



COSMOS-standard

COSMOS-standard CONTROL MANUAL Accreditation and certification requirements

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Developed by leading associations and certifiers in organic and natural cosmetics

www.cosmos-standard.org

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1. Foreword

The COSMOS-Standard is owned and managed by the COSMOS-standard AISBL, a notfor-profit, international association registered in Belgium (hereafter known as COSMOS).

Our ultimate objective is to safeguard, in the area of cosmetics, the welfare of the environment and of people. For this, we want to stimulate the development of cosmetics that are ever more natural and organic. We want to ensure consumers have clear and transparent information so that they can make sustainable choices.

Therefore, the COSMOS-standard sets out innovative, challenging and progressive criteria for organic and natural cosmetics that are clear for the industry and good for the environment, validated through third party certification which consumers can trust.

Certification Bodies (or Certifiers) will assess a company against the standard's requirements, issue a certificate of conformity and continually monitor adherence to the standard. Each Certifier is assessed by an Accreditation Body against requirements detailed in this Control Manual. The main purpose of the Control Manual is to set out the details of this oversight process to ensure credible, consistent and reliable implementation.

2. Objectives

This Control Manual sets out the certification and accreditation requirements for the COSMOS-standard. It specifies the procedures and requirements for Certification Bodies to achieve and maintain authorisation to perform certification according to the COSMOS-standard, to gain and maintain authorisation to use the COSMOS-standard, and to implement their related quality assurance systems.

This document also specifies the approval and monitoring procedures that the nominated Accreditation Body will use to evaluate the Certification Body.

3. Principles

Organizations performing audits and certification can apply for authorisation as Certifiers to the COSMOS-standard AISBL. Certification Bodies are those that operate independent, third party product certification systems.

For this authorisation process, as well as for continuous monitoring of the authorised Certification Bodies, COSMOS is cooperating with 'Accreditation Bodies' that will provide oversight of the Certification Bodies and agree to follow the approval and monitoring procedures and requirements specified in this document.

The applying Certification Body may assign its actual or preferred Accreditation Body, as long as the chosen Accreditation Body:

- is a recognized national or international Accreditation Body (e.g. member of the International Accreditation Forum),
- has the necessary competence, and
- follows the given procedures to accredit to the COSMOS-standard.

The requirements for Certification Bodies set out in this document are specific requirements relating to the COSMOS-standard and are in addition to the requirements of ISO/IEC 17065: 2012 "Conformity assessment — Requirements for bodies certifying products, processes and services". These requirements are ordered below in the same structure as ISO/IEC 17065 for ease of application. The Certification Body must comply with the requirements of ISO/IEC 17065.

4. Scope

These procedures and requirements apply to all Certification Bodies that apply for authorisation to certify to the COSMOS-standard and to the Accreditation Body performing the accreditation.

5. Normative References

The following referenced documents are required for the application of this document and are to be used in conjunction as binding requirements wherever applicable.

For Accreditation Bodies:

- ISO/IEC 17011 Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies;
- IAF MD 7 IAF Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies;
- IAF/ILAC A5 Multi-Lateral Mutual recognition arrangements.

For Certification Bodies:

- ISO/IEC 17065: 2012 Conformity assessment Requirements for bodies certifying products, processes and services;
- The COSMOS-standard, COSMOS Labelling Guide and the COSMOS Technical Guide.

6. Requirements for Accreditation Bodies

Accreditation Bodies must comply with the procedures of ISO/IEC Guide 17011: 2004 "Conformity assessment - General requirements for Accreditation Bodies accrediting conformity assessment bodies", follow the Scheme Documents and are expected to follow the procedures and requirements as detailed in this Manual.

Accreditation bodies have to be previously approved by COSMOS, formalized by a signed agreement by both parties.

6.1 Audit and Evaluation requirements

COSMOS requires that the assigned Accreditation Body includes the following specific minimum audit and evaluation elements in its respective accreditation and monitoring procedure:

- a) A review of the applicant Certification Body's documentation for the scopes applied for;
- b) an update accreditation visit every 15 months to the/an office conducting standard certifications and concerning all COSMOS scopes;
- c) A minimum of 5 client files, representing at least 1.5% of the files of clients contracted by the Certification Body, should be checked on each accreditation visit. If less than 5 clients, all have to be checked; and
- d) Accreditation Bodies are required to submit to COSMOS the accreditation status following each accreditation audit.

6.2 Approval decision

The Accreditation Body decides if accreditation to the standard, based on the requirements of this document, can be granted to the Certification Body. If not, the certification body has to reinitiate the application for accreditation.

7. Authorisation procedure for Certification Bodies

7.1 Prerequisites

Certification Bodies applying for authorisation as COSMOS-standard certifiers must first meet the following requirements:

- a) Be a legal entity;
- b) Simultaneously apply for (associate) membership of COSMOS-standard AISBL;
- c) Have a valid accreditation to perform certification for at least one standard according to ISO/IEC Guide 17065: 2012 "Conformity assessment - Requirements for bodies certifying products, process and services " (note, it does not have to be cosmetics);
- d) Have sufficiently qualified/experienced staff to perform certification for the scopes for which they are applying;
- e) Have financial stability to properly, impartially and effectively perform certification activities; and
- f) Name a representative as member of the COSMOS Certifier Committee.

7.2 Application procedure

The application procedure occurs in the following order:

- 1. Applications for authorisation should be sent to the General Manager of the COSMOS-standard AISBL at: 124 rue du Commerce, 1000 Brussels, Belgium, or info@COSMOS-standard.org.
- 2. Applications will be considered only if they contain the following information/ declarations:
 - a) duly completed application form;
 - b) duly completed application form for membership of COSMOS-standard AISBL (if the Certification Body is not already a member);
 - c) legal name and status, address and legal representative of applicant;
 - d) list of all offices and branches;
 - e) scopes for which the applicant seeks authorisation (for Scope 2 'approval', the applicant must be approved for Scope 1 too);
 - f) a copy of ISO 17065 accreditation certificates already obtained;
 - g) details of the nominated Accreditation Body to undertake the COSMOS accreditation;
 - h) a summary of the relevant professional qualifications and experience of the applicant's designated cosmetics personnel; and

- i) declaration that, when seeking authorisation, the applicant agrees to:
 - operate in compliance with the requirements of this document,
 - pay the applicable fees to COSMOS,
 - certify according to the COSMOS-standard, and
 - enter into a formal contract with COSMOS.
- 3. An application fee is payable as stipulated in the 'COSMOS fees' document.
- 4. After acceptance of the application by COSMOS, the Certification Body must apply to the nominated Accreditation Body to conduct the accreditation process.

7.3 Accreditation and Authorisation decision

- 1. The Accreditation Body shall review conformity of all application documents of the Certification Body (see 6.1.a) and if positive COSMOS shall be informed of the acceptance of the application.
- 2. After receiving the acceptance of the application by the Accreditation Body COSMOS will conclude a certifier contract with the Certification Body: once signed by both parties, this gives permission to the Certification Body to start to certify.
- 3. The Accreditation Body shall decide in accordance with this Manual to grant or grant with conditions or not grant accreditation to the Certification Body for the applied scope(s) as described in the COSMOS-standard. The accreditation must happen within eighteen months of the date of application to the Accreditation Body.
- 4. Once accreditation is granted, COSMOS will issue an Authorisation Certificate to the Certification Body which completes the authorisation process.
- 5. COSMOS will publish the contact details of the authorised Certification Bodies, together with their authorised scope(s) and any other limitations or conditions, on the COSMOS-standard.org web site.

7.4 Duties to COSMOS

7.4.1 Annual Fee

The Certification Body shall pay relevant fees as determined in the 'COSMOS fees' document.

The Certification Body shall collect fees from its certified and approved clients as determined in the 'COSMOS fees' document.

7.4.2 Cooperation with other authorised Certification Bodies

Certification Bodies must accept certificates issued in accordance with the COSMOS Standard by other authorised Certifiers in order to conclude their COSMOS-standard certification.

Certification Bodies must interact with each other in order to secure equal application of the COSMOS-standard.

On client's request Certification Bodies will issue audit reports about the basic outcome of audits and other relevant documents (e.g. specifications, draft copies of labels) for specific products, and other Certifiers will accept these reports and documents in the framework of their audit system, in order to avoid multiple auditing of products or clients already audited by another Certification Body. COSMOS reserves the right to define additional rules which will be added to this document.

Certification Bodies shall refuse to accept certificates which are obviously not in accordance with the COSMOS-standard and shall notify COSMOS in such cases.

7.4.3 Reporting on activities

Certification Bodies shall keep COSMOS updated about names, addresses, production category and products of the certified clients on the online COSMOS database.

Upon request, Certifiers shall submit detailed documentation to COSMOS to ascertain adherence to the COSMOS-standard and any rules and interpretations issued from time to time. COSMOS will treat this information confidentially.

Certification Bodies that are authorised for Scope 2, 'approval of non-organic raw materials' shall ensure that up-to-date lists of these ingredients are available to COSMOS and the other authorised Certifiers. However, ingredients that are approved on a confidential basis for a specific client need not be disclosed to the other authorised Certifiers.

In cases where Certification Bodies reach conflicting decisions on an ingredient, the Bodies concerned shall share their proofs of assessment with the aim of achieving a consensus decision. If this fails, COSMOS will consider all the proofs of assessment and shall decide whether the specific ingredient is acceptable or not.

7.4.4 Suspension or withdrawal of accreditation

In case of suspension or withdrawal of the accreditation, the Accreditation Body shall inform COSMOS immediately and stop reference to accreditation of that Certification Body (subject to the normal appeals process of the Accreditation Body).

In case of accreditation suspension, the Accreditation Body, in conjunction with COSMOS, will provide an action plan. During suspension, the certification body cannot make new COSMOS certification decisions, though existing certifications are unaffected.

In case of accreditation withdrawal, the Certification Body must stop any COSMOS certification activity and remove any reference to COSMOS. For already certified companies, COSMOS, in conjunction with the Accreditation Body, will provide an action plan. COSMOS will not reauthorize the Certification Body for a minimum of two years.

8. Requirements for certification bodies

Any requirements listed in this Control Manual that are above and beyond ISO/IEC 17065 must be met.

Information below is in addition to or expands on the criteria in the corresponding ISO/IEC 17065 section and gives clarification or further requirements. Section paragraphs from ISO/IEC 17065 are identified **[in square brackets]**.

8.1 General requirements [§ 4]

8.1.1 Legal structure [in addition to 4.1.1]

The structure of the Certification Body shall foster confidence in its certification operations. In particular, the Certification Body shall:

- Have documents demonstrating its status as a legal entity;
- Have documented the rights and responsibilities associated with its certification activities; and
- Identify the management (body, group or person) that has overall responsibility for its functioning, including its finances.

8.1.2 Contract [in addition to 4.1.2]

The Certification Body shall provide its certification service based on an agreement (contract) signed by the applicants and clients. In particular, the contract shall:

- Contain provisions to allow the Certification Body to exchange information with other authorised Certifiers, Accreditation Bodies and COSMOS to verify information, especially the certification status of certified products, as part of its ongoing evaluation;
- Grant to both the Certification Body and its nominated Accreditation Body the right of access to all appropriate facilities, including to non-organic production in the unit or related units, and all relevant documentation and records, including financial records;
- Allow COSMOS to follow audits if necessary or to request certification documents;
- Contain provisions for confidentiality to protect the clients' data;
- Require the client to inform the Certification Body about any other certifications and Certifier relationships that it has in the same or similar scopes as the COSMOS-standard, including other COSMOS certifications;
- Ensure the client informs the Certification Body if they do not want their certification information that is reported monthly to COSMOS to be made publicly available as requested in paragraph 7.4.3;
- Oblige the client to accept supplementary audits and provide samples to the Certification Body if required; and
- Require clients to inform the Certification Body about any change related to its activity or certification.

For raw material approval (Scope 2), the contract shall:

- Confirm that the Certification Body is authorized by COSMOS for the approval of raw materials;
- Enable the Certification Body and COSMOS to refer to the approved raw material on their respective websites. To this end, the client allows the Certification Body to transfer to COSMOS for publication purposes, its contact details along with the trade name, the Chemical Name or INCI name (as the case may be), and the purpose and status of the approved raw material; and
- Enable the Certification Body to exchange information related to approvals with other authorised Certifiers, particularly to verify the status or the conformity of the raw materials with the COSMOS-standard. Should these exchanges concern confidential information, the Certification Body and the Client shall jointly and previously identify the information that can be transmitted in this framework.

8.1.3 Management of impartiality [in addition to 4.2]

Conflict of interest

The Certification Body shall identify, analyse and document the possibilities for conflicts of interest arising from its provision of certification, including any conflicts arising from its relationships. Rules and procedures shall be established to prevent or minimise the threat of conflicts of interest. In particular, the Certification Body shall:

- a) Require personnel, committee, if applicable, and board members to declare existing or prior association with an operation subject to certification. Where such an association threatens impartiality, the Certification Body shall exclude the person concerned from work, discussion and decisions at all stages of the certification process related to the potential conflict of interest;
- b) If a conflict of interest between certification personnel and an operation is found after assessment has occurred, assign another unbiased person to assess if it has affected the certification process as well as complete the remainder of the process if possible; and
- c) Ensure that personnel do not assess their own work.

8.1.4 Confidentiality [in addition to 4.5]

The Certification Body shall make adequate arrangements to safeguard the confidentiality of the information obtained in the course of its certification activities at all levels of its organisation, including committees and external bodies or individuals acting on its behalf. Arrangements shall:

- a) Protect a client's proprietary information against misuse and unauthorised disclosure; and
- b) Ensure that the Certification Body has the right to exchange information with other Certification Bodies and/or authorities including COSMOS for verification and assessment purposes.

8.2 Personnel requirements [§ 6]

8.2.1 Personnel of the certification body

Qualification criteria and documentation [addition to 6.1.2.1 a)]

The criteria must specify minimum education, training, technical knowledge and work experience relevant for all the personnel involved in evaluation and/or certification decisions and/or review, and in particular:

- a) for Scope 1, at least one of its personnel must have:
 - a university degree in the field of cosmetics, chemistry or related subject plus experience in quality management issues;
 - or at least 3 years professional experience in the cosmetics industry or related field plus experience in quality management issues;
 - or at least 2 years professional experience in audit and certification of cosmetics;
- b) for Scope 2, at least one of its personnel must have:
 - a university degree in chemistry or biochemistry plus at least 3 years professional experience (or further qualifications) in chemistry or related field plus experience in quality management issues;
 - or at least 6 years of professional experience in chemistry or biochemistry or related field including experience in quality management issues.

Competence review [in addition to 6.1.2.1 b)]

The Certification Body shall ensure that new personnel have sufficient competence and receive adequate training including theoretical training and practical training. For auditors, the practical training shall include at least 4 audits including accompanying and being accompanied on-site audits for organic or natural cosmetics certification.

8.2.2 Personnel for the Evaluation - Sub-contracting [in addition to 6.2.2.4]

When a Certification Body decides to outsource work related to certification (e.g. audit) to an external body, an agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The Certification Body shall:

- a) Keep final responsibility for the granting, maintaining, renewing, extending, suspending or withdrawing of certification - delegation of certification decisions is not permitted;
- b) Ensure that the subcontracted body or person is:
 - competent to perform the subcontracted work;
 - committed to the policies and procedures as defined by the Certification Body; and
- c) Monitor the performance of the persons or bodies subcontracted for the work.

8.3 Process requirements [§ 7]

8.3.1 Client's application [in addition to 7.2]

The Certification Body shall require completion of an application form. To enable evaluation and assignment of qualified personnel, the Certification Body shall require clients to:

- a) Provide information about the scope of the desired certification, including a description, as specified by the Certification Body, of the production, products and area to be certified;
- b) Provide information as to whether another Certification Body has denied or withdrawn certification; and
- c) Provide information as to whether they are co-operating also with another authorised Certification Body.
- 8.3.2 Evaluation [in addition to 7.4]

<u>Scope</u>

- 1. For organic or natural certification, the Certification Body shall evaluate clients against all certification requirements specified in the Scheme Documents. An onsite audit includes a review of documents, personnel interviews and a supply chain review. The audit shall happen annually according to the certification process.
- 2. For approval of ingredients with no organic content under the COSMOS-standard:
 - a) The certification body must develop specific control documents and procedures; and
 - b) The verification of compliance shall be based on a review of all the necessary information and documents needed for the approval.

Audit protocol

Audit by on-site visit is carried out in order to verify information and compliance with certification requirements applicable to the client. It shall follow a set protocol to facilitate non-discriminatory and objective audit.

The certification body shall implement its own checklist.

The audit protocol shall at the very minimum include:

- a) Checking all relevant COSMOS criteria;
- Assessment of the processing system by means of visits to facilities and if necessary storage units (according to the risk and information availability). It may also include visits to non-organic areas if there is reason for doing so;
- c) Traceability and mass balance conformity assessment;
- d) Verification that corrective actions have been taken; and
- d) Verification of any complaints received as well as of the actions taken.

Frequency of audit

- 1. All clients that have applied for certification (including brand owners) shall be audited at least annually.
- 2. In addition to the regular audit, the Certification Body may conduct follow-up or unannounced on-site audits of certified operations, chosen randomly and/or on the basis of the risk or threat to the organic integrity of the production or products.
- 3. For clients with multiple sites, all manufacturing sites must be audited annually; the frequency of auditing other sites shall be determined on the basis of a risk assessment.
- 4. There is no requirement for audit of operations for the approval of raw materials with no organic content, though the Certification Body has the right to carry out audits in case of suspicion.

Particular requirements to address high-risk situations

The Certification Body shall amend and adapt its certification procedures to address higher risks found in certain situations specific to COSMOS-standard certification. Potential high-risk situations include parallel processing of COSMOS-standard and non-COSMOS-standard products.

In order to prevent co-mingling or contamination of organic products with other products that do not meet the standards, the Certification Body must verify whether handling and documentation regarding manufacturing, formulation, storage and sales is well managed and makes clear distinctions between certified and non-certified products. In cases where products are not visibly distinguishable, specified measures must be applied to reduce the risk.

Audit report

The Certification Body shall report evaluation findings according to documented reporting procedures, as detailed below.

- a) Audit reports shall follow a format appropriate to the type of operation audited, and facilitate a non-discriminatory, objective and comprehensive analysis of the respective processing system.
- b) The audit report shall cover all relevant aspects of the Scheme Documents, and adequately validate the information provided by the client. It shall include:
 - A statement of any observations relating to conformity with the certification requirements;
 - Date and duration of the audit, persons interviewed, facilities visited; and
 - Type of documents reviewed.
- d) The Certification Body shall document and apply measures to verify effectiveness of corrective actions taken by clients to meet the requirements.

8.3.3 Certification decision [in addition to 7.6]

Responsibility for certification decisions

The Certification Body shall have final responsibility for granting, maintaining, extending, suspending and withdrawing certification. Certification may not be granted in cases of external conditions such as:

- known critical non-conformity with the general regulations in force on cosmetics;
- a geographical location that makes certification technically impossible or risky for those involved.

Responsibility for clients' use of references to COSMOS certification

The Certification Body has primary responsibility for monitoring misuse of the trademark or incorrect reference to COSMOS certification by a client. The certification body shall implement appropriate measures such as reduction, suspension or withdrawal of certification, and potentially undertake legal action if the misuse persists.

Documentation

Documentation of certification decisions shall include the basis for the decisions.

8.3.4 Certification documents [in addition to 7.7]

Issuing of certification documents

The Certification Body shall issue official certification documents to each client. Documents shall contain the following information:

- a) The name and address of the client whose products are the subject of certification;
- b) The name and address of the Certification Body that issued the certification documents;
- c) The scope of the certification granted, including:
 - the products certified (or process/handling), which may be identified by type or range of products, with the level of certification for each product;
 - the COSMOS scheme that is the basis for the certification;
 - the reference to the COSMOS Standard with its publication date;
 - the effective date and term of certification if applicable;
- d) In the case of approval of raw materials with no organic content, clear reference to the approved status (being different from certification) and the following percentage of:
 - PPAI;
 - CPAI;
 - Petrochemical moiety;
 - Non natural ingredients;

- e) For certified ingredients, the percentage of:
 - PPAI;
 - Organic PPAI;
 - CPAI;
 - Organic CPAI;
 - Petrochemical moiety;
 - Non Natural ingredients;
- f) The reference to accreditation (if applicable).

8.3.5 Certified products list

Information about clients and their certified or approved products require a specific data format provided by COSMOS for use in its databases with public access.

The Certification Body shall provide each month the list of products and ingredients certified and raw materials approved if applicable.

8.3.6 Re-evaluation [in addition to 7.9]

- 1. The Certification Body shall annually re-evaluate clients in order to verify whether they continue to comply with the applicable standard. Mechanisms shall be in place to effectively monitor whether corrective actions have been implemented.
- 2. The Certification Body shall report and document its re-evaluation activities, and shall keep clients informed about their certification status.
- 3. Re-evaluation generally follows procedures outlined in 8.3.2 (i.e. Evaluation). However, evaluation for the purpose of renewal may focus on certain measures related to risk, and might not repeat all procedures listed in 8.3.2.
- 8.3.7 Changes with consequences for the certification [in addition to 7.10.2]

Notification of changes made by the client

- 1. The Certification Body shall determine whether the notified changes require further investigations. If such is the case, the client shall not be allowed to release certified products produced under the changed conditions until the Certification Body has notified the client accordingly.
- 2. In response to an application for amendment to the scope of a certificate already granted, the Certification Body shall decide what evaluation procedure, if any, is appropriate, in order to determine whether or not the amendment may be made, and shall act accordingly.

8.3.8 Termination, reduction, suspension or withdrawal of certification [in addition to 7.11]

- 1. For any non-conformities identified, a correction plan must be developed. The correction plan must list the non-conformities and classify them according to their degrees of severity ("major" or "minor" non-conformity). It must identify for each non-conformity the consequence for the certification (according to the nature and the severity of the non-conformity as well as its occurrence and the risk of fraud), and appropriate actions to be taken.
- 2. Reasons for denial, withdrawal or suspension of certification shall be stated with clear reference to the COSMOS-standard criteria or other certification requirement violated.
- 3. The Certification Body shall notify COSMOS within one working week of any Client where it has withdrawn certification because of violation of COSMOS requirements. COSMOS has the right to determine that the Certification Body will not offer certification services to that Client for a specified period.

8.3.9 Maintaining and managing records [in addition to 7.12]

- 1. The Certification Body shall maintain a system of records (either electronic or paper documents) to demonstrate that the certification procedures have been effectively fulfilled, particularly with respect to application forms, evaluation or re-evaluation reports, and other documents relating to granting, maintaining, renewing, extending, suspending or withdrawing certification.
- 2. Client records shall be up to date and contain all relevant information, including audit reports and certification history.
- 3. Records shall also be kept of exceptions granted, appeals and subsequent actions.
- 4. Records shall be kept for at least five years, or as required by law, in order to be able to demonstrate how certification procedures have been applied.

9. Synonyms and Definitions

The terms defined in ISO/IEC 17065 and in these procedures that are used interchangeably are listed below in the table.

ISO/IEC 17065	COSMOS
Evaluation	Audit
Evaluator	Auditor

COSMOS-standard AISBL, Rue du Commerce 124, 1000 Brussels, Belgium

info@cosmos-standard.org

www.cosmos-standard.org