

## Conformity ASSESSMENT & CERTIFICATION PROCEDURES

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### 1. CONFORMITY ASSESSMENT PROCEDURES

PROGRAM NAME	Certificate of Conformity for Shipments: Cosmetic Products
PROGRAM MANDATED BY	Saudi Food and Drug Authority (SFDA)
IMPLEMENTATION DATE	01.01.2020
REGULATED PRODUCTS	Cosmetic
PROGRAM OBJECTIVES	Assess and verify compliance of Cosmetic products that will be exported to the Kingdom of Saudi Arabia, in accordance with the updated technical regulations, standards, rules, specifications, requirements and conditions approved by SFDA.
ROUTES	<p><b>Route A:</b> Non-registered products – It involves pre-shipment inspection and pre-shipment testing of products. Physical inspection carried out to verify the labeling/marketing, storage, and other visual verification.</p> <p><b>Route B:</b>  <b>Overview:</b>  Route B is generally applicable to importers, distributors, or brand owners who are registering Cosmetic products with the SFDA for the first time. It is focused on product safety and proper documentation. Here is a detailed explanation:  <b>Steps Involved in Route B Certification:</b>  1. Account Registration on SFDA Platforms:  Create an account on Ghad's platform for Cosmetic product registration.  2. Product Notification via Ghad's platform:  Submit a Product Information File (PIF), which includes: <ul style="list-style-type: none"> <li>• Product description.</li> <li>• Safety assessment (e.g., toxicological data, ingredient safety).</li> <li>• Manufacturing information (Good Manufacturing Practice (GMP) compliance).</li> <li>• Ingredient list following INCI nomenclature.</li> <li>• Certificate of Analysis (CoA) for ingredients and final product.</li> </ul> 3. Labeling Compliance:  Ensure that the product label complies with SFDA's Cosmetic labeling guidelines, including:  Product name and usage.  Manufacturer details.  Batch number and expiration date.  Arabic and English text.</p>

	<p>4. Fees Payment: Pay applicable fees for the review and approval process.</p> <p>5. Approval and Notification Number: Once approved, the SFDA issues a Product Notification Number, allowing the product to be imported and sold in Saudi Arabia.</p> <p>6. Ongoing Responsibilities: Ensure continuous compliance with SFDA regulations. Report any adverse events associated with the product.</p> <p><b>Key Requirements Specific to Route B</b></p> <ul style="list-style-type: none"> <li>• The applicant must be an authorized entity in Saudi Arabia (importer or local distributor).</li> <li>• The focus is primarily on imported products rather than locally manufactured ones.</li> <li>• Safety documentation and ingredient transparency are critical for approval.</li> </ul> <p><b>Why Choose Route B?</b></p> <p>Route B is suitable for entities that aim to introduce foreign products to the Saudi market while ensuring compliance with strict SFDA standards.</p>
DOCUMENTATION	<p>Exporter submits to ASTC the following documents:</p> <ul style="list-style-type: none"> <li>• Request for Certification and Declaration of Conformity</li> <li>• Commercial Invoice</li> <li>• Documents: Ingredient list with concentrations, Certificate of Analysis/Test report {batch-wise}, product labels/artworks, Hygiene certificate</li> <li>• SFDA Registration number for product</li> <li>• Test reports from SFDA-approved labs / ISO/IEC 17025 accredited labs only</li> <li>• Company's Quality Management System documents (ISO 9001, ISO 22000, GMP, HACCP, any FSMS certification or likewise)</li> <li>• Halal Certificate from SFDA-approved bodies (as applicable)</li> <li>• Slaughter Certificate from SFDA-approved bodies (as applicable)</li> <li>• Certificate of Origin (as applicable)</li> <li>• Health Certificate (as applicable)</li> <li>• Establishment Registration (Mandatory for Fishery products, poultry products, meat products, and honey products, for Egypt-origin products – frozen and processed vegetables and fruits, milk and milk products)</li> </ul>
RECEIVING STAGE	<p>ASTC application receiver receive the application on Fash platform and send the Request For Certification (RFC) form to the client to be filled out and ask the client to send it back after being completed together with all of the other requested documents.</p> <p>ASTC application receiver send all of received documents to the Application Reviewer after making sure that all of the required documents are available.</p>
INTIAL REVIEWING STAGE	<p>ASTC application reviewer Check the RFC, invoice, packing list and all required document using the relevant application review form.</p> <p>ASTC application reviewer open new job using Job Order form where he fill out and sign and then send it to the evaluator.</p>
FIRST EVALUATION STAGE	<p>ASTC evaluator check and see if there is any specific required details regarding labelling and sampling and if there is specific requirements he will add it to the Job order form and sign.</p> <p>ASTC evaluator will send job order to the inspector.</p>

INSECTION & TESTING STAGE	<p>Based on the filled Job Order Forms, the inspector will:</p> <ul style="list-style-type: none"><li>• Perform physical inspection on the products</li><li>• Perform physical inspection of the container/ transportation medium of the goods in terms of physical condition and hygiene</li><li>• Along with physical inspection sample collection is carried out from each container/transportation medium of shipment. The sampling process will follow specific product standards/SFDA requirements. Samples are marked with ASTC reference/sample sticker (the sticker serial number will be considered as the 'reference number') and transferred to sterile single-use bags</li><li>• Sampling for testing will be done based on the risk of the product category. Batch-wise testing is mandatory for all the consignments</li><li>• Seal the carton from which samples are removed using ASTC Tape</li><li>• Fill in the 'sampling receipt' form which includes full details of sample collected, seal number, etc.</li><li>• Every batch detail included in the consignment is to be captured along with the production expiry and updated in the inspection report</li></ul>

	<ul style="list-style-type: none"> <li>• Attaching copy of sampling receipt to the inspection report</li> <li>• Attaching copy of the sample-receipt with the collected sample which serves as reference document for the testing laboratory</li> <li>• Handover samples to client for testing. Testing is to be carried out at SFDA approved labs / ISO/IEC 17025 accredited labs only</li> <li>• On availability of passing test results, ASTC inspector supervises container loading, ensures only batches examined and captured during initial inspection is loaded and seals the container</li> <li>• For Issuance of CoC (Certificate of Conformity). The CoC shall include: <ul style="list-style-type: none"> <li>▫ Full reference and traceability to samples drawn (sample reference number) for testing</li> <li>▫ Seal numbers (each container)</li> </ul> </li> <li>• Issue NNR (Non-negotiable report) if the test reports are found failing</li> </ul>
SECOND EVALUATION STAGE	<ul style="list-style-type: none"> <li>• After completing testing, the evaluator check test report and make sure that it complies with SFDA regulation.</li> <li>• After completing inspection, the evaluator check inspection photos and report to comply with SFDA regulation.</li> <li>• Evaluator also check labels to comply with SFDA regulation.</li> <li>• After evaluation and checking all corresponding information related to the certification file for the concerned product, the evaluator recommends the evaluation result if accepted or rejecting or pending.</li> </ul>
TECHNICAL REVIEWING STAGE	ASTC reviewer reviews all information and results related to the evaluation considering all the documents related with the certification file, and declares the results of the technical review is either positive or negative depending on the product if comply or not with the SFDA requirements.
DECISION MAKING STAGE	ASTC Decision maker will make the certification decision based on all information related to evaluation, review and any other relevant information and in case the product satisfies all of SFDA requirements and have successfully passed all of the above mentioned stages of application review, evaluation and technical review processes, the decision maker will decide to issue the certificate of conformity.
CLIENT NOTIFICATION	ASTC will notify the client of the decision to or not to grant certification, and will identify the reasons for the decision in case of rejection for the application
<b>2- CERTIFICATION PROCEDURES</b>	
Granting of Consignments Conformity Certificates	A Certificate of Conformity (CoC) for the shipment will be issued in case of compliance of the product with all of the SFDA requirements
Maintenance of Consignments Conformity Certificates	<ul style="list-style-type: none"> <li>• For maintaining the certification, only in case of typing error, or if client change some details do not include inspected shipment products.</li> <li>• In case if client want to change shipment products, new loading inspection will be and new sampling in case if new products added.</li> </ul>

	<ul style="list-style-type: none"> <li>No maintenance will be after shipping.</li> </ul>
Scope of Expansion of Consignments Conformity Certificates	<p>If the client what to add new products on his shipment before it ships, if sealing did not occur yet, new sampling will be for new products, and after result, loading inspection and sealing will be.</p>
Suspension of certification	<ul style="list-style-type: none"> <li>- This instruction covers suspension procedures of the certification. <ul style="list-style-type: none"> <li>• Grounds for action are brought to the attention of the Certification Manager, who reviews the information and decides whether to proceed.</li> <li>• If the Certification Manager decides to proceed, the certified client must reply to ASTC within fifteen days of receipt of letter.</li> <li>• 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.</li> <li>• 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.</li> </ul> </li> <li>- The following reasons are considered as grounds for suspension: <ul style="list-style-type: none"> <li>• Improper use of the certificate, symbol, or logo not remedied to the satisfaction of ASTC.</li> <li>• Certified client fails to meet financial obligations to ASTC.</li> <li>• Infringement by the certified client of any contractual conditions between the certified client and ASTC.</li> </ul> </li> <li>- Subject to actions by the certified client, the following steps will be taken leading to possible suspension of the certified client's product certification: <ul style="list-style-type: none"> <li>• 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.</li> <li>• The certified client's response to the accompanying letter will be reviewed and the proceedings may be put on hold while clarification is sought.</li> <li>• 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.</li> <li>• In the case of serious circumstances, ASTC may invoke suspension during the period pending the implementation of corrective action.</li> <li>• During suspension, suspension remark shall be placed in the register of certified clients.</li> </ul> </li> </ul>
Refusing certification	<p>Refusal of the certification application is done in the following circumstances:</p> <ul style="list-style-type: none"> <li>• Client fails to submit the corrective actions within 60 days' time frame from the date of evaluation;</li> <li>• Corrective actions submitted by the client are not satisfactory considering the nonconformities / observations;</li> <li>• Client fails to pay the required fees in the given time frame;</li> <li>• Client does not want to have certificate after completion of the assessment;</li> <li>• Objective evidence submitted during the evaluation is found fake.</li> </ul>

	<ul style="list-style-type: none"> <li>- 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.</li> <li>- 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.</li> <li>- Client is requested to reply in writing against the show-cause notice.</li> <li>- The details of refusal of certificate are maintained in the client file and then file is closed.</li> <li>- Certification Manager maintains the list of refusal of the certificates.</li> </ul>
<p>Reducing the scope of certification</p>	<ul style="list-style-type: none"> <li>- Reduction in the scope of certification is possible in the below circumstances: <ul style="list-style-type: none"> <li>• Any of the product from the present certification may fail to comply with the relevant requirements;</li> <li>• Client requires voluntarily withdrawal of the product from the present certificate;</li> <li>• Due to some other unavoidable circumstances.</li> </ul> </li> <li>- 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.</li> <li>- New loading inspection will be to re sealing containers.</li> </ul>
<p>Withdrawal of certificates</p>	<p>(Withdrawal could be effective only if shipment did not reach boarders)</p> <ul style="list-style-type: none"> <li>- This instruction covers withdrawal procedures. <ul style="list-style-type: none"> <li>• Grounds for action are brought to the attention of the Certification Manager, who reviews the information and decides whether to proceed.</li> <li>• 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.</li> <li>• 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.</li> </ul> </li> <li>- The following reasons are considered as grounds for withdrawal: <ul style="list-style-type: none"> <li>• Major nonconformance(s) or effective corrective action not implemented within a specified time period.</li> <li>• Certified client ceases to supply services of the certified quality for an extended period of time.</li> <li>• Certified client persistently fails to meet any of the requirements for certification, including requirements for the effectiveness.</li> <li>• Existence of a serious complaint, or a large number of second or third party complaints, which indicate that the system is not being maintained.</li> <li>• Certified client is unable or unwilling to ensure conformance to revisions of standards.</li> <li>• Certified client does not allow periodic evaluation to be conducted at the required frequency.</li> </ul> </li> <li>- Subject to actions by the certified client, the following steps will be taken leading to possible withdrawal of the certified client's product certification: <ul style="list-style-type: none"> <li>• Where suspension has been invoked, unless otherwise specified, the certified client must advise ASTC every 15</li> </ul> </li> </ul>

	<p>days of the current situation of corrective action. Failure to meet this requirement will result in withdrawal of the certified client's certification.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• In extreme circumstances ASTC may invoke the withdrawal of certification with immediate effect without recourse to initial certification suspension.</li> <li>• Withdrawal of certification will require the certified client to assume the status of non-approval and return all certification documentation to ASTC.</li> <li>• 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.</li> <li>• 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.</li> <li>• The de-certification will be published as a separate list and will be available at the ASTC office upon request.</li> <li>• 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.</li> <li>• Certification Manager shall remove from the register of certified clients the company whose certificate has been withdrawn.</li> <li>• For all withdrawal cases, the certified client's files shall be archived for a period of 3 months and then destroyed.</li> </ul> <p>- 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.</p>
Restoration of certificates	<p>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.</p>
For Certificates in General	<p>The suspension, rejection withdrawal and restoration of certificates should also be notified to customers via Mail.</p>
Use of license, certificates and marks of conformity	<ul style="list-style-type: none"> <li>- ASTC exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.</li> <li>- Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.</li> </ul>