	
		4. Make up powders, after bath powders, hygienic powders, etc.	
		5. Toilet soaps, deodorant soaps, glycerine soaps, etc.	
		6. Perfumes, toilet waters and eau de cologne	
		7. Bath and shower preparations (salts, foams, oils, gels, etc.)	
		8. Depilatories	
		9. Deodorants and anti-perspirants	
		10. Hair care products: hair tints and bleaches, products for waving, straitening and fixing, settings products, cleansing products (lotions, powders, shampoos), conditioning products (lotions, creams, oils), hair dressing products (lotions, lacquers, brilliantines).	
		11. Shaving products (creams, foams, lotions, etc.)	
		12.Products for making up and removing make up from the face and eyes	
		13. Products intended for application to lips	
		14. Products for care of teeth and mouth (Mouthwash products containing alcohol are considered as banned products)	
		15. Products for nail care and make up	
		16. Hair Removing Products (Wax, Sugar, Creams, Depilatories)	
		17. Products for external intimate hygiene	
		18. Sun-bathing products	
		19. Products for tanning without sun	
		20. Skin whitening products (except Hydroquinone containing products)	

		21. Anti-wrinkle products 22. Eye decorative cosmetic products (eye shadow, mascara, brows, lids, pencil, lashes, cream and athmad (Al Kohl) 23. Handwash liquid soaps 24. Wet wipes	
Chemical	**Perfumes**	1. Perfumery Products 2. Odoriferous substances	**Certificate of Conformity (COC)**

6. Mandatory Schemes and Applicable Standards:

SFDA scheme to control Cosmetics and Personal Care products and SFDA scheme to control Perfume products.

Applicable standards:	
GSO 1943:2016	Safety Requirements of Cosmetics and Personal Care Products
SASO 1512:2010	Skin Cream
SASO GSO 2063:2010	Cosmetic Products - Hair Conditioner (Balsam)
SASO 1871:2010	Cosmetic Products - Lip Sticks
SASO GSO 1786:2007	Cosmetic Products - Toilet Soaps
SASO GSO 1895:2009	Cosmetic Products - Toilet Soaps for Children
SASO 2807:2010	Cosmetic Products – Hair Fixative
SASO 725:2010	Cosmetic products -Hair shampoo
SASO-2807:2010	Cosmetic Products – Hair Fixative
SASO-2614:2010	Cosmetics – Toiletries – Industrial Hand Cleaners (Petroleum Solvent Type)
GSO 2302:2013	Cosmetics – Face Mask
SASO ISO 11609:2010	Dentistry - Dentifrices - Requirements, test methods and marking
SASO-ISO-16408:2007	Dentistry - Oral hygiene products - Oral rinses
GSO 2237:2012	Cosmetics – Sunscreen Products
SASO 776:2009	Cosmetic Products – Oxidation Hair Dyes, Liquid, Gel and Cream – Method Of Test
GSO 885:1997	Cosmetic Products – Shaving Soap
GSO 1115:2002	Cosmetic Products – Shaving Cream
SASO 1389:1998	Cosmetic Products – Vaseline (Petroleum Jelly)
GSO 1201:2002	Cosmetic Products – Talcum Powder
GSO 1223:2002	Cosmetic Products – Deodorant

GSO 1846:2011	Cosmetics – Al Kohl
GSO 1887:2009	Cosmetic Products - Nail Polish (Nail Enamel)
SASO 2017:2010	Cosmetic Products - Wet Wipes
SASO-GSO-2240	Cosmetic products - Synthetic detergents - liquid soap for hands
SASO-GSO-2063	Cosmetic Products - Hair Conditioner (Balsam)
GSO 2236:2012	Cosmetics – Face and Eye Makeup Remover
GSO 1046:2000	Cosmetic Products – Perfumery Products based on Ethanol
EC Regulation no. 1907:2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

If needed, Client refers to RACS to identify applicable scheme and standards.

RACS Staff to refer to RACS/REC/79 Scope of Certified Products by RACS to identify certification applicable schemes.

7. Requirements for Certification:

Requirements vary depending on the scope of certified products; details of the documents required for certification for the scope of Cosmetics and Personal Care Product as per scheme owner (SFDA) requirements are detailed as following:

7.1 Documents Required

- Commercial Registration of MOCI indicating the type of activity (perfumes and cosmetics).
- Attested certificate of conformity
- Purchased invoice issued by the manufacturer attested by Chamber of commerce from the country of origin (export). In case the invoice issued by an agent or distributer of the company it should be accompanied with a proof that this agent/distributor is authorized in the country of export, invoice should have the below information.
  a. Product name
  b. Batch number
  c. Validity date (expiry date)
  d. Manufacturer company and its origin
  e. Storage temperature advised by manufacturer,
- Country of origin certificate attested from the chamber of commerce at the country of origin
- A copy from agency registration document issued by MOCI in KSA or an original letter from the manufacturer authorizing the importer to import and distribute their products in Saudi Arabia
- A bill of lading's copy.
- Cosmetic Products Clearance requirements from Customs Ports
- Satisfactory Physical Inspection
- Final E-Cosma Listing Number

8. Related Forms:

Listed Agreements, SOPs, Records related to the SOP as follows:
Note: RACS/SFDA/REC/07 is the part 5 continuation of RACS/SFDA/REC/06.

TITLE OF DOCUMENT	IDENTIFICATION

Quality Master List	RACS/REC/01
Quality Manual with Branch	RACS/QM/01
General Conditions for Certification Services	RACS/Ag/10
RACS Schedule of Fees	RACS/REC/46
SFDA Process Flow Diagram	RACS/SFDA/REC/01
SFDA Certification Process Flow	RACS/SFDA/REC/02
Registration for Certification (RFC)	RACS/SFDA/REC/03
Initial Assessment Form (Checklist)	RACS/SFDA/REC/04
PCA Process Checklist	RACS/SFDA/REC/05
Inspection Report for PCA (4of5)	RACS/SFDA/REC/06
Inspection Report for PCA (5of5)	RACS/SFDA/REC/07
SFDA Certificate Template	RACS/SFDA/REC/08
Physical Inspection Result - PCA	RACS/SFDA/REC/09
Application Review Form	RACS/REC/103

9. References:

- ISO/IEC 17065, Conformity Assessment - Requirements for bodies certifying Products, Processes and services.
- ISO/IEC 17021, Conformity Assessment — Requirements for bodies Providing audit and Certification of management systems.
- ISO/IEC 17000, Conformity Assessment — Vocabulary and general principles.
- ISO/IEC 17020, Conformity Assessment— Requirements for the operation of various types of bodies performing inspection.
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.
- ISO17067, in combination with ISO Guide 28 and ISO Guide 53
- ISO/IEC 17030, Conformity Assessment — General requirements for third-party marks of conformity.
- ISO Guide 23:1982 Methods of indicating conformity with Standards for third-Party certification Systems
- ISO Guide 27:1983 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- RACS Quality Manual RACS/QM/01
- All controlled QMS records-Please refer to RACS/REC/01-Quality Master List.
- Saudi Food and Drug Authority Product Conformity Assessment Program

Revision History:

Date	Revision #	Description of Changes
August 19, 2020	00	Initial
August 23, 2020	01	Add the test report validity
September 13, 2020	02	Add the acceptance criteria during Initial Assessment under 4.6.2 Evaluation Outcome results
July 25, 2021	03	In clause 2 (Definition) added the below abbreviation • **CE**: Conformity Engineer • **MOCI:** Ministry of Commerce and Industry • **IAF:** Initial Assessment Form • **RFC:** Registration for Certification • **IJO:** Inspection Job Order In clause 8 (Related Forms) added the below note. Note: RACS/SFDA/REC/07 is the part 5 continuation of RACS/SFDA/REC/06.