Designation Regulation of Conformity Assessment Bodies (CAB) and Private Laboratories

Saudi Food and Drug Authority

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1st Chapter

General Conditions

According to SFDA Law issued by Royal Decree No.(M/6) dated 25/01/1428 A.H and its implementing regulations issued by the Board of Directors Resolution No. (7-7-1428) dated 6/1/1436 A.H where Article 34 stipulates "SFDA licenses laboratories that fall within the competence of SFDA fields of work."

Along with the Food Law issued by Royal Decree No. (M/1) dated 6/1/1436 A.H. where Article 43 stipulates, "SFDA may seek the assistance of any other government agency or the private sector to perform any task assigned to it according to this law and its regulations."

The regulation herein prepared to designate bodies that carry out conformity and private laboratories as authorized bodies to cooperate with the Authority to complete any of the tasks assigned to.

Article 2: Terms and definitions

The following terms and expressions, wherever mentioned herein, shall have the following meanings unless the context requires otherwise.

Kingdom: Kingdom of Saudi Arabia.

Authority: Saudi Food and Drug Authority (SFDA)

Conformity Assessment Body (CAB): The body that verifies the conformity of products, establishment and/or manufactory to the Authority requirements. Including the Inspection bodies, certification bodies, laboratories, and any other conformity assessment bodies that will be added by SFDA for its activities.

The private laboratory: The body that carries out the tests and measurements that fall within the scope of the Authority's work under standard conditions, whether the private laboratory is stand-alone or affiliated with a conforming assessment body.

Concerned Authority: The approved authority that is delegated and designated by the designating authority (SFDA) to implement the conformity assessment procedures specified in the regulations and technical specifications for the product categories that SFDA supervises.

Scope of the designation: A specific scope of work provided by the conformity assessment body or a private laboratory on behalf of the Authority.

Conformity assessment: A proof that the requirements is specified by the Authority related to a product, process, law, person, or entity have been met.

Accreditation: Third party authentication by conformity assessment body that officially indicates the efficiency of the conformity assessment body to perform specific tasks.

Conformity Verification: A proof that the product, service, process, system, entity or person is met the requirements according to the legislation and technical regulations in force.

Testing: A technical process consisting of determining one or more characteristics of the subject matter of conformity according to a specific procedure. Traditional tests include dimensional measurement and determination of chemical composition, microbiological purity, microbiological strength, or other physical properties of materials such as free from defects.

Inspection: A set of conformity assessment procedures through which the concepts of gathering specific information are applied through monitoring (testing, measurement). Then making judgments about the suitability for use and adherence to specific requirements mentioned in the technical regulations and related technical specification.

Certification: A mechanism whereby one of the conformity assessments bodies (CAB) implements the processes of (examination and testing / inspection) and certifies that (product / service / process / law / person) is committed to implement the conformity assessment procedures specified in the related technical regulation or specification.

Product: It refers to every product that issued by any process, a group of manufacturing or analytical processes, which directed to the consumer for the purpose of consumption or use.

Sampling: An activity related to obtaining a representative sample of the conformity assessment component according to the procedure.

Certificates of Conformity: Third party authentication for products, processes, systems, or people.

Food establishment: Any legal entity that carries out work related to food circulation during the stages of the food chain, except for family home kitchens.

Guideline: A guide to clarify all the procedures and requirements related to the designation of conformity assessment bodies and private laboratories. Besides, granting certificates of conformity to be approved by His Excellency the chief executive officer (CEO).

Article 3: Goal

This regulation aims to:

- Determine the conditions, technical requirements, and procedures for designating and authorizing CAB to implement the conformity assessment procedures specified in the regulations and technical specifications for product categories in the Authority's field of competence.
- Determine the rights and obligations of SFDA, CAB and private laboratories besides their legal responsibilities.

Article 4: Domine

This regulation applies to the CAB and private laboratories that fall within the scope of the Authority's work, whether these bodies are in or outside the Kingdom.

2nd Chapter

Assigning Conformity Assessment Bodies (CAB)

Article 5: Requirements for assigning CAB:

1. Submit a commercial license to practice the activity.
2. Submit a proof of acceptance by submitting the acceptance certificate and admission appendix issued by the competent authority.
3. CAB shall have a legal entity in the Kingdom.
4. Submit a Saudization plan to CAB in the Kingdom within (3) years for technical jobs gradually at a rate of (50%) as a minimum. Provided that this does not contradict the localization plan issued by the Ministry of Labor.
5. CAB requesting designating shall have an electronic system for granting certificates of conformity, issuing technical and financial reports, and all about the certification procedure. Provided that SFDA is given full authority to enter the electronic system, and the system shall include, as a minimum:

- The number of applications submitted in detail based on the origin country or the source.
- The number of applications for which conformity certificates were granted.
- The number of requests rejected.
- The number of requests for which corrective action was requested.
- Corrective actions performed and documented.
- The number of objections submitted by the customer to the verification results.
- Any reports or special statistics needed by the Authority.

6. Paying the financial compensation for the request to study the file of designation of CAB according to Article 6.

Article 6: CAB Scopes of designation

Activity	Scope of the designation	Verification procedures	Obligation application	Financial compensation (Saudi Riyal)	
				Determination	Adding Country
Food	Accept the export establishments	Verification of compliance export establishments with SFDA requirements.	In the countries specified by SFDA.	20.000	1000
	Certification bodies for quality management (ISO 22000) law and HACCP certificates.	Verification of the conformity of ISO 22000 and HACCP certificates.	Based on the strategic plan of SFDA.	40.000	-
	Consignment Conformity Certificate	Verification of compliance consignment with Saudi and/or Gulf standard specifications.	Based on SFDA website.	20.000	1000
Drug	Conformity Certificate for health, herbal and veterinary products manufactory.	Verification of the conformity of SFDA condition.	Based on the risk assessment and the manufactory specified by SFDA.	40.000	-

Medical products and Devices	Inspect the medical products and devices establishments to verify the quality management law.	Verification of compliance medical device establishments and manufacture with SFDA and ISO 13485 requirements.	Based on risk assessment	40.000	-
	Evaluating the technical file for the purpose of verifying compliance with SFDA regulations and requirements to obtain permission for marketing medical devices and products.	Verification of compliance medical products and devices with SFDA requirements.	Based on risk assessment.	40.000	-
Cosmetic products	Manufactory inspection	Verification of compliance with SFDA requirement.	Based on risk assessment.	40.000	-
	Consignment Conformity Certificate	Verification of compliance consignment with SFDA requirement.	Based on risk assessment.	20.000	1000

* SFDA collects a financial compensation for each Consignment Conformity Certificate for food and cosmetic products (1000 riyals / certificate).

** SFDA does not deduct financial compensation for the manufactory quality certificates.

3rd Chapter
Special Conditions for Scope of The Designation CAB

Article 7: CAB special conditions for food.

First: CAB shall be certified according to the requirements of the international standard (ISO/IEC 17065).

Second: CAB issues conformity certificates for consignments of food products exported to the Kingdom in accordance with the procedures as foresaid in the guide of the regulation.

Third: CAB approves the acceptance of establishments for exporting food products to the Kingdom in accordance with the procedures as foresaid in the guideline of the regulation.

Fourth: CAB that issue food safety management system certificates (ISO/IEC 22000) and/or Hazard Analysis Critical Control Point certificates (HACCP) shall have the ability and competence to assess the conformity in accordance with ISO/IEC 22000 certificates and/or HACCP certificates. CAB is issued according to the forms and mechanisms Approved by the Authority.

Article 8: CAB special condition for medical device and products.

CAB issues certificates or/and reports of conformity in accordance with the guiding of the regulation and the following implementing rules:

A. The implementing rule for the requirements of the Authority on conformity verification offices that perform the technical review of medical devices/products and audit activities (MDS-IR1).
B. implementing rule on marketing authorization (MDS-IR6).
C. Requirements for the Saudi Quality Management System for Medical Devices.

Article 9: CAB special requirements for cosmetic products.

First: CAB shall be certified in accordance with the requirements of the international standard (ISO/IEC 17065).
Second: The audit shall be in accordance with the procedures as foresaid in the guideline.

Article 10: CAB requirements for health, herbal and veterinary products manufactories subject to registration.

First: CAB issues conformity certificates upon ensuring that the manufactory adheres to the requirements, standards and good manufacturing practice approved by the Authority in the Saudi Food and Drug Authority Good Manufacturing Practice Guideline which is issued by SFDA and the World Health Organization (WHO).

Second: CAB shall have the capacity and competence to assess conformity according to the principles of good manufacturing approved by SFDA. CAB shall issue conformity certificates according to the guideline of the regulation.

4th Chapter
Designating Privet Laboratories

Article 11: Designating private laboratories conditions.

1. Obtaining a private laboratory license by the Authority.
2. Participating in Proficiency Tests required by the Authority in accordance with the requirements of the international standard (ISO/IEC 17025).
3. Presenting Test Method for each of the items in accordance with the related clauses.
4. Paying the financial compensation for the request to study the file for designating the private laboratory according to Article 12.

Article 12: Designating scope for private laboratories.

Activity	Scope of the designation	Verification procedures	Obligation application	Financial compensation for determination (Saudi Riyal)
Food	Examination and analysis of products.	Imported and locally manufactured products are examined and analysed at the expense of the importer or the producing company.	Based on risk assessment.	1000
Feed	Examination and analysis of products.	Imported and locally manufactured products are examined and analysed at the expense of the importer or the producing company.	Based on risk assessment.	1000
Drug	Examination and analysis of products.	Imported and locally manufactured products are examined and analysed at the expense of the importer or the producing company.	Based on risk assessment.	1000
Tobacco	Examination and analysis of imported products.	Imported and locally manufactured products are examined and analysed at the expense of the importer.	On all products.	1000
Cosmetic products	Examination and analysis of products.	Imported and locally manufactured products are examined and analysed at the expense of the importer or the producing company.	Based on risk assessment.	1000
Medical device and products	Examination and analysis of products.	Imported and locally manufactured products are examined and analysed at the expense of the importer or the producing company.	Based on risk assessment.	1000

* The Authority deducts 25 % of the value of each examination and analysis.

Article 13: Special conditions based on designation scope of private laboratories.

1. The laboratory shall identify the special tests that is wishing to apply for designation, according to the publication on SFDA website.
2. The laboratory shall commit to not have conflict of interest between the laboratory and the client.
3. All communication channels with the Authority shall be direct, and the communication with clients is not allowed at all. If any, the authority shall be informed of that.

5th Chapter

Article 14: Final provisions of the regulation.

First: SFDA may take appropriate measures when violating any of the provisions of these regulations, for example:

1. If an explicit violation or transgression is proven by CAB or private laboratories on SFDA Laws, conditions, and administrative/technical regulations which associated with these regulations. The Authority has the right to take the appropriate penal action, which includes the following penalties:
    A. Suspending or reducing the scope of the designation: The Authority has the right to suspend part /all the scope of CAB or private laboratory designation, according to specific procedures it sets, in the following cases:
        1. Based on the request of CAB or private laboratory, on a voluntary basis, due to its inability to continue fulfilling the requirements of the designation for part / all the designation field.
        2. The inability of CAB or private laboratory to close cases of non-compliance with the designation requirements during the period specified by the Authority.
        3. The inability of CAB or private laboratory to address any reason for the suspension of the designation field within the specified time, affecting only a specific part of the designation scope.
        4. Provide any information, false information or contrary to reality.
        5. Failure to maintain accreditation in the admission field.
        6. Inability to continuously achieve accreditation requirements for part of the accreditation field.
        7. Failure to pay hiring financial compensation.
    B. Cancellation of designation: The Authority has the right to permanently cancel the field of designation from CAB or the private laboratory according to specific procedures that it sets in the following cases:
        1. Based on the request of CAB or private laboratory, on a voluntary basis, due to its inability to continue achieving the designation requirements or any other reason.
        2. Inability of CAB or private laboratory to address any of the reasons for suspending the designation scope.
        3. If there is evidence of fraudulent behaviour or that CAB or private laboratory has provided false or erroneous information.

4. Practicing illegal activities or violating the principles of neutrality and impartiality, objectivity and non-discrimination or unfair competition in terms of CAB, a private laboratory, or one of its affiliates (auditors, experts, employees, sub-contracted laboratories, etc.).
5. If CAB or private laboratory does not fulfill its specific obligations.
6. If discrepancies are discovered in the reports issued by CAB or private laboratory.
7. If there are observations, or it becomes clear to the Authority that CAB or private laboratory is not feasible.
8. Failure to maintain accreditation in the admission field.

2. If a failure or a non-conformity situation is proven on the performance of CAB or private laboratory on it, the Authority has the right to impose a penalty and demand compensation for all damages that occur to the Authority because of the failure of CAB in performing its work.

Second: SFDA rights and obligations

1. The Authority has the right to amend the financial compensation according to what it issues in this regard.
2. The Authority has the right to use the information it obtains from CAB or private laboratory and publish it in the way it deems appropriate.
3. The Authority has the right to ensure that the information provided is correct in the way it deems appropriate.
4. The Authority monitors CAB and private laboratories periodically to ensure their compliance with the SFDA regulations and requirements, which include inspection visits according to the mechanisms approved by the Authority.
5. The Authority is not responsible for any errors that may occur from CAB or private laboratory.
6. The Authority is obligated to ensure the confidentiality of the information that it accesses or its employees or those contracted with during the designation process for CAB or private laboratory are kept confidential.
7. The Authority shall consider any complaint filed by CAB, private laboratory, or beneficiaries of its services and study it objectively. Besides, taking what is necessary to address it according to specific procedures laid down by the Authority.

8. The Authority shall publish the CAB and private laboratories list on its website.

Third: CAB and private laboratories rights and obligations

1. CAB and private laboratory are obligated to follow up on all the regulations, guidelines, requirements, and circulars issued by the Authority in the designation scope, as soon as they are issued, and any amendments or additions made to them on the website.
2. Compliance with all requirements of the technical regulations approved by the Authority and follow-up updating them. Beside not issuing any conformity certificate for the banned products by the Authority.
3. CAB or private laboratory has the right to object SFDA decision not to designate and to provide the justifications for that within 30 days of the issuance of the decision. The objection shall be in accordance with the followed legal procedures.
4. Full commitment to cooperate and facilitate the work of the SFDA officials during inspection visits.
5. Commitment to implement SFDA recommendations after inspection visits, to make approved corrective plans, and to determine the time required for their implementation.
6. Issuing conformity certificates and analysing products according to the laws, technical regulations, terms, and requirements for that. They legally bear any damage resulting from that.
7. Preserving the intellectual property of the standard specifications used in addition to the information of interest to the beneficiaries.
8. CAB and private laboratory shall be independent, impartial, and maintaining the confidentiality of the information that is seen or seen by its employees or who were hired, during the period of its designation and after its end. Besides not to disclose any information related to the services it has provided, and not to disclose it definitively without prior written consent from the Authority and in certain cases only assessed by the Authority.
9. Keeping the beneficiaries files for not less than 5 years from the date of expiration of the certificates of conformity for reference as needed.
10. Inform the Authority promptly if CAB or the private laboratory is unable to continue fulfilling the designation requirements.

11. CAB or private laboratory shall perform all the tasks assigned to, and if a third party is designated to carry out some of its tasks, it shall subject it to all the stipulated requirements. CAB and private laboratory shall obtain written approval by the Authority and provide it with a copy of the contracts concluded between them. Bearing the CAB and private laboratory are fully responsible for those services provided by the third party.
12. If CAB or private laboratory is from the local authorities, enough technical and scientific competencies shall be provided at its headquarters in the Kingdom, based on the standards of the Authority.
13. Commitment to the financial compensation for the services mentioned in the financial compensation tables, according to what is issued by the Authority in this regard.
14. Commitment not to share any SFDA documents to any other party, whether inside or outside the Kingdom, except with the prior written approval by the Authority, and it bears full responsibility for the security of the information provided for the purpose of performing its mission.
15. Commitment not to use SFDA name for advertising purposes or any logos and place them on products.
16. Commitment to inform the Authority of suspicious cases or related illegal practices.