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REGULATION FOR COSMOS CERTIFICATION

ICEA

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1. FOREWORD

Ethical and Environmental Certification Institute, hereinafter referred to as **ICEA**, is the nonprofit Consortium constituted between associations and organizations operating in the field of activities connected with environment-friendly, fair and long-lasting development, pursuant to article 2612 and following ones of the Civil Code.

The Consortium was founded by AIAB (Italian Association for Organic Farming), Banca Etica (Ethical Bank), Demeter (Association for the protection of bio-dynamic quality in Italy), ANAB (National Association for Bioecological Architecture) and ACU (Consumers' Association), with a view to offering a certification service based on the principles of independence, transparency, objectivity, impartiality and competence, capable of building up suppliers' and consumers' confidence in the certified products, through verification of product conformity to voluntary or binding regulations.

The Consortium's registered office is in Bologna (Italy), Via Nazario Sauro 2.

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ICEA obtains financial support from proceeds resulting from certification and training activities.

ICEA is entitled to open offices, branch-offices and agencies in Italy and abroad.

ICEA authorizes all operators, who observe the certification scheme governed by this Regulation, to affix to products the conformity label and the certification mark provided by relevant regulations and/or standards.

- a) ICEA guarantees Applicants admission to the certification schemes governed by this Regulation, without any discriminations of any sort. In particular:
 - no undue conditions of economic or other nature are applied;
 - f access to evaluation and certification is not conditioned by the size of the unit or by membership of particular associations or groups.
- b) ICEA undertakes to apply current procedures and expenditure accounts based on its own national List of Fees in force, guaranteeing uniformity of application.
- c) The request for inspection and certification does not entail for the concerned Organization any obligation to utilize other ICEA's services not contemplated in this Regulation.

2. DEFINITIONS

Product: the result of a process.

Process: the total of correlated or interacting activities which transform inputs into outputs

Product Specification: a document which establishes the requisites of a product. (Hereafter it is called Standard).

Regulatory Body: a public or private body which draws up and publishes the regulations governing product standards.

Organization: a body, unit, organism, enterprise or parts thereof, with share capital or not, public or private, with its own functions and administration, which concurs in the formation, marketing and supply of the product. **Applicant**: an organization requesting certification. In case the certification concerns a chain of products, the Applicant is also the coordinator of the chain.

Licensed Operator: an organization to which ICEA issued the conformity certification and which is, consequently, authorized to use conformity label and certification mark.

Operator: An organization which has requested or obtained the certification.

Cosmetic Products: Products defined by the Regulation (EC) N° 1223/2009 and successive changes and integration.





- 3. REFERENCES
 - ICEA Operational Manual
 - UNI EN 45011 (hereinafter EN 17065)
 - Law ISO 19011
 - Law ISO 22716
 - COSMOS Standard (www.cosmos-standard.org)
 - Regulation (EC) N° 1223/2009

The above mentioned references are in force at the moment of the issuance of the hereby document. Therefore, the references in force at the moment of the development of the certification activity must be applied.

4. GENERAL CONDITIONS

- **4.1** This regulation outlines the procedures followed by ICEA to check and certify the conformity of Cosmetic products, obtained according to COSMOS standard, which is property of the association COSMOS AISBL (www.cosmos-standard.org).
- **4.2** The cosmetic products/ingredients defined COSMOS ORGANIC and COSMOS NATURAL are obtained according to the COSMOS Standard, to the rules of the Control Manual, and to Technical and COSMO labelling guidelines.
- **4.3** Cosmetics ingredients/raw materials "Cosmos approved" are specially assessed by ICEA in compliance to the requirements provided in the standard and the eligibility for the production of certified cosmetics COSMOS ORGANIC and COSMOS NATURAL. All of this in accordance to the COSMOS Manual regarding "the approval of non-organic ingredients that are acceptable to use according to the Cosmos Standard"
- **4.4** All products certified and approved by ICEA must be obtained according to international and national norms in force and in compliance with good processing practices (GMP).
- **4.5** The certification system is based on auditing and approving the production process management system set up by the applicant operator in order to obtain products, and also on the execution of type tests (where required by the Standard), followed by continuing surveillance through periodical verification of the conformity of processes and quality system management, and through the testing of samples taken both from the market and from production and/or processing sites.

In particular, the quality system established by the organization shall take into consideration the management and application of the following requisites:

- traceability and possibility to recall the product in case of serious non-conformities;
- · identification and separation of certified product from non-certified product;
- management of customers' complaints;
- management of quality records

Approval procedures of cosmetic raw materials are based on the assessment of documentation that demonstrates compliance of non organic raw materials to COSMOS requirements. The assessment procedure does not provide, as a rule, site visits and inspections at production sites.

4.6 Application for certification or approval can be forwarded by any Organization whose activity falls within the scopes of production, distribution under mark and importation of such products. The certification or



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approval are normally granted to the responsible of the product marketing and/or proprietor of the trademark that individualize the product.

- **4.7** In order to obtain certification, the Applicant Organization shall demonstrate that it complies with the Standard and current legislation applicable to the concerned type of products. ICEA conformity certification authorizes the Applicant Organization to affix the conformity indications and certification mark specified in this Regulation and in the guidelines for COSMOS labelling.
- **4.8** If certification projects involve more than one applicant under the responsibility of only one organization, the applications shall be directly submitted by this responsible organization. In this case, the responsible Organization shall have legal status and shall:
 - a) have entered into precise written agreements with the other Organizations involved in the certification project for the implementation of the provisions laid down in the relevant Standard and in this regulation;
 - b) have defined criteria for involved Organizations' admission to, participation in and renunciation of the certification project;
 - c) have established procedures for informing each sub-licensee about reference standards, regulations, certification procedures and subsequent revisions, and also about the rights and duties connected with the organic production scheme;
 - d) formally assume (through a Statement) the responsibility for the conformity of all Organizations interested in the project, and allow ICEA's and accredited bodies' personnel access to Organizations' premises and production sites and to all records, including fiscal ones, concerning the certified product at any stage of the production chain.
- **4.9** ICEA does not supply Organizations with any sort of advisory service as for example ways to overcome eventual non conformities that prevent obtaining certification or promotional and information activity aimed at marketing specific products of certified organizations.
- **4.10** On the Italian territory, ICEA carries out its activity with Italian staff and documents in the Italian language. For inspection and certification activities abroad, ICEA undertakes to use, when necessary, the English language or a language known by the local populations, reserving the possibility to utilize translators and interpreters appreciated for their ability and accepted also by the operator under the inspection scheme.

The same principle is adopted when drawing up and distributing documents which are necessary for requesting, obtaining and maintaining the certification (standards, regulations, registration forms, etc.)

Certification documents are generally issued in Italian and English. When the product is intended for countries where the English language is not widely known, ICEA undertakes to use the local language or another language known by the population.

4.11 In order to facilitate access to information for people interested in this certification scheme, ICEA is committed to provide all materials and non-sensitive documents directly on request or via the website <u>www.icea.info</u>.

ICEA, moreover, to increase the transparency of the system, reserves the right to make public through the internet and other communication tools the non-confidential information relating to its activities and in particular the licensors, the control and certification fees, penalties issued and analytical test results.

4.12 The results of inspection visits and documented evaluations are subject to examination of a Risponsible of Certification (RCV) or Certification Committee (CCERT), with the necessary requirements of competence and independence, which decides on the issuance, extension, suspension or withdrawal of certification or attestation of approval.

All personnel involved in the inspection visits has a degree in chemistry or biochemistry and at least three years of professional experience in the chemical industry, or adequate experience in quality control. The

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figures involved in the activity of document assessment and decision on certification have a degree in chemistry or biochemistry, or at least some years of professional experience in the chemical industry, or adequate experience in quality control.

4.13 On the application of this Regulation shall supervise the Committee of Impartiality Safeguard, guarantor of impartiality and authority of the proper implementation of the certification, which ensures the equitable representation of interested parties to the certification.

The Members of the CIS are the delegates designated by the parties concerned in the activities of these types of certification products and processes.

5 CONDITIONS FOR OBTAINING AND MAINTAINING THE CERTIFICATION

5.1 In order to obtain and maintain the certification, the Applicant Organization shall observe the provisions of this Regulation and:

- a) implement and maintain a documented management system demonstrating compliance with product and/or process requirements laid down in the reference Standard;
- b) identify and monitor the specified requirements, including the ones legally binding and regulating;
- c) have completed the document assessment stage and any necessary type tests with satisfactory results;
- d) take all measures which may be needed for correct assessment, as required by this Regulation;
- e) maintain, throughout certification validity,(or during the validity of the certificate of approval for non organic raw materials), the conditions that permitted such certification to be granted;
- f) downgrade or recall the product from the market, as needed, as soon as it learns of any irregularities which invalidate the conformity of the product, and promptly inform ICEA accordingly;
- g) promptly inform ICEA of any change in the Organization;

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- h) in case ICEA ascertains any Non Conformities (NC), propose Corrective Actions (AC) by filling out and signing the appropriate forms, one copy of which shall be sent, via fax, to ICEA within 10 calendar days from the date of notification;
- i) satisfy all ICEA's requests for corrective actions within the agreed deadline;
- j) to respect all the terms of the hereby contract;
- k) pay to ICEA the fees due for inspection and certification activity, no matter what the outcome is; Any inspection visits not included in the surveillance plan, which should be necessary as a consequence of non conformities found, will be charged to the Applicant Organization according to the List of Fees in force at the moment such visits are carried out.
- I) pay the annual flat rate for maintaining the certification also in case of suspension;
- m) retain, throughout certification validity, a record of all complaints received and the documents pertaining to the relevant corrective actions implemented; The Applicant Organization is required to take into consideration also any complaints received by other subjects involved in the certification project, for which the Organization assumes responsibility as far as product conformity is concerned.
- n) inform ICEA of the Organization's involvement in cases of judicial proceedings for infringement of laws on product responsibility or related to the certification obtained.
- o) accept that ICEA exchange information and documents with other certification bodies concerning problems related to the control and certification and eventual sanctions.
- p) allow the staff appointed by ICEA, or by accreditation bodies, access to all premises, documentation, records, areas considered necessary to do a proper inspection;

5.2 Certified Organizations shall keep the records related to the product, which shall be made available to ICEA's personnel.





5.3 The above mentioned records shall be updated daily. They may be kept in electronic format, subject to ICEA's previous approval.

When records are in electronic format, it is necessary to keep in file a monthly summary hard copy (or backup disk, to guarantee high levels of security).

ICEA reserves the possibility to ask for one copy of such records (also in electronic format).

The records concerning productions subject to conformity certification shall be clearly distinguishable from those concerning products which are not subject to certification.

5.4 ICEA's Control Technicians shall also be allowed to access all the accounting, fiscal and financial documentation which may be needed in order to cross-check mandatory records with a view to verifying correct and systematic obligatory keeping.

5.5 If the above mentioned conditions are not fulfilled, ICEA will take the necessary measures proportioned to the frequency and severity of infringements, to the extent of certification suspension and withdrawal.

6. APPLICATION FOR CERTIFICATION

6.1 To start the certification process, the Applicant Organization shall forward to ICEA the appropriate APPLICATION FOR CERTIFICATION (Form M.RCCOSMOS 01) duly filled in.

The application shall contain, in particular, the following elements:

- Applicant Organization's business name and registered address;
- Type of activity (production, manufacturing, outsourcing and distribution) and category of product for which the certification is requested.
- Other certifications obtained by the applicant organization, eventual denied certifications in addition to other eventual important non conformities and/or sanctions detected by involved control and certification bodies.

6.2 By signing the APPLICATION FORM FOR CONTROL AND CERTIFICATION OF COSMETICS (M.RC.COSM 01) the Applicant Organization accepts the contractual conditions given by ICEA (described in the application form) and undertakes complying the Regulation in its entirety. The application for certification shall be accompanied by the following documents:

- 1. copy of receipt for payment of the entry fee due to the Inspection System according to ICEA List of Fees.
- 2. Applicant Organization's Chamber of Commerce Registration Certificate.
- 3. Copy of VAT Number Certificate.
- 4. ICEA LIST OF FEES FOR CONTROL AND CERTIFICATION OF COSMETICS (M.RCCOSM 03) signed on the original for acceptance.

Afterwards, but before the pre-certification visit is carried out, the applicant organization must forward ICEA the following documents:

- 1. INFORMATIVE QUESTIONNAIRE FOR COSMOS CERTIFICATION (M.RCCOSMOS 02) with the description of the production process and involved production units, products composition and the identification of the raw materials certified organic.
- 2. Facsimile of label on the package.
- 3. ICEA will assess the compliance of the label with the relevant Standard and the correctness of the conformity indications and LOGO description.
- 4. names of qualified organic providers and the certifications attesting the conformity of organic ingredients:
- 5. Quality Plan of products to be certified, indicating measures implemented for monitoring and governing critical points.
- 6. Organization Chart and signed by the responsible of the production





- 7. (In case of third-party processing) Copy of the contract signed with the Processor, whereby the Processor
- a) undertakes to perform contract operations in compliance with this Regulation and all the relevant regulations and/or standards.
- b) undertakes to give advance notice of date and time when processing begins.
- c) undertakes to allow ICEA appointed staff free access to relevant processing units and documentation.
- d) indicates the Processor's broad qualitative/quantitative Annual Production Plan.

For the assessment of cosmetic products and ingredients to be certified, under COSMOS the applicant organisation must send to ICEA the appropriate modules of: quality-quantitative formulation, calculation of organic percentage (for extracts), composition of packaging materials, labels/graphic drafts and any other relevant questionnaires and forms required by COSMOS.

For the purposes of conformity assessment of non-organic cosmetic raw materials (NOI = Non Organic Ingredient) the applicant organisation must submit the appropriate forms of: NOI request approval, Technical summary Document with annexes (technical sheets, safety data sheets), non-GMO statements and any other relevant questionnaires and forms required by COSMOS.

All the above mentioned documents may be requested to Icea and are published on the website of ICEA

7. PRE-CERTIFICATION INSPECTION VISIT

7.1 If the Applicant Organization considers it advisable, it may ask ICEA to carry out a precertification inspection visit. The request shall be made when filling in the Application for Certification.

The purpose of the pre-certification inspection visit is to

- determine the Applicant Organization's size, structure and activity;
- determine to what extent the Applicant Organization is prepared to face the certification process and guarantee compliance with the ICEA Standard and with this Regulation.

7.2 The pre-certification visit is optional and can be requested only once. The relevant time and costs will be established on the basis of the Applicant Organization's type and size.

The date and schedule for the pre-certification visit will be jointly fixed by ICEA and the Applicant Organization.

8. ASSESSMENT

Assessment is performed by ICEA with the purpose of verifying the conformity of Applicant Organization's product and/or process to the requirements laid down in the relevant Standard. It includes:

- 1. evaluation of documents:
- 2. inspection visit to the structure of the Applicant Organization (and of any other Organizations involved in certification);
- 3. analytical tests (when required by ICEA Regulations)

The assessment phase starts only after the Applicant Organization has submitted the documents mentioned in chapter 6.

ICEA classifies the situations where requirements laid down in relevant documents are not met as Non-Conformities (NC). Non-Conformities are subdivided into Essential (E) Important (I), and Minor (M).

Serious NC are the ones which do not guarantee the product requisites laid down in ICEA Standard. Such Non-Conformities require immediate downgrading of product and the arrangement of corrective actions accepted by ICEA.

ICEA classifies some remarks (O) as recommendations to be carefully taken into consideration by the Applicant Organization in order to obtain improvements.

When the Applicant Organization's documentation is complete, ICEA will make arrangements with the Organization regarding the verifications to be carried out for the purpose of certification.



8.1 Evaluation of documents

8.1.1 Documents are evaluated by a qualified staff appointed by the Voluntary Certification Responsable (RCV), by filling the form DOCUMENT EVALUATION CHECK LIST (M.RCOSM 04) within 30 working days from receipt of document.

The appointed technician shall evaluate all the documents submitted by the Applicant Organization with a view to verifying their compliance with the relevant Standard, shall draw up a Document Evaluation Report and shall send it to the Applicant Organization.

ICEA reserves the possibility to ask for other information which may be useful for the purpose of evaluation. In this case, as in any other case where documents are incomplete, the 30 days' term for the fulfillment of verification starts again from the date of receipt of the new documents.

8.1.2 When the assessment of Applicant Organization's documentation is completed, a judgment is issued, as follows:

a) **Approved**: if no NCs have been found;

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- b) Approved on condition: where ICEA's overall evaluation of detected NCs does not prejudice the following evaluation phases (elimination of NCs can be directly demonstrated on occasion of the first inspection visit);
- c) **Non Approved**: where ICEA's overall evaluation of detected NCs prejudices the following evaluation phases. In this case, the evaluation process is suspended until NCs are eliminated.

8.1.3 If the operator does not eliminate the NCs detected and does not update the documentation within 60 working days, the application will become null and void. A new application may be presented against a new payment of the fees due to ICEA.

8.1.4 In the cases a) and b), a qualified Control Technician will be entrusted with the execution of the first inspection visit.

8.2 Inspection Visits

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8.2.1 The purpose of first inspection visits is to verify the conformity of the Applicant Organization, and of any other subject participating in the project, to the requirements laid down in the relevant Standard. In case the Organization has several production units, the number of sites subjected to inspection will be determined on the basis of a significant Risk Analysis and it will be equivalent, at least, to the square root of all the concerned production units. In the case of production units considered critical to the scope of the Standard conformity in the opinion of the ICEA Certification Responsible, the inspections will be carried out

8.2.2 The first inspection, which shall be carried out within 30 working days from the conclusion with positive results of document evaluation, includes:

- an initial meeting with the Applicant Organization's Responsables (or a Representative appointed by the Responsables) and with other concerned persons included in the Organization Chart. The purpose of the initial meeting is to introduce ICEA Evaluator or Evaluating Team, illustrate the inspection schedule and confirm that all ICEA evaluators are bound by a confidentiality agreement.
- accurate verification of compliance of all products to be certified with the provisions of the relevant Standard and verification of correctness and reliability of statements written on the label and in the presentation of the product;
- audit of production process management, analysis and control of points which are critical as concerns product conformity and application of Applicant Organization's control plan;
- verification of Quality Plan implementation and effectiveness; verification of relevant records;
- a final meeting where the Applicant Organization's Responsables will be informed of the result of the inspection visit.



During the final meeting, ICEA Responsible Evaluator or the responsible of the Evaluation Group shall:

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- a) illustrate the contents of the INSPECTION REPORT (M.RCOSMOS 06), write down any remarks made by the controlled Organization and ask it to countersign the Report for acceptance. One copy of the report is given to the Applicant Organization
- b) illustrate the remarks written down in NON CONFORMITY REPORT form, and ask the Organization to sign these forms for acceptance;

8.2.3 One copy of the INSPECTION REPORT written by the technician shall be given to the Organization.

One copy of NON CONFORMITY REPORTS shall be given to the Organization that shall return them (also via fax) to ICEA within 10 calendar days from the date of the visit, complete with Corrective Actions (AC) and/or Non Conformity Treatments (TNC), implementation times and names of persons responsible for implementation.

The TNCs and the ACs proposed by the operator are verified by the RCV or by his delegate. If no communication to the contrary is given within 5 calendar days from receipt, they are intended as approved.

In case such TNCs and ACs are not considered sufficient or valid, the RCV or his delegate shall inform the operator in writing, giving reasons.

8.2.4 In case of serious Non-Conformities, ICEA may arrange special inspection visits with a view to evaluating the effective implementation of approved treatments and/or Preventive Actions.

If irregularities concern documentation, it will be sufficient to complete such documentation and send it to ICEA within the deadline

8.2.5 The inspectors involved in inspection activities must be entered in the ICEA registry of qualified controllers technicians for the specific schema COSMOS.

For the purposes of proper conduct of audit activity, Icea provides all the documentation submitted by the operator and useful for the purposes of the inspection (informative questionnaire, formulations, technical sheets, graphics tags, analytical referents, records of previous inspections, any external reports, etc.).

All Non-conformities detected by the inspector or, later, by Icea, as well as treatments of non-conformities and corrective actions taken by the company, shall be communicated to the Inspector who will carry out the next test in order to check the correct and effective solution in the next surveillance.

8.2.6 The inspection activity (as well as the analytical tests) are scheduled by ICEA on the basis of a risk analysis and with the purpose of ensuring the integrity and the conformity of production.

This plan will also provide for monitoring inspections without notification with possible sampling for analysis.

8.3 Analytical Tests

8.3.1 To complete evaluation, the Organization shall supply three samples of each product for which certification is requested.

ICEA reserves the possibility to subject the products to type tests (analyses) and to any other tests as may be needed in order to verify their conformity to the related Standard and to the general reference regulations.

8.3.2 The tests shall be carried out by test laboratories accredited, within the European certification system, in accordance with international rules governing test laboratory accreditation. The costs incurred shall be borne by the Applicant Organization.

In case it is difficult to find accredited laboratories for the execution of certain tests, such tests will be carried out by other laboratories, Applicant Organization's laboratory included, subject to ICEA's previous evaluation of their competence and reliability.





ICEA shall give the Applicant Organization advance notice of the type of tests to be carried out. When evaluating whether tests are needed, also tests reports produced by the Organization will be taken into account, if they are significant and carried out by test laboratories accredited in accordance with the above mentioned criteria.

8.3.3 In case the tests show that the product does not comply with reference Standard and general regulations; the assessment will be suspended until the Applicant Organization, within the agreed deadline (which may not exceed 60 working days), restores the conformity of the product and asks ICEA to subject the product to new type tests.

The samples for type tests may be taken on occasion of the First Inspection Visit.

9. DELIBERATION

9.1 The certification file will be submitted to Certification/Responsable (RCV) for evaluation only when the Applicant Organization has eliminated any existing NCs and/or has clearly and credibly committed itself to reaching full conformity within a deadline established and considered acceptable by Certification/Responsable (RCV). On completion of the evaluation, Certification/Responsable (RCV) will decide whether to grant or deny the Conformity Certificate.

ICEA undertakes to submit the certification file to Certification/Responsable (RCV), or to the delegated Committee, for evaluation, within 30 working days from the date of elimination of the non conformities found during the previous evaluation phases (documents, first inspection visit and type tests). On completion of the evaluation, Certification/Responsable (RCV) will decide whether to grant or deny the Conformity Certificate.

9.2 In case a negative resolution is passed and the certificate is not granted, the Applicant Organization will be informed in writing of the decision and of the reasons for the decision.

9.3 If, within sixty calendar days, the Applicant Organization does not implement the necessary corrective actions, the application for certification will officially become null and void. A new application may be presented against a new payment of the fees due to ICEA.

10. ISSUANCE OF CONFORMITY CERTIFICATE

Following Certification/Responsable (RCV)'s positive opinion and resolution to grant certification, ICEA (within 15 working days) will issue the CONFORMITY CERTIFICATE (M.RCCOSMOS 05) showing the following details:

- Certificate registration number;
- Name and/or business name of the Organization holding the certification;
- Code of Operator;
- Date of issuance (beginning of validity period);
- Validity end date;
- Name of products subject to certification;
- Revision status of document;
- Standards, and category to which conformity was granted.

The Conformity Certificate will be signed by ICEA President or his delegate. The delegates' list is available as document in ICEA's office or visiting the web-sites <u>www.icea.info</u>. On the Organization's specific request, ICEA may issue certification documents attesting the conformity of specific production lots or batches, reserving the possibility to request additional checks or analyses. All costs incurred, including secretarial fees, will be borne by the Organization.





In any case, such documents will be issued only after the Organization has obtained the Conformity Certificate.

10.1 Use, validity and renewal of Conformity Certificate

- a) The validity of the Conformity Certificate is subject to the observance of the reference Standard and of this Regulation for Certification.
- b) During the validity period, surveillance visits will be carried out in order to verify continuing compliance with requirements.
- c) The term of the Unit Conformity Certificate is three (3) years. On expiry, Certification/Responsable (RCV) reassesses the Organization in its entirety and decides whether to renew the Certification. The new assessment will be based on all the information gathered in the course of inspections during the preceding two years.

Once the Organization has received the certificate, it is entitled to:

- publicize the certification obtained;
- make the Conformity Certificate public;
- affix the conformity label and Logo specified in this Regulation to the label of certified products;
- utilize in the technical sheets and promotional material explicit statements referring to certified products, the conformity label and Logo.

The operator may renounce inspection and certification by communicating his withdrawal by registered letter or Certified Electronic Mail (PEC). In any case, the operator will be obliged to pay the fee due for ICEA's activity in the course of the year.

Withdrawal from certification of conformity to ICEA Standards has no influence on the other services offered by ICEA.

10.2 Register of Licensed Operators

All the Organizations which are granted the Conformity certification and the authorization to use ICEA Mark are entered in the REGISTER OF LICENSED OPERATORS (M.RCCOSM 07) with the following data:

- Date of issue and validity of certification
- Registration number of certificate/license
- Name and/or business name of the Organization holding the certification, registered address of the main office and of the production plants, phone/fax number, e-mail address and website (if any);
- Commercial Name of products and/or category of activity subject to certification;
- Indications as to certification status (operating, suspended on ..., withdrawn on...)

The Register of Licensed Operators is a public document updated daily, and is available on the web site www.icea.info.

ICEA may send it (also in electronic format) to any subject submitting a written application, and may also publish it in the own publications, promotional material and/or web site www.icea.info.

10.3 Declaration Of Conformity to the Cosmos Standard Non Organic Ingredients (N.O.I.)

For non-organic ingredients (NOI) conform to the COSMOS standard a certificate is issued (M.RCCOSMOS 05 RW-NOI) in order to declare that the raw materials listed in this document may be used for cosmetic





products for which COSMOS certification is required. The certificate will be issued only after the positive evaluation of the COSMOS AISBL Technical Commission.

10.4 Reciprocity policy (acceptance of certificates issued by other organisations)

ICEA recognizes the certification issued by the same certification scheme issued by institutions participating in the COSMOS Association AISBL, according to the criteria of full compliance and in compliance with the provisions in regulations Cosmos.

11. LOGO PROVIDED

Organizations that get from ICEA Certification of Compliance in accordance with the COSMOS Standard, guidelines for COSMOS labelling and these Regulations, will have access to the use of this logo in accordance with the rules laid down in the Regulation Logo Usage and Certification (annexed to the Operation Manual) ICEA marks

The different admitted graphic versions may be requested to the competent ICEA office. Some admitted versions in green and black colors are shown as follows:

CERTIFIED COSMETIC PRODUCTS AND RAW MATERIALS



APPROVED BIOLOGICAL RAW MATERIALS

Under construction

Under construction

11.1 Support to protection initiatives

In addition to the ordinary surveillance activity, ICEA will check, at least once a year, whether certification mark and conformity label are correctly used. ICEA personnel will also check these marks and labels in shops, supermarkets and other points of sale, trade fairs, web sites etc., also as a follow-up to objective evidence supplied by third-parties.

In case of irregular use, ICEA will:

• require corrective actions and apply sanctions to the organizations subjected to the control system;

• send warning letters and, where necessary through legal actions which can include claim compensation for damages and withdrawal of the product from the market.

The person responsible for all the above-mentioned activities is ICEA RCV, who may avail himself of the support and collaboration of all ICEA staff.

ICEA is committed to communicate to COSMOS AISBL of any irregularity concerning the trademark use and references to COSMOS of which it is aware.



12. MODIFICATION OF CERTIFICATION CONDITIONS

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12.1 Modification of Regulations and/or Standard

All certified Organizations shall be informed about changes through notices displayed in the web site www.icea.info and shall also be given a deadline for meeting the new requirements.

The term within which the requirements for formulations certified under the previous standard must be met shall not be in excess of 24 months from the date of notice, without prejudice to other requirements imposed by COSMOS AISBL.

After the deadline, the Applicant Organization has the right to renounce certification.

If the Organization decides to maintain certification, ICEA will check conformity to new requirements through verification of documents or, where needed, through inspection visits and/or type tests.

Following the entry into force of the amendment, ICEA can verify compliance with the new conditions of conformity in accordance with the most appropriate and technically effective modalities.

12.2 Modification of Regulation for Certification

In case of modification to the provisions laid down in this Regulation, the revised Regulation will be sent by mail to the Applicant Organization at least thirty (30) calendar days before the changes are applied. ICEA will publish the updated version of the regulation in the web site www.icea.info

After the deadline, the Applicant Organization is obliged to accept the new conditions provided by the Regulation but in case of non-acceptance, the Organization shall send ICEA its renunciation to the certification within 30 calendar days from receipt of communication.

12.3 Modification of List of Fees

If the economic terms specified in the List of Fees are changed, the revised List of Fees will be sent to the Applicant Organization at least thirty (30) calendar days before the changes are applied.

The certified Organization is obliged to accept the new fees, in case of non acceptance, it shall send ICEA its renunciation of certification within 30 calendar days from receipt of communication. ICEA will publish the updated List of Fees in the web site www.icea.info

In all the above-mentioned cases of renunciation, the operator will anyway be obliged to pay the fees due to ICEA for its activity throughout the year.

13. SURVEILLANCE ACTIVITY

13.1 During the period of validity of certification, ICEA will perform surveillance activity with its own qualified personnel, through inspection visits and type tests within a specific sampling plan.

The purpose of surveillance activities is to verify continuing compliance with all requirements laid down in the related Standard, in general regulations in force, and in this Regulation.

13.2 ICEA will carry out product tests on samples taken either from production line and storage premises, or from distribution points and points of sale, in accordance with the Sampling Plan (and whenever the Control Technician, during inspection, gathers evidence of irregularity).

Such tests will be carried out in accordance with the same criteria established for type tests.

They aim at supporting and validating the tests directly carried out by the Applicant Organization in the context of its own Quality Plan.

Also in this case, ICEA undertakes to communicate in advance to the Organization the type of tests it intends to carry out and the estimate cost.

www.icea.info





If samples are taken from processing and storage sites under inspection, they shall be taken in the presence of the person requesting certification and/or Technical Responsable (or their delegates). If samples are taken from distribution points, wholesalers or points of sale, the Organization accepts that such samples be directly collected by ICEA technical staff (also by simply purchasing them), provided that each sample be formed by three packages of the same lot.

Each package constitutes a sub-lot. One original package will be made available and, on request, delivered to the concerned Organization.

13.3 Surveillance visits may either be announced or unannounced.

In case of announced visits, ICEA's inspectors will communicate the date of the visit directly to the Applicant Organization.

The announced visits scheduled are at least one per year, in compliance with the surveillance plan.

In case of announced visits, the operator has the right to ask for a change of the date proposed by ICEA, giving reasons. ICEA reserves the right to accept the change only if that is not prejudicial to the significance of the inspection.

The surveillance visit schedule always includes:

- evaluation of changes in the Applicant Organization's production processes (if any);
- verification of remedial action for NCs detected during previous inspections and satisfaction of conditions;
- verification of continuing conformity to the requirements of the Standard and conformity to any modification occurred;
- observance of Certification/Responsable (RCV)'s specific requirements and correct implementation (also within the deadlines of any derogations granted);
- examination of customers' complaints;
- verification of requirements laid down in this Regulation;
- substantial changes in the production plan.

13.4 The procedures for Non-Conformity Report keeping and management are the same as the ones described in paragraph 8.2.

13.5 Unannounced visits are scheduled, within the surveillance plan, to cover a sample of units determined on the basis of statistical criteria (approved by CSI). They may also be decided, at ICEA's discretion, with a view to verifying continuing conformity, as a follow-up to complaints, reports from the market, product test results and surveillance activity in other organizations.

During inspections, the operator shall offer the greatest collaboration to the staff appointed by ICEA. If the operator fails to communicate his absence on occasion of announced inspections, he shall bear the cost of the visit.

14. MODIFICATION AND EXTENSION OF CERTIFICATION SCOPE

14.1 The certified Organization is entitled to request changes in the scope of certification. These changes may be:

- change of business name and/or modifications in the Organization;
- modification or extension of production units;
- modification or extension of products and/or processes subject to certification.



14.2 The procedure for requesting such modifications is the same as the one indicated for submission of application for certification. Of course, the request shall exclusively refer to the elements and/or products modified or extended.

14.3 The issue and/or revision of Conformity Certificate, keeping into account the modification and/or extension of certification scope, is subordinate to the positive fulfillment of the provisions laid down in art. 8 of this Regulation.

15. CONFIDENTIALITY

15.1 ICEA undertakes to treat as strictly confidential (except in case of particular legislative or judicial provisions) all the data and information gathered in the course of the relationship with the Applicant Organization.

Also ICEA's personnel involved in inspection and certification activities undertake to treat as strictly confidential the data acquired, in particular as regards product process and formulation.

15.2 The documentation acquired will be filed only at ICEA's offices and access to files will only be allowed to competent functions who signed the appropriate Confidentiality Agreement.

15.3 ICEA will not divulge Organization's data and information (other than the ones contained in the Register of Licensed Operators) to third parties, without the Organization's written consent.

If the Judicial Authority requests data and information, ICEA will supply the information requested and will inform the Organization accordingly.

15.4 The data which may be considered public and which can be disseminated without any written consent, are the ones contained in the Register of Licensed Operators and penalties (if any) imposed on the Organization (date, type, concerned products). Notice of such penalties may also be displayed in the website <u>www.icea.info</u>.

15.5 ICEA reserves the right to exchange with other inspection bodies and accreditation bodies involved in COSMOS certification scheme information regarding the outcome of the inspection and certification activities as well as any non-compliance and sanctions. This exchange of information is aimed at the proper functioning of the control system and the protection of the market and consumers.

16. VALIDITY OF CERTIFICATION CONTRACT

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16.1 By signing this Regulation, a contractual relationship between ICEA and the Applicant Organization is constituted.

16.2 The hereby contract shall become effective starting from the day ICEA receives a copy of it signed by the operator. This contract shall be valid until December 31 of the following year from the year of its signing. It shall be considered as tacitly renewed for the following years if no written notice of termination is sent by any of the parties. Such communications shall arrive at least thirty (30) days before the expiry of the contract.

16.3 In particular, the validity of the contract is bound to the fulfillment of the following obligations:

- a) Observe the current provisions of national and Community regulations concerning the production of cosmetics.
- b) Supply the documentation required by the application of the inspection system.
- c) Fill in and constantly update the forms envisaged by the application of the inspection system.



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- d) Allow inspection personnel access to locations and documentation, as required by such inspection personnel.
- Make available to inspection personnel all the products and raw materials for analysis as may be e) required for the purpose of inspection and certification.
- Comply within the deadlines provided by ICEA, whether for the fulfilment of the requirements of the f) inspection system or for the payment of any fees due to ICEA.
- Notify any substantial change in the operator's situation or in any activity connected with inspection a) system and product conformity, within the prescribed deadlines. In case the variations occurred require a specific evaluation by ICEA, the operator shall wait for ICEA's conformity judgment before affixing conformity label or logo to the concerned products.
- h) Observe the provisions of the current regulations concerning product labeling and the Regulation for Use of ICEA Marks, promptly reporting to ICEA any misuse, even by other operators.
- i) Make comments about the certification only when referring to the purposes for which the certification was issued.
- Not use the certification in such a way as to discredit the Certification Body and not make comments j) about product certification, which may be considered not correct or not authorized by the Certification Bodv.
- In case of suspension or withdrawal of the conformity certification, stop using all documents bearing k) indications referring to the certification and/or stop using, in case of withdrawal of the certification, advertising material containing such indications. Return any certification document on Certification Body's request.
- Use the certification only to indicate that the products have been certified in compliance with relevant I) regulations.
- Behave as prescribed by the Certification Body when dealing with media regarding product m) certification (i.e. documents, brochures or advertising).
- Accept, without prejudice to the possibility to file an appeal, the penalties applied in accordance with n) the provisions laid down in this Regulation.
- Keep record of all complaints received regarding the products subject to inspection and certification. O)
- Manage in a controlled way the distribution of ICEA's Conformity Certificates to customers, recording p) for each distributed copy: registration number of copy (to be indicated also in the document), date of delivery, and name of recipient.
- Communicate any withdrawal or suspension of Conformity Certificate to all subjects to whom such q) certificate had been distributed.
- Accept that ICEA exchange information and documents with other certification bodies concerning r) problems related to the control and certification and eventual sanctions.
- Allow ICEA personnel in charge and accrediting body free access to all facilities, records and s) documents considered useful to do a proper inspection.

17. RENUNCIATION OF CERTIFICATION

The Organization may renounce certification in case it decides not to accept the modifications to certification conditions which ICEA might possibly introduce (see point 12) and in any other case, by sending ICEA a 30 calendar days' (minimum) written notice.

In any case, the Organization shall remain subject to the inspection system until all labels have been used (that is until packaging and labeling operations have been completed), and until no material showing conformity labels and certification mark is left, bearing inspection and certification costs due to ICEA.

In any case, the placing of the product already packaged and labeled on the market shall be discontinued within 18 months from the date of withdrawal of certification.



18.1. Precautionary suspension of the use of Product Certificate and Labels

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18.1.1 The precautionary suspension of the use of Conformity Certificate and, consequently, of the license to use the mark and the conformity indications is applied

- whenever the operator does not allow access for the execution of surveillance visits at the stages of the production cycle which are critical or, anyway, most significant in the context of a regular and effective control;
- ſ whenever infringements or serious irregularities have been found in the course of surveillance visits and product inspections, or when analysis results are such as to cast doubts on product compliance with ICEA Standards and the provisions laid down in general regulations and in this Regulation and/or when they may pose hazards to consumers' health.

18.1.2 The measure is decided by the RCV and communicated to the operator by registered letter (sent in advance via fax) signed by ICEA President or his delegate, pending the necessary evaluation by Certification/Responsable (RCV). The measure can be applied to specific parcels, production lots and batches, typologies of products/production lines or to the entire production of the enterprise, on the base of detected infringements.

The evaluation by Certification/Responsable (RCV) will take place, in any case, within 30 days from the date of application of the measure. The RCV or his delegate will inform the operator about test report results and any other element which determined the measure, and about the deadlines for submission of any remarks, comments, documents and/or counter-analysis reports.

18.2 Suspension of certification validity

18.2.1 The suspension of certification validity for a limited period of time is decided by Certification/Responsable (RCV) after ascertaining substantial infringements of the certification rules laid down in this Regulation.

18.2.2 ICEA will send written notification of the measure and of its own decisions to the Applicant Organization, stating the deadline for completing the corrective actions that are needed to eliminate Non-Conformities, and the deadline for filing any appeal against the decisions.

The suspension will be revoked only when the Applicant Organization has given objective evidence (within the prescribed time limits) that the corrective actions have been successfully completed.

The suspension will last sixty (60) calendar days maximum. On expiry of that period, if the suspended Organization has not implemented the corrective actions required, ICEA will proceed by notifying the Certification Withdrawal.

Where the detected non-conformities prejudice the conformity of specific products, the measure will be applied to these products only. Consequently, the Conformity Certificate will be revised by updating the list of certified products and/or activities.

The Organization is required to return to ICEA the outdated version of the Conformity Certificate.

18.2.3 The Organization itself may ask ICEA to suspend the certification for a limited period of time (also for specific types of products), giving reasons, and ICEA will accept such request.



18.3 Withdrawal of certification

18.3.1 The resolution to withdraw the certification is passed by Certification/Responsable (RCV) in the following cases:

- inadequate and insufficient corrective actions implemented by the Organization after certification suspension;
- substantial non-conformities detected during surveillance visits, and violation of obligations laid down in the regulations in force;
- serious or repeated infringements of obligation to properly use certificate and conformity label;
- cessation of Organization's production activity;

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- bankruptcy of Organization;
- Organization's formal request not to renew the certification on expiry, or formal request to renounce certification in the course of validity;
- non-payment, before the deadlines, of fees due for inspection and certification activities and of any fees due for the use of mark.

18.3.2 ICEA will send written notification of the measure and of its own decisions to the Applicant Organization, stating the deadlines for the implementation of corrective actions aimed at the elimination of Non-Conformities, and for filing any appeals against the decisions.

18.4 Notification of sanctioning measures of certification suspension or withdrawal

18.4.1 The sanctions will be signed by ICEA President, after Certification/Responsable (RCV)'s resolution, and will be communicated to the Applicant Organization by registered letter (sent in advance via fax).

18.4.2 The Applicant Organization may file a written appeal with CUR (Appeal Committee) against these measures, stating detailed reasons, within 30 calendar days from the date of receipt of notification. In addition, the CSI will supervise ICEA's activity, verifying files and technical documents (besides administrative documents regarding payment requests and reminders for defaulting Organizations), in order to guarantee that these measures are taken fully observing the principles of independence and impartiality of the Inspection System.

19. CONSEQUENCES OF RENUNCIATION, NON-RENEWAL, SUSPENSION AND WITHDRAWAL OF CERTIFICATION

19.1 In case of renunciation, non-renewal, suspension and withdrawal of the certification, the Organization is obliged to

- immediately stop using Conformity Certificates and, in case of withdrawal, renunciation or non-renewal, immediately return them to ICEA;
- immediately stop using all documents/publications and headed notepaper bearing indications referring to certification and ICEA marks;
- immediately stop using the conformity label and the certification mark provided;
- on ICEA's request, inform all the customers who had been advised of the certification.

19.2 In case the Applicant Organization uses the certification infringing the above mentioned obligations, ICEA reserves the right to publicize, as it considers most convenient and without prejudice to any further action, that the Organization is no longer entitled to use the certification.



The costs incurred for publication will be borne by the defaulting operator, without prejudice to ICEA's possibility to claim compensation for any other damage.

20. INSPECTION AND TESTING ACTIVITY

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20.1 For the purposes of inspection and testing, ICEA may avail itself of the services of contracted and/or qualified external structures, for whose professional competence it can vouch, fully complying with the Standards UNI CEI EN 45011 (hereinafter EN 17065), concerning Subcontracts, without prejudice to the same activity being carried out by its own national structures.

In any case, ICEA is the only one entitled to and legally responsible for the issue, maintenance, extension, suspension or withdrawal of certification.

Any subcontractors of control and test activities, whether organizations or individuals, shall be communicated promptly to COSMOS AISBL, within 7 working days of the formalization of the relationship. ICEA will publish on its website the updated list of COSMOS qualified subcontractors.

20.2 The Organization may, in advance, express grounded objections to any particular Control Technician, inspection body or test laboratory which ICEA decides to utilize. For this purpose, ICEA undertakes to communicate in advance the names of the appointed professionals or bodies to the Organization.

The Organization shall communicate such objections and reasons, in writing, to the RCV. As concerns analyses, the Organization may write down its request in the Sampling Report.

The RCV shall evaluate whether to accept the request or not. The request may be accepted in those cases where there is formal evidence of conflicts/disputes/controversies/disagreements, either under way or past, between the operator and the professional or body appointed by ICEA.

The operator's request and RCV's consequent decision shall be communicated to the Responsible of Quality Assurance (RAQ) for information.

21. COMPLAINTS

If the Applicant Organization deems that the quality of service supplied does not correspond to what stated in this Regulation, it may file a complaint with ICEA.

Complaints may be forwarded by mail, fax, e-mail or telephone to the attention of ICEA Quality Assurance Responsable (RAQ) who will evaluate whether the complaint is justified and will give a reply within thirty (30) calendar days.

22. APPEALS

22.1 If the Organization deems that the resolutions passed by Certification/Responsable (RCV), or by ICEA in any case, are unjustified and/or discriminating, it may file an appeal with CUR (Appeal Committee) of ICEA.

22.2 The appeal shall be filed in writing, stating reasons, within thirty (30) calendar days from the date of notification of ICEA's decision.

Within thirty (30) calendar days, ICEA will convene CUR, which will examine the appeal within sixty (60) calendar days from date of filing.

On occasion of such meeting, the Applicant Organization's representatives may request a hearing.

22.3 The decision made at this point will be final and binding on the parties.





22.4 All expenses incurred for the appeal will be charged to the losing party.

If the Operator's appeal is to include analysis results, these must be carried out by Laboratories accredited within the European certification system, in accordance with European regulations concerning laboratory accreditation.

23. JURISDICTION

For all disputes arising out of the execution and/or application and/or interpretation of ICEA Certification System, that were not able to be solved through complaints and appeals, the competent and exclusive Court will be Bologna.

24. INTERNAL AUDITS AND PERIODICAL REVIEWS

In order to verify and monitor the correct application, compliance and effectiveness of this inspection and certification system, ICEA, under the responsibility of the Quality Assurance Responsable, will carry out periodical internal audits (VII) at the national office.

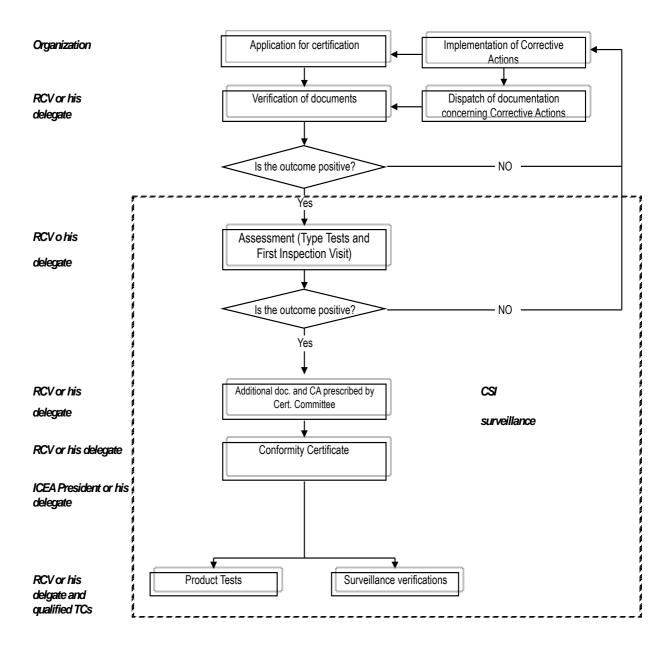
The results of the audits will be reviewed by the Directors in accordance with the procedures applied for all the other certification schemes.





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25. INSPECTION SYSTEM CHART





26. ACCEPTANCE OF TERMS PROVIDED BY THE HEREBY RULES

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(This page, signed by the Applicant Organization's legal representative, must be sent to ICEA)

The Applicant Organization ______in the person of the

Legal Representative _____

DECLARES that all the provisions laid down in this Regulation for COSMOS Certification have been carefully read and accepted.

	Stamp and signature
Date:	

In accordance with the provisions of articles 1341 and 1342 of the Civil Code, the Applicant Organization expressly approves the articles 12, 14, 16, 17, 18, 19, 20, 23.

	Stamp and signature
Date:	