Regulation for Eco Bio & Natural Cosmetics Certification

Sommario

Ed.	Rev.	Date	Reasons for the revision	Drafted	Verified	Approved
05	00	09.06.2022	Re-edition	RSC (Responsible for the Scheme)	RAQ (Responsible for Quality Assurance)	CDA
06	00	02.05.2023	Header and summary	RSC (Responsible for the Scheme)	RAQ (Responsible for Quality Assurance)	CDA
06	01	01.12.2023	Evaluation, Certification Resolution, Measures	RSC	RAQ	CDA

1 SCOPE AND FIELD OF APPLICATION

1.1 Preamble

Istituto per la Certificazione Etica ed Ambientale, hereinafter referred to as ICEA, is the non-profit Consortium established under the Articles 2612 f.c.c. among associations and entities operating in the field of activities related to sustainable, ethical and environmentally friendly development. The Consortium was founded with the aim of offering a certification service according to the principles of independence, transparency, third-party, impartiality and competence, capable of increasing the trust of suppliers and customers towards the certified product by attesting the compliance of the product with voluntary standards or product Regulations.

ICEA, in collaboration with a group of producers and the Institute of Cosmetology of the University of Ferrara, has developed a Technical Specification (TSD 06) in order to define the requirements by a cosmetic boasting the claim "organic" or "natural" and enable all stakeholders to access the certification of their products.

ICEA is also a founding member, along with leading European certification Bodies, of the international COSMOS project that gave rise to the COSMOS-Standard AISBL, an international non-profit association registered in Belgium that aims, in the cosmetic field, to promote environmental and human well-being by stimulating the development of cosmetics that are increasingly organic and natural.

1.2 Scope

This Regulation establishes the conditions and procedures adopted by ICEA for releasing, not releasing, maintaining with the renewal the certification, issuing measures for suspension, revocation and withdrawal of certification following the standards for which ICEA is authorized and accredited.

This Regulation outlines the procedures followed by ICEA for Organic and Natural Cosmetic, according to DTR 06 Technical Regulations for Eco Bio and Natural Cosmetic.

1.3 Field of application

The field of application of the Scheme includes cosmetic products as defined in Regulation EC No. 1223/2009 and subsequent amendments and addenda.

Products for animal use, as well as adjuvants, ingredients, raw materials, auxiliaries or simple natural substances that can be used in cosmetics and for animal use also fall within the field of application.

1.4 Reference standards

Standard	Requirement	Title	Annotations
ISO/IEC 17065:2012	All	Requirements for Bodies certifying products, processes and services.	
UNI EN ISO 9001:2015	§ 8.1.	Planning and Operational Control-Guidelines for Quality Management System Audits	
UNI EN ISO 22716:2008	All	Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on good Manufacturing Practices .	
Regulation (EC) No 1223/2009	All	On cosmetic products and subsequent amendments and additions	
Regulation (EU) No.655/2013	All	On common criteria for justification of claims concerning cosmetic products.	
Ecobio Cosmetics & Natural Cosmetics Technical Regulation. Ed.01 Rev. 04 02.04.2015	All	Criteria and procedures for : Certifying the conformity of the products of the "Eco Bio Cosmetics ICEA" and "Natural Cosmetics", obtained following the guidelines of the Institute of Ethical and Environmental Certification (ICEA).	
Standards and Regulations in effect in Non-EU Countries		USA, Japan, Lebanon, Turkey, Russia, Ukraine, India, Australia, Saudi Arabia.	Specific requirements for the reference

related to the Scope of Certification Schemes			countries are reported and updated in the Annual Control Plan

2 GENERAL TERMS & CONDITIONS

This regulation outlines the procedures followed by ICEA to check and certify the conformity of the products of the "Eco Bio Cosmetic ICEA" and "Natural Cosmetic", obtained following the specifications of the *Istituto di Certificazione Etica e Ambientale*(ICEA).
The certified products *Eco Bio Cosmetic* or Natural Cosmetics are cosmetic products or other similar products with similar functionality and characteristics even if intended for animals, obtained in compliance with the Technical Specifications (DTR 06 - Technical Regulations Eco Bio Cosmetic & Natural Cosmetic) and specifically:

- free from the use of genetically modified organisms;
- free from the use of ionizing radiation;
- with the use of certified organic agricultural products and primary zootechnics (according to the procedures provided for in the specification);
- with the use of chemicals of natural origin or sourced from green chemistry, selected on the basis of criteria of environmental sustainability and health.

ICEA Eco Bio Cosmetic and Natural Cosmetics products must be obtained according to international and national applicable standards and in compliance with Good Manufacturing Practices.
The scope of the control and certification activity carried out by ICEA is to give, through an initial assessment and subsequent surveillance audits, independent assurance with adequate level of confidence that such products (even so compliant with legal standards and good manufacturing practices) comply with the ICEA Technical Specification of Reference.
The certification system is based on the audit and approval of the management and control system of the production process, put in place by the applicant operator to obtain the production and type tests (when required by the specification); followed by continuous monitoring, carried out through the periodic verification of the conformity of the processes and the management of the quality system, as well as control tests on samples taken both from the market and manufacturing and/or processing places.
In particular, the quality system implemented by the organization shall take into account the management and application of the following requirements:

- traceability and possible recall of the product in case of serious non-conformity;
- separation and identification of the certified and non-certified product;
- claims managements received from customers;
- quality record management.

The application for certification can be submitted by any applicant Organization whose activity falls within the production, brand distribution and import of such products.
The certification is usually granted to the person responsible for placing the product on the market and/or holders of the trademark that distinguishes the product.
In order to be certified, the applicant body must demonstrate compliance with the relevant Technical Specifications and applicable laws for this production type.
ICEA certification allows the requesting organization to display on the label and/or other product-related advertising and informational material the claim of conformity and certification mark required by this regulation.
The certification marks "Eco Bio Cosmetic" and "Natural Cosmetic" are property of "Istituto di Certificazione Etica ed Ambientale" " and must be used in compliance with this regulation.
In the case of certification projects involving multiple production units under the responsibility of one entity, applications are submitted directly by the single entity responsible.
In this case, the Responsible Body must have legal personality and must have:

a) entered into written agreements with other Bodies participating in the certification project for the implementation of what provided in the Technical Specification of Reference and this regulation;
b) defined criteria for adherence, participation and renunciation to the certification project of the participating Bodies;
c) procedures that allow the communication to each production unit involved, of the regulations and certification process and the further revisions, other than of the rights and duties related to the participation in the organic production program;
d) must formally assume, in addition, responsibility for the compliance of all Bodies involved in the project, ensuring access to ICEA and accredited bodies personnel at all organizations and production sites involved and to all records, including fiscal records, inherent to the product certified at any level of the supply chain involved.

ICEA does not provide any kind of consultative service to the Bodies; including methods of addressing non-conformities that prevent the granting of the certification and promotional and direct information activities related to the marketing of specific products of certified organizations.
ICEA, on Italian territory, carries out its activities with personnel and documents in the Italian language.
For the control and certification activities abroad, ICEA undertakes to operate (when necessary) in English or, in any case, in the language known by the local population, reserving the possibility of using translators and interpreters accepted and considered capable and prepared, also by the inspected operator.
A similar principle is followed when drafting and distributing to the operators documents relevant to the application, attainment and maintenance of certification (Specifications, regulations, registration forms, etc.).
Certification documents are normally issued in a bilingual version (Italian/English).
When the product is intended for countries where English is not a common and known language, ICEA undertakes to use the local language or other language known by the population.
In order to facilitate the access to useful information for those interested in this certification scheme, ICEA undertakes to make available all non-confidential materials and documents directly on request or through the website www.icea.bio.
ICEA, furthermore, for increasing the transparency of the system, reserves the right to make public through the Internet and other communication tools non-confidential information related to its activities and, in particular, the licensees list, the inspection and certification fee schedule, the sanctions issued and the results of type tests.
On the application of this regulation supervises CSI (Committee for Safeguarding Impartiality), a body guaranteeing the impartiality and good performance of certification activities, appointed by the ICEA Board of Directors (BoD), which ensures the fair representation of the parties involved in the certification.
The members of the CSI are the delegates designated by the parties involved in the certification activities of these types of products and processes.

3 REQUIREMENTS FOR OBTAINING AND MAINTAINING THE CERTIFICATION

In order to obtain and maintain the certification, the applicant Body must comply with the provisions of this Regulation:

a) Fill in, keep up-to-date and properly archive the documentation and records required under the SdC (Certification Scheme). Specifically, implement and maintain a documented management system to give evidence of compliance with the Regulation for the Certification .
In particular, in the case of cosmetic products and/or cosmetic ingredients PPAI and CPAI, implement and maintain a documented management system to give evidence of compliance with the product and/or process requirements set out in the technical Specification of reference . In particular, the management system must consider the following:
- traceability and potential recall of the product in the event of serious non-conformity;
- separation and identification of the certified and the non-certified product;

- management of claims from customers;
- management of quality records.

b) take all necessary measures to enable the proper conduct of the assessment activities provided for in this Regulation;

c) maintain, throughout the period of validity of the certification (or attestation of approval for non-organic raw materials), the requirements that allowed the issue;

d) as soon as any irregularities are known to affect the conformity of the product, downgrade it, and possibly, withdraw the product from the market, promptly communicating these circumstances to ICEA;

e) in case of significant non-conformity, accept the measures taken by ICEA, provided for by the specific Regulations and implement processing operations, propose and carry out the necessary corrective actions in the time agreed with ICEA, by completing and sending the relevant forms within 10 calendar days from the date of notification of the outcome.

f) meet all ICEA corrective action requests within agreed upon timeframe.

g) notify ICEA of all cases in which it is involved in legal proceedings resulting from product liability laws or, otherwise, violations of applicable laws in connection with the certification obtained.

h) inform ICEA of the geographical location of the production units, in order to assess the risks related to the feasibility of the control.

i) adopt a system which allows tracking and traceability of products subject to certification at all stages of the production, preparation and distribution, communicating, preventively, the type of accounting and traceability used.

j) agree that ICEA applies appropriate measures stemming from reports, verifications, requests and measures taken by the owner of the Standards and accreditation bodies.

k) in the event of founding a significant non-conformity, accept the measures taken by ICEA, provided for in the specific Regulations and implement the operations, propose and carry out the necessary corrective actions within the timeframe agreed with ICEA, completing and submitting the relevant forms within 10 calendar days from the date of notification of the outcome.

l) the non-conformity of the product or suspension of the certification must be communicated to its buyer, giving adequate evidence to ICEA.

m) under suspension, revocation or expiry of the certification, the customer is obliged to:

- immediately cease using the Certificates of Conformity and, in applicable cases, immediately return them to ICEA;
- immediately, cease using all documents, including advertising, and letterhead in which references to certification and the ICEA mark appear;
- immediately, cease using the conformity declarations and certification mark provided for;

n) implement the measures taken by the ICEA, even if they follow the withdrawal or exclusion for pre-existing facts.

Certified bodies must ensure that records of products covered by certification are maintained and accessible to ICEA personnel.

4 APPLICATION FOR CERTIFICATION

Upon submitting an application for registration, the Body is required to fill in, undersign and submit the following documents in the original copy:

1. Contract for the certification ECO BIO COSMETICS AND NATURAL COSMETICS (M6.04.02)
2. Regulation for the certification ECO BIO COSMETICS AND NATURAL COSMETICS (RC6.04.02)
3. List of Fees

The Customer, following the provisions of the Regulation for the Certification, is required to draw up, and subsequently to update, a Management Plan (M6.404) relating to processes/ products subject to certification containing at least: (must be a general one of the applicant and, in the case of other sites, a specific one for those)

a) a full description of the unit and/or site and/or activities;
b) all concrete measures to be carried at the level of the unit and/or site and/or activity to ensure compliance with certification requirements and reference standards.
c) the precautionary measures to be carried to reduce the risk of contamination by unauthorized products or substances and the cleaning measures to be taken at storage sites and throughout the Customer's production chain;
d) control inspections aimed at confirming the effectiveness of all the precautionary measures put in place;
e) the records required to ensure the traceability of the processes and products subject to certification, also for a possible recall or withdrawal of the product or segregation thereof.

In the case where operations are carried out at third-party sites, a copy of the contract signed with the preparer must be supplied, in which at least the following particulars are listed:

a) the commitment by the third-party operator to carry out the operations covered by the contract in compliance with the rules and/or technical Specifications and the Regulation for Certification;
b) the commitment to allow free access to the facilities and the documentation related to the processing in object to the personnel appointed by ICEA;

And the applicant organization signs: a) the commitment to inform the preparer of any changes and updates to the technical Specification of reference and this Regulation.
The necessary agreements between the third-party operator and the requesting organization are dealt with in the form M6.405 SUPPLY AGREEMENTS.
The Customer is obliged to:

1. accept the application of the provisions provided for by the cited regulations;
2. inform its customers in writing in the event of product cancellation, recall or withdrawal of non-compliant products;
3. notify ICEA of any change in the concrete measures adopted and included in the Management Plan within a reasonable time and in any case no later than 30 days from the change;
4. consent, on behalf of themselves and their subcontractors, to the various CBs exchanging information on the operations subject to their control;
5. document the data included in the company accounting;
6. guarantee correspondence between the quantities of incoming and outgoing certified products, and of all incoming and outgoing materials used in the production process

For the request for evaluation of cosmetic products and/or cosmetic ingredients with organic content, in addition to what is described above, the following documents must be submitted:

1. M6.07.07 Product Evaluation Form ECO BIO and NATURAL COSMETICS for the evaluation of finished products (with the description of the production process and production units involved, and the identification of certified organic raw materials; qualitative-quantitative formulation and composition of packaging materials)
2. Results of patch tests and challenge tests
3. draft labels of the products for which certification is requested.

5 PRELIMINARY INSPECTION VISIT

If deemed necessary, the Customer may request a preliminary inspection visit from ICEA. The application must be submitted, in writing, at the time of completing the certification application.
The only purpose of the preliminary inspection visit is to:

- identify the extent, structure and organization of the activities carried out by the applicant Customer;
- assess the degree of preparation of the applicant Customer to support the certification process and ensure compliance with the reference standard (any design activity is excluded).

The Preliminary inspection visit is optional and can only be requested once. The involvement and the number of days required for its execution are determined according to the type and extent of the Customer. The fee is shown in the Rate card under Inspections Audits. The date and planning of the Preliminary Inspection visit are defined by ICEA in agreement with the requesting Customer.

6 EVALUATION

The evaluation carried out by ICEA is aimed at verifying the conformity of the product and/or process of the applicant Body with the requirements of the Technical Specification of reference and includes:

1. the documentary check;
2. the inspection audit on site of the applicant Body (and possibly at the other Bodies involved in the certification);
3. analytic testing (where required by the Specification).

DOCUMENTAL EVALUATION

The objective of the documental evaluation is aimed to verify that:

- the documentation submitted by the Body is both complete and correctly completed;
- the composition of the products for which certification is required complies with the reference standard;
- the raw materials and their sources of supply comply with the reference standard.

ICEA reserves the right to request further information influential for evaluation purposes.

The outcome of the documental evaluation can be:

a) **approved**: in case no Non-conformities (NC) has been detected

b) **approved under reservation**: in the case of NCs detected that do not affect the performance of the following evaluation steps

c) **not-approved**: in the case of NCs detected which affect the performance of the following evaluation steps. In this case, the evaluation process is suspended until the NCs are corrected. If, within 60 working days, the Operator does not provide the correction of the detected NCs and the updating of the documentation, the application lapses (archiving) and may be resubmitted only with the consequent new charge of the amount of the fee due to ICEA

6.2 INSPECTION VERIFICATIONS

The IV is a systematic, independent and documented process to acquire adequate objective evidence and to assess it objectively, in order to determine to what extent the requirements of the standard have been met. It applies to business processes and products. The IV is conducted at the manufacturing facilities declared by the Customer.

The Inspection Verification represents, within the certification process, the evaluation phase.

The IV refers to the individual business activity and represents the minimum unit of the Inspection. The Inspection Verification or the set of Inspection Verifications carried out on the same Customer, even at different times, but which complete the verification of all business processes carried out by the Customer, constitute the Control.

The IV is conducted by the qualified TC and appointed by the ICEA within the period and in accordance with the procedures provided for in the annual Control planning. The IV, depending on the criteria established by the Control, may be with or without prior notice and with or without sampling.

The IV is recorded on the specific Inspection forms that also represent the guideline for its conduct. The outcome of the review of the evidence collected during the Inspection Verification is recorded in the Inspection Report. The Report represents the notification to the Customer of the outcome of the evaluation on the requirements of the standard.

The Inspection Report is signed by the TC that conducted the Inspection Verification and by the Customer or his delegate for acceptance of the content. Any claim made by the Customer will be evaluated by ICEA, during the review, only if recorded in the Report signed at the end of the IV, without prejudice to the Customer's ability to lodge a complaint or appeal against the decisions taken by ICEA. A copy of the Inspection Report and the Sample Report is provided to the Customer at the end of the inspection verification.

The Inspection in relation to the stage of the certification process (issuing or maintaining the certification) and the Risk Class, is divided into:

A) Initial inspection: inspection verification, carried out by the technical controller, upon first application for certification, for the purpose of determining the suitability of the company to the requirements of the standard.
B) Surveillance inspection (with or without prior notice): an inspection verification, carried out by the technical controller for the purpose of determining the continued eligibility for the requirements of the standard.
C) Non-routine inspection (with notice or without notice): an inspection carried out in addition to the targeted annual planning aimed at a specific target.
The **initial inspection** has the purpose to:
1. verify the compliance of the Customer's declaration (Contract or Certification Request, Management Plan, Information Questionnaire) with the effective corporate reality;
2. assess the degree of compliance of the corporate structural, organizational and management aspects with the general and specific requirements contained in the reference standards of the certification scheme, including through:
    a. testing of the corporate procedures during the manufacturing and/or processing and/or commercial process, if applicable;
    b. sampling of matrices/products, if applicable;

The **Surveillance inspection** has the purpose to assess the maintenance of compliance of the corporate structural, organizational and management aspects with the general and specific requirements contained in the reference standards of the certification scheme, through:
    a. verification of the corporate procedures during the manufacturing and/or processing and/or commercial process;
    b. testing of the preventive, precautionary and control measures implemented to mitigate the risks of internal and external contamination of corporate processes;
    c. testing of the conformity and congruity of the inputs employed in the corporate processes and the generated outputs;
    d. sampling of matrices/products, if applicable;
    e. evaluation of any modifications made to the Customer's production processes;
    f. verification of the NC correction, the measures and recommendations identified during the previous assessment activities;
    g. maintaining compliance with the requirements of the standards and adjustment to any modification occurred;
    h. review of customer claims.

The **non-routine inspection** is scheduled in addition to the Annual Inspection Plan.
Instances where non-routine inspection applies are:
- verification of the adoption and effectiveness of the corrective action proposed by the Customer in the event of a non-conformity detected;
- following reports, claims;
- following the issue of Application following the first with significant variations;
- in all instances where events which do not meet the standard programming criteria are detected.

6.3 ANALYTICAL TESTS

The Customer is responsible for the conformity of the products manufactured and placed on the market. For this purpose, the customer adopts a preventive measures plan to mitigate the risks of non-compliance with the requirements of the standard and safety/ stability of cosmetic products. This plan must include monitoring of procedures and sampling of products for analytical tests.
The ICEA Control Plan includes the selection of samples of information to be checked during inspection verification and sampling, and the determination of analytical tests on matrices/products according to the risk of contamination or non-compliant ingredients.
With regard to the inspection audit, the information sample must cover:
- In the case of inspection at customers with assets on behalf of third parties, the sample must refer to at least 33% of its clients
- within the selected clients, the information sample should cover the product manufactured in the largest quantity. However, the product to be sampled may be different depending on a risk

analysis carried out by the TC during the inspection audit or determined according to the diversification of the inspection on the products.

- As part of the identification of the tests to be carried out during the inspection on the selected product, the following is established:
  - Check of the conformity of the qualitative and quantitative formulation (COSMOS) and qualitative formulation (ECO BIO COSMETICS and NATURAL COSMETICS)
  - Check of the conformity with graphics and packaging
  - Check of conformity of the raw materials employed
  - Traceability test
  - Mass balance 1
  - Mass balance 2 (applicable once during the three-year cycle)
- In the case of inspection with clients with own account assets, the information sample must refer to the product belonging to at least two different categories of the following list:
  1. rinse products
  2. emulsions
  3. solid soaps
  4. make up
  5. wet wipes
  6. raw materials
- within the categories identified, the information sample must refer to the product manufactured in the largest quantity. However, the product to be sampled may be different depending on a risk analysis carried out by the TC during the inspection audit or determined according to the diversification of inspection on the products.

6.3.1 Scheduling and sampling procedures.

The analytical tests are scheduled by ICEA according to the criticality of the industrial process, the assessment of risk factors and the type of product.
The characteristics of the product/matrix object of selection and determination of the test are identified by the TCS at the planning stage. However, the TC at the inspection verification stage may, depending on the risk identified, select additional samples and determine their testing.
The samples taken may cover, as appropriate, products and raw materials (such as, for example, those of direct agricultural origin for the purposes of research into the detection of prohibited pesticides), the packaging material and be picked up at the production and storage sites or even at distribution and trading locations, as per Regulation for the Certification.
The sampling procedure is closely linked to the place (in the warehouse, in the production phase) and to the type of product/matrix to be taken. Sampling is performed by the TC and minute in the Sampling Report countersigned by the Custom[1] or his delegate. The Customer receives a copy of the sampling report and therein, before signing it, he can make declarations in his own protection.
Samples are taken at the Customer's sites (production and/or warehouse) or at the market (customer warehouses and distribution sites), according to methods defined in the ICEA operating instruction, drawn up in compliance with the reference standard. These operating procedures ensure that precautions are taken to avoid any modification that may affect the content of the analytes sought and to compromise the validity of the tests or the representativeness of the samples.
The analytical tests to be carried out on samples of matrices or products are geared to detect the presence of analytes and, if present in a quantifiable concentration, their concentration level.
In Annex B, the active ingredients to be researched are listed in tabular form by matrices.
The assessment of analytical test results must refer to the product requirements specified by the mandatory standards or voluntary reference standards (quali-quantitative aspects of the detected substances). If the customer has identified improved features with respect to the baseline requirements, the assessment will be conducted in accordance with what the customer himself declared.
The final sample of matrix/product taken is normally divided into 4 (four) regularly sealed aliquots (so that

[1] If the sampling is made on the market, the customer's signature on the report is not applicable, in such instances, the guarantees are given either by the signing of the report by the customer with whom the sampling takes place or by the proof of purchase (e.g. receipt) of the product taken from the distribution.

it is not possible to replace the contents without damaging the seal or packaging) of which:

a. one aliquot is intended for the test laboratory;
b. two aliquots are stored, for any comparison and/or revision tests, at ICEA;
c. one aliquot is delivered to the Customer.

The samples are subjected to analytic tests:

a. in Laboratories certified by ICEA in accordance with ISO/IEC 17025;
b. the samples are tested with analytical limits of quantification, less than or equal to the critical limit set by the current rules.
    1. If the result of the first test is **compliant,** the analytical[2] investigation is concluded.
    2. If the result of the first test **detects residues** between the limit of quantification of the analytical method and the critical limit defined by the standards in force, ICEA requires the Customer to analyze the causes of the event in order to demonstrate that the detected contamination is accidental and technically unavoidable, and implement the related corrective actions. ICEA's verification of what has been declared by the Customer constitutes an initial investigation in order to evaluate the accidental and technically unavoidable cause of the contamination. In case the Customer is not able to give adequate and exhaustive demonstrations on the causes of contamination, the result of the first test must be considered as **NOT compliant.**
    3. If the result of the first test is **NOT compliant** (presence of ingredients not allowed above the critical limit established by the current standards), the following procedure shall apply:
        a. ICEA, by written communication, notifies the Customer of the ongoing investigation activity, communicates the analytical result, prescribes for precautionary purposes the confinement of the batch until the end of the investigation and requires the Customer to analyze the causes and any information useful to the investigation;
        b. The Customer, within **15 days** from the date of receipt of the communication, may request, under penalty of expiration, the second test on one of the additional aliquot stored at ICEA, at another laboratory, already indicated in the sampling report;
            i. the outcome of the second trial settles the case;
            ii. during the **15 days** the Customer may decide to conduct a test on the sample aliquot in his possession, kept in accordance with the rules of reference; the outcome of this test is freely assessable by ICEA;
            iii. ICEA, at the conclusion of the investigation, based on its outcomes, will proceed to determine the definitive measures to be taken.

7. REVIEW

The Review is the verification of the suitability, adequacy and effectiveness of the entire evaluation activity which combines the Review of the Application, the results of the Inspection and Sampling. The evaluation process concludes with the Review. The TCS is the function responsible for the Review. The outcome of the Review can generate the proposal to the CCERT, with the description of the structural and management characteristics of the Client, accompanied by the certification document for the subsequent Decision phase. All the documented information on which the Review is based is available on the WICEA management system.

8. CERTIFICATION RESOLUTION

The CCERT (Certification Committee), based on the review and the proposal of the TCS, decides on compliance with the certification scheme necessary for the next management steps.
CCERT also decides on derogations and concessions.

8.1 DECISION TO ISSUE THE CERTIFICATION

The decision to issue the Certification provides:

a) Issuing the Certificate of Conformity and sending the certification documents to the customer;

[2][If the first sample detects residues between the limit of quantification of the analytical method and the critical limit established by current standards, the CB reserves the right to perform the second sample and the Responsible Client shall perform a root cause analysis of the event and implement relevant corrective actions

b) registration of the customer and certified products in the WICEA database.
c) publication on the ICEA website of certification documents relating to the customer
d) Communication to COSMOS

The decision to issue the Certification is registered on the WICEA computer system.

8.2 DECISION NOT TO ISSUE CERTIFICATION

The decision not to issue the Certification is notified by ICEA to the customer within **10 days** of its recruitment, by email/CEM, with the following specifications:

a) the reasons for the decision;
b) timing and procedures for the submission by the customer of any corrections or corrective actions required;
c) timing and procedures of filing an Appeal.

Following the decision not to issue the certification, the customer can continue the admission procedure by demonstrating that they have implemented the corrections/ corrective actions requested by sending, within the established deadlines, complete supporting documentation. In this case, ICEA will proceed with the Review and will carry, if appropriate, further inspections.

If, within the communicated deadlines, the customer does not ensure the restoration of the conformity, the application for the certification is to be considered automatically forfeited and may be resubmitted, resulting in a new charge of the fee due to ICEA.

8.3 CERTIFICATE OF CONFORMITY (COC)

The Certificate of Conformity is issued following the favourable decision of the CCERT, to each customer who meets the requirements of the Regulation.
The responsibility for the decision-making and issuing process lies with the CCERT.
The CC has a validity period of **36 months** from the date of issue or until revocation by ICEA.
The information contained in the COC complies with the reference standards and, in any case, the COC shall include the following data:

- unique identification number of the document, the customer, references to ICEA and accreditation;
- name, the address of the registered office of the customer;
- full address of the production/site/s/s verified (if applicable);
- date of first issue and expiry of the certificate;
- Field of application of the Certification
- For COSMOS certified ingredients the following percentages shall be reported:
  - PPAI;
  - organic PPAI;
  - CPAI;
  - organic CPAI;
  - petrochemical moiety;
  - non-natural ingredients;
- for COSMOS certified products, which could be identified by the type or range of products, the certification level must be reported
- signature of the Responsible for the Issuance with the extension of the name, surname and job title.

The CC is issued within **30 days** of the date of resolution of the certification requirements.
The CC shall be updated in the following circumstances:

1) following a **three-year revaluation;**
2) following amendments of the Application for Certification
3) as a result of variations involving the extension or reduction of certified processes and products

The update of the publication on the website www.icea.biorelative to the certification takes place simultaneously with the issuance or within the deadlines set by the reference standards.

The customer to whom the CC is issued is directly responsible for the proper use of such documentation and material.

The customer, only following the issuance by ICEA of the CC, has the right to:

- make the Certificate of Conformity public;
- make Declarations of Conformity on the product;
- use on the label of the products subject to certification the declarations of conformity provided by the Certification Standards and the related Labelling Guides;
- use, in the technical sheets and advertising material, only referring to the products subject to certification, the declarations of conformity required by the standards and reference standards.

The withdrawal or suspension of the certification implies the automatic termination or suspension of the CC.

8.4 RAW MATERIAL APPROVAL CERTIFICATE

The certificate of conformity to the COSMOS Non-organic Raw Materials (NOI) Specification is the declaration of conformity of ingredients that can be used in COSMOS-certified products and raw materials. It is issued following a request from the customer and provides for a documental evaluation.

The verification of ingredients to COSMOS compliance requirements is carried out by the qualified and authorized technical secretariat. The evaluation is shared with the COSMOS Technical Committee (TC APPROVAL COMMITTEE).

The technical secretariat sends the TC Approval Committee by the 15th of each month the evaluation carried out and within 10 days the TC Approval Committee expresses itself on the conformity of the assessment. In cases where Certification Bodies reach conflicting decisions on an ingredient, ICEA 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.

The overall evaluation is entrusted to the TCS which proposes the issuance of the certificate to the CCERT.

Following the Control Manual 8.3.6 Scope 2, the Raw Material Approval Certificate (APPR) is reviewed every 12 months or, in the event of any amendments, or until revocation by ICEA. The revaluation of the certificate must be carried out at least every 3 years or in case of any modifications or, anyway, until revoked by ICEA.

The information contained in the certificate is following the reference standards and, in any case, the certificate must include the following data:

- The unique identification number of the document, the customer, references to ICEA and accreditation;
- The name and address of the customer's registered office;
- The date of the first issue and expiry of the certificate;
- the scope of the Certification
- For non-organic Raw Materials (US) the following percentages must be reported:
  - PPAI;
  - CPAI;
  - petrochemical moiety;
  - non-natural ingredients;
- The signature of the Responsible of the Issuance with the extension of the name, surname and job title.

The certificate must be issued within **30 days** of the date of the resolution of the approval requirements.

The update of the publication on the website www.icea.biorelative to the approval takes place at the same time as the issue, or within the deadlines set by the reference standards.

The customer to whom the certificate is issued is directly responsible for the proper use of such documentation and material.

The customer, only following the issue by ICEA of the certificate, has the right to:

- make the certificate of approval public;
- make Declarations of Conformity on the product;
- use on the label of the products subject to certification the declarations of conformity provided by the Certification Standards and the related Labelling Guides;
- use, in the technical data sheets and advertising material, only referring to the products submitted for approval, the declarations of conformity required by the standards and reference standards.

The withdrawal or suspension of the certification shall automatically terminate or suspend the certificate.

8.5 RENEWAL OF CERTIFICATE

The Certificate of Conformity are renewed after the end of validity of 36 months, following a review and positive decision by the CCERT.

The renewal involves carrying out the phases of the certification process starting from the review of the application, the evaluation and the final review.

The renewal process can be developed through audits conducted no later than 12 months prior to the review.

The CCs are issued within 30 days from the date of resolution of the requirements relating to certification.

The updating of the publication on the website www.icea.bio relating to the certification/approval takes place simultaneously with the issue or within the deadlines set by the reference standards.

8.6 EXTENSIONS/REDUCTIONS OF THE SCOPE AND PRODUCTS SUBJECT TO CERTIFICATION/APPROVAL INCLUDING CHANGES TO CERTIFIED PRODUCTS

The extension or reduction of the scope and products subject to certification/approval is released following a review and positive decision by the CCERT.

The extension and reduction involve carrying out the phases of the certification process starting from the review of the application, the evaluation and the final review.

The extension process can be developed through audits conducted no later than 12 months prior to the review

The CC and the raw material approval certificate are issued within 30 days from the date of resolution of the requirements relating to certification.

The updating of the publication on the website www.icea.bio relating to the certification/approval takes place simultaneously with the issue or within the deadlines set by the reference standards.

Please refer to the Management Instruction for Certificates of Conformity and Certificates of Approval for further details.

8.7 DEROGATIONS

In accordance with the reference standard, it is possible to establish specific conditions for the application of derogations. The CCERT decides on the application of the exemptions.

9. LOGO PROVIDED

Companies that obtain Conformity Certification from ICEA, in compliance with the ICEA Eco Bio Cosmetics and Natural Cosmetics Disciplinary and these Regulations, will be able to access the use of the following logos according to the rules set forth in the Logo Use and Certification Regulations (attached to the Operations Manual) of the ICEA trademarks.
The different graphic versions authorized can be requested from the competent ICEA office.
Please find below some of the black and green versions.

XXX BC XXX

XXX BC XXX

XXX BC XXX

XXX CN XXX

XXX CN XXX

XXX CN XXX

The alphanumeric code shown within the mark is composed as follows: **XXX** (operator code) **BC** (cert scheme) **XXX** (product number) **XXX** (operator code) **CN** (cert scheme) **XXX** (product number)

10 ICEA LABELS AND TRADEMARK

10.1 Labels and Declaration of Conformity

All labels, primary and secondary packaging accompanying the placing of the product on the market and indications concerning the certification reported on those, must always comply with the requirements of the certification regulations and specifications and be authorized by ICEA.
Only packaging not intended for the consumer, useful for the handling of the product, may bear simplified information for the purpose of identification and do not require authorization from ICEA.

10.2 Use of the ICEA trademark

The registered ICEA trademark is the exclusive property of ICEA Consortium. The ICEA trademark distinguishes the homonym Certification Body and enables the identification of the certified operators who have obtained the certification on the Certification Schemes implemented by ICEA.
It is therefore agreed that the use of the ICEA trademark and the Certificate of Conformity is regulated by the following.

10.3 Granting and use of the trademark.

The use of the ICEA trademark for the labeling of products is excluded from the scope of this chapter.
The Customer subject to the Certification Scheme may request the authorization to use the ICEA trademark for its own communication (press, *internet, television radio, etc.).*
The Certified Customer may make public the Certificate of Conformity and documents related to the products covered by the certification, complying with the specific requirements of the Specification, mandatory standards, as well as ICEA Regulations.
The Customer is not allowed to implement incorrect or misleading forms of certification communication, that is, such as to mislead the recipients of the message. The communication must always be clear, and truthful and related to the scope of the certification, meant as the set of information on the certificate of conformity (reference standard, certified bodies, date of issuing, current issuing of the certification, certified products, etc.). It is forbidden to make references to the certification, as well as the use of the logo when the certification has not yet been issued or has been revoked or suspended or the Customer has waived it.
The Customer must not implement forms of communication which might discredit ICEA.
The certification, its publication and advertising use is reserved to the certified Customer and is not transferable to other subjects not authorized by ICEA.

10.4 Requirements for the communication of the certification and use of the logo

The certified Customer must, always and in advance, request the authorization of ICEA for any communication regarding the certification (advertising, letterhead, etc.), by sending the drafts that will be subject to conformity assessment.
The authorization of ICEA is binding and the Customer must comply with the decisions of ICEA itself regarding the communication of the certification.

The specifications regarding the use of the certification logo are set out in the Product Specification, in the labeling guidelines and in the Certification Regulation for the single scheme.
It is forbidden to extract the logo from documents, or any other form of publication. In the case of reductions or enlargements, the dimensional proportions of the figures and text must always be respected, within the single logo and between the different logos.

10.5 Irregular use of the ICEA Trademark

In cases of irregularities and infringements under the conditions laid down in this document, the measures provided for in the Regulation for the Certification shall apply. However, ICEA may activate, in the appropriate venues, the instruments provided by law to protect the trademark or for breach of contract.
ICEA establishes, in the case of non-certified operators (Companies/ Bodies not included or no longer part of the ICEA Certification Scheme), the severity levels of inappropriate use of the trademark:

a. **minor**: when the good faith of the Company using the trademark is demonstrated and the image of the trademark is not affected;
b. **major**: when the good faith of the Company using the trademark is not demonstrated and a concrete danger to the image of the mark is determined;
c. **serious**: when incorrect or fraudulent behavior of the Company using the trademark is revealed which damages the image of the trademark, as well as in case of repetition of minor violations.

In all cases ICEA activates, in the appropriate venues, the instruments provided by law to protect the trademark or for breach of contract.

11. NON CONFORMITIES

Non-conformity defines the non-compliance with the certification requirements of the reference standards and the ICEA regulation for certification.
Finding of a non-conformity occurs as a result of:

- inspection audit
- documentary check
- analytical test results
- re-examination
- claims and/or information acquired from outside

Non-conformities are divided into:

- MARGINAL NON-CONFORMITIES,
- IMPORTANT NON-CONFORMITIES (Minor),
- ESSENTIAL NON-CONFORMITIES (Major).

Following the non-resolution of the Non-conformity, ICEA applies measures proportionate to the importance, nature and circumstances that led to the non-conformity based on the reference standard.
The non-conformities detected during the audit, as well as the measures applied, are clearly stated at the points of the Regulation for the certification of the selected certification scheme.
The Customer, following the issuance of the Non-conformity, submits to ICEA, within the established terms, the analysis of the causes, the correction of the non-conformity and any corrective action.
Following the release of the decision, any lodge of Appeal against the decision does not suspend the effectiveness of thereof and does not, in any case, exempt the Customer from complying with all the obligations and requirements contained therein.

Marginal Non-Conformities

Marginal Non-conformity is a minor non-compliance that does not compromise the conformity of the production process and/or the self-reliance system control over the production method or the management of the company documentation and it is characterized by not having long-lasting effects and not causing substantial changes in the "status" of the company and/ or product compliance and/ or customer reliability.

Marginal Non-conformities do not involve the application of a measure but, in case of repetition in the subsequent inspection, will be considered Important Non-Conformities (Minor).

Important Non-Conformities (Minor)

Important Non-conformity (Minor) is a non-compliance that compromises the qualification of the products, but not the conformity of the manufacturing process and/or the self-control system over the production

method or management of business documentation, and it is characterized by not having long-lasting effects and not causing substantial changes in the "status" of the company.

Failure to resolve Important Non-conformities results in the application of the Deletion of Conformity claims on the product.

Essential Non-Conformities (Major)

Essential Non-Conformity (Major) is a substantial non-compliance that compromises the conformity of the production process and/or the self-control system over the production method or the management of the company documentation or compliance with the contractual obligations assumed towards ICEA, and it is characterized by having prolonged effects such as to determine substantial changes in "status" company and/or product compliance and/or customer reliability.

Essential Non-Conformities that are not corrected involve the application of the Deletion of certification or the Revocation of certification.

ICEA notifies the Non-conformity through the Report provided to the customer, containing the indication of the detected failure, the evidence collected and the regulatory requirement not fulfilled. The notification must also include a request to the customer for analysis of the causes, correction and/or corrective measure. The customer must carry out this activity within 15 days of the detection of the NC.

ICEA, through the review of the TCS, is entitled to modify the classification or cancel or issue ex novo a Non-conformity by notifying the customer within 15 days from the date of the inspection or its detection.

The TC that accepted the proposed corrective action, within 10 days of receiving evidence of the planned correction and/or corrective action, formally notifies the TC of the closure of the non-conformities and indicates the measures for verifying the effectiveness of thereof.

Verification of the closure of the non-conformity is carried out by a documentary check or, where appropriate, a new Audit.

Verification of the effectiveness of the measures implemented to correct the non-conformity may be done through inspection visits planned for this purpose or included in the regular annual planning.

12. MEASURES

Measures are prescriptive actions that are taken as a result of failure to meet requests for corrections and/or corrective actions.

The measures consist of actions for

i. Deletion of the declaration of conformity on the product
ii. Suspension of the Certification or reduction of field of application
iii. Revocation of the Certification

Measures is managed by TCS and follows the procedures outlined for non-conformities.

The Technical Secretariat fills out the specific form for the measure, TCS performs a review and sends the request for a resolution to CCERT through WICEA. Decisions on the measures are taken by the CCERT for both the issue and the suppression/revocation.

The timeframes for the management of the measures, that is to say between the expiration date of the management of the non-conformity and the decision of the CCERT, must fall within the **10** working days.

If the certification is deleted (at the request of the customer), suspended or revoked, or the purpose of the certification is reduced, the TCS takes the actions specified in the certification scheme and amends the formal certification documents, public information, trademark authorizations, etc., to ensure that the customer does not provide any declaration that the product continues to meet the certification requirements.

12.1 Revocation of declarations of conformity from the product

The deletion of the declarations implies the prohibition for the customer to include, in the graphics and the documents of the products concerned, the declarations concerning the certification concerning the lot or the entire production affected by the measure. Failure to comply with a Deletion of references to the certification may lead to the application of a more significant measure.

The measure is decided by the Certification Committee and is notified by sending the form M6.10.02 to the customer by e-mail and/ or CEM, which will specify the reasons for the cancellation, the conditions under which the deletion may be lifted and the timeframe within which the appeal may be lodged.

In case of no appeal, the measures, as well as the corrective actions required, will be considered accepted by the operator.
The Cancellation of the declarations also provides for the obligation for the Customer to give evidence of the required compliances and to submit a proposal Corrective for Action within 15 days of receipt of the measure.
The TCS verifies the application of the requirements relating to the measure, the effectiveness of the correction of the Non-conformity and evaluates the proposal for Corrective Action within 10 days of receiving the Customer's communication, through a documentary check, or, if necessary, by carrying out a new inspection. At the end of the implementation phase of the Corrective Action, the TCS plans the actions for the verification of the effectiveness of the same through a documentary evaluation, or, if necessary, through the execution of a new inspection.
Failure to comply with a Deletion of Declarations (failure to process the non-conformity by the Customer, within the prescribed period) or the recurrence within 24 months of the same type of non-conformity, leads to a more serious non-compliance resulting in the application of the corresponding measures.
Where the irregularity is caused by unforeseeable events, the same shall not be calculated for recurrence.

12.2 Suspension of certification

The suspension of the certification consists in the temporary suspension of the certificate of conformity and is applied if the Non-conformities detected compromise the reliability of the customer audited.
The suspension shall result in the prohibition for the customer, for the specified period, to place on the market products with references to the certification.
The verification of the corrective action is carried out in the terms and in the modalities provided for by the measure itself. Failure to comply with a suspension normally results in the exclusion of the customer from the ICEA certification system.
The measure is decided by the Certification Committee and is communicated to the customer by sending the M6.10.03 form by e-mail and/or CEM. The notice of action specifies the reasons for the suspension, the conditions for the restoration of certification, including the conditions under which it may be lifted, and the timeframe within which the appeal may be lodged.
In case of no appeal, the measures, as well as the corrective actions required, will be considered accepted by the operator.
The effectiveness of the Suspension of Certification starts from the date on which the Customer received the notification of the measure; where the measure also provides for the Deletion of Declarations, the provisions of the previous paragraph shall also apply.
The Suspension of Certification also provides the Customer to provide evidence of the required procedure and to submit a proposal for Corrective Action within 10 days of receiving the measure.
The TCS verifies the implementation of the provisions relating to the measure and evaluates the proposal for Corrective Action within 10 days of being notified by the Customer, either by a documentary check or, if necessary, by carrying out a new audit. At the end of the implementation phase of the Corrective Action, the TCS plans the actions for the verification of the effectiveness thereof through a documentary evaluation, or, if necessary, through the execution of a new audit.

12.3 Revocation of certification

The revocation of the certification measure applies in the case of infringements that compromise the operator's reliability in the management of the company and, therefore, its permanence in the control system, including when there is a recurrence in committing infringements, or if the customer does not comply with the binding commitments and contractual obligations towards ICEA.
The following cases of non-compliance with the standards set out in the ICEA Regulation for certification adopted will result in the revocation of the certification and will constitute a cause of law resolution of all the agreements "inter partes":

a) failure to carry out corrective actions, which should have resulted from the suspension of the certification referred to in point 6.9.2 above;
b) detection of ESSENTIAL NON-CONFORMITY and breaches of the obligations under the reference standard and the applicable Regulation for the Certification;
c) objection by the customer to the execution of the surveillance inspections;
d) use by the customer of the Certificate of Conformity in breach of the provisions of the relevant articles of the ICEA Regulation for the certification, applicable.

e) serious or repeated breaches concerning the appropriate use of the certificate and the indications of compliance;
f) cessation of the productive activity of the customer;
g) failure to submit the documentation requested by ICEA within the prescribed/prescribed timeframes;
h) exclusion in cases of default: in case of non-payment of the fees due for the control and certification activity on the due dates and after two demands for payment from ICEA.

The exclusion of the customer, with consequent termination of all "inter-partes" agreements, is resolved by ICEA, following the decision of the Certification Committee and notified to the customer by e-mail and/or CEM by sending of the M6.10.04, specifying the reasons and time frame within which an appeal may be lodged.
The TCS notifies COSMOS within 5 days of the revocation of the certificate of conformity to the Cosmos standard in the manner established by the owner of the scheme. COSMOS has the right to establish that ICEA does not offer certification services to the Customer whose certificate of conformity has been revoked, also establishing the period

12.4 Termination of certification

12.4.1 Voluntary withdrawal

The customer may waive the certification if he does not accept any amendments made by ICEA to the certification conditions and, in any other case, following submission of a written request to be presented with a notice of at least 30 calendar days.
The customer, in any case, must comply with the control and certification system until complete disposal of the labels (intended as completion of packaging and labelling) and other material bearing the indications of conformity and the certification mark, bearing the costs of control and certification due to ICEA.
Placing the compliant product, already packaged and labelled, on the market must, in any case, be discontinued within 18 months of the date of withdrawal of the certification.
In the event of a voluntary withdrawal request by the customer, it proceeds with its exclusion and consequent resolution of all the "inter-partes" agreements.
By resolution of the Certification Committee, ICEA notifies the customer of the exclusion from the certification system by sending the CD-M0608 form by e-mail and/or CEM.
The Customer is obliged to carry out any measures taken by ICEA, even if following the withdrawal, for facts before thereof. In the case that the Customer has measures for deletion and suspension not closed yet, ICEA, before accepting the withdrawal request, proceeds with the verification of the application of the correction, carrying out, if appropriate, also a non-routine Inspection.

12.5 Actions resulting from the termination, reduction, suspension or revocation of certification

In case of evidence of non-conformity concerning certification requirements, arising from surveillance activities or another detection process, ICEA shall consider and decide on the actions to be taken, including

- Maintaining the certification according to the requirements specified by ICEA;
- Reducing of the scope of application by removing non-compliant products and processes;
- Suspension of certification pending corrective action by the operator;
- Revocation of certification.

Each action must include the assessment, review or decision on the certification.
In the case of withdrawal at the request of the customer, suspension or revocation of the certification, TCS is in charge of all necessary modifications to the certification documents, public information, trademark authorizations, etc., to ensure the management of individual cases including the case where the product/process can continue to be certified.
In the case that, as a condition of restoration of the certification, the decision to reduce the scope is taken, ICEA takes the actions specified by the certification scheme and makes all the necessary amendments to the formal documents, public information, trademark authorizations, etc., to ensure that the reduction in scope is clearly communicated to the customer and is clearly specified in the certification documents and public information.

12.6 Annulment and revocation of measures

12.6.1 Annulment of a measure

The annulment of a measure is implemented when an issued measure is made to lose its effectiveness, as a result of an appeal lodged by the customer, or it can be operated on a self-defense basis by ICEA following

the review process.
The annulment has a retroactive effect and causes the measure to lapse from the moment it was issued and with it all its effects allowing the "full reinstatement".
The cancellation must be decided by the CCERT and communicated to the operator by e-mail and/or CEM.

12.6.2 Revocation of a measure

The revocation of a measure applies when the audited customers obtain the revision of the measure and its withdrawal, with a non-retroactive effect (ex nunc, that is "from now"), therefore, the effects of the act are maintained and are valid until the moment of revocation.
The revocation of the measure can be applied only after a positive outcome of a verification carried out by ICEA to detect the effectiveness of corrective actions taken by the Operator.
The revocation must be decided by the CCERT and is communicated to the operator by e-mail and/or CEM.

12.7 Obligation to cease the use of the Certification

The Customer is obliged to immediately cease the use of the Certificate of Conformity and the identification trademark in the following cases:

- Upon expiration of the validity period of the Certificate of Conformity;
- in the cases provided for by the ICEA Regulation for Certification;
- in all cases in which the Customer waives the certification;
- in all cases of termination, at any title, of the Contract;
- in all cases stipulated in the standard of reference.

In order to ensure that there is no indication that the product continues to be certified, ICEA notifies the customer of the decision, deletes the product certification references from the ICEA and COSMOS databases and verifies, within 3 months of the notice of termination, any use on the market of references to the certification (website or other communication systems).
If the Customer uses the Certification in breach of the above obligations, ICEA, without prejudice to any other action, may make public, in the ways deemed most appropriate, that the Customer is no longer entitled to the use of the Certification.

12.8 Record of measures

The different types of measures are recorded in the WICEA computer system where the following information is present:

- Company name and its identification code;
- The registered office and the operational headquarters;
- The date, protocol and type of measure taken;
- The justification of the measure taken and the reference to the disregarded point of the standard and/or the Internal Technical Regulation for the Certification;
- The type (=description) and the date of the detected non-conformity and its code;
- The duration and/or term of the measure.

ICEA will make these records available to those entitled upon submission of appropriate and motivated requests.

13. AMENDMENTS TO THE CERTIFICATION REQUIREMENTS

13.1 Amendments to the Standards and/or Technical Specifications

These amendments are notified to all Certified Bodies by means of a notice of publication on the website www.icea.bio, indicating the deadline by which they must adapt to the new requirements or specifications.

The period within which adapt the certified formulations, based on the previous version of the specification, may not exceed 12 (twelve) months from the date of notice of publication.

After the expiry of this period, the applicant Body has the right to waive the certification. If it decides to maintain it, ICEA (through documentary checks or, where relevant, inspection checks and/or type tests) will check compliance with the new requirements.

The costs of any visit shall be charged to the applicant Body .

13.2 Amendments to the Regulation for the Certification

In the event that amendments are made to the requirements contained in this Regulation, the new revision of the same will be communicated by email to Certified Bodies at least 30 days (calendar) in advance of the date of the start of application. ICEA will also ensure to publish the updated text of the regulation on the web page at www.icea.bio.

After this deadline, the Certified Body is required to accept the new conditions provided by the Regulation or, if not, notify ICEA of the waiver of certification (within 30 calendar days of receipt of the communication).

13.3 Amendments to the Contract for the Certification

In the event of amendments to the requirements contained in the Contract for the Certification , the new revision will be notified by email to the certified Bodies at least 30 days (calendar) in advance of the date of application. ICEA will also ensure to publish the updated text of the Contract for the Certification on the web page at www.icea.bio.

After this deadline, the Certified Body is required to accept the new conditions provided by the Application for the Certification or, if not, notify ICEA of the cancellation of the certification (within 30 calendar days of receipt of the communication).

13.4 Amendments to the rate card

In the event of amendments to the economic conditions contained in the rate card, the new revision thereof will be notified to the requesting Body at least 30 days (calendar) in advance of the date of application.

The certified Body is required to accept the new rate conditions, otherwise, notify ICEA of the waiver of the certification (within 30 calendar days of receipt of the communication). ICEA will also ensure to publish the updated rate card on the web www.icea.bio.

In all cases of waiver mentioned above, the operator will still be obliged to pay the fee due for the activity carried out by ICEA during the year.

14. AMENDMENTS AND EXTENSION OF THE FIELD OF CERTIFICATION

The certified organization may request amendments to the scope of the certification. Such amendments may concern:

- changes to the Company Name and/or changes to the Organisation;
- modification or extension of production units;
- modification or extension of products and/or processes subject to certification.

The procedure for applying for such amendments is the same as that for the submission of the application for certification. The request must make clear only the aspects and/or products subject to modification and extension.

The issuing and/or revision of the Certificate of Compliance, that takes into account the modification and/or extension of the scope of the certification, is subject to the favorable judgment of the documentary evaluation by the RCS/TCS.

15. CONFIDENTIALITY

In order to gain access to the proprietary information necessary to conduct effective conformity assessment activities and to convey confidence that confidential information will not be disclosed, ICEA, except for information that the customer makes publicly available, or when agreed with the customer, or when the law and the relevant rules require the disclosure of proprietary information, consider all other confidential information and adopt specific procedures for keeping it confidential. All ICEA personnel undertake, through specific statements, not to disclose the proprietary information acquired through the Certification Scheme.

ICEA is accountable for managing all information obtained or produced during the performance of certification activities. Except for information that the Operator makes publicly available, or when agreed between ICEA and the Operator, all other information shall be considered proprietary information and

shall be kept confidential. ICEA must indicate to the customer, in advance, the information that it intends to make public.
Information about the Operator obtained from sources other than the Operator itself (for example, the complainant or legislative authorities) shall be treated as confidential information.
The above does not apply to requests from surveillance and accreditation bodies.

16. CLAIMS, APPEALS & LITIGATIONS.

The Operator has the right to submit claims or appeals to ICEA in writing.

- Claim is the manifestation of the dissatisfaction of the Operator with regard to the administrative and technical aspects of the activities carried out by ICEA.
- Appeal is the explicit and documented manifestation of non-acceptance of the decisions taken by ICEA within the scope of its activities.
- Litigation derives from the possible non-acceptance by the Operator of the decisions communicated against the Appeals or, from disputes generated by alleged errors.

16.1 Claims

Claim is an expression of dissatisfaction, other than the appeal, manifested by a person or an organization to ICEA related to the activity of this, where a response is expected.
RSC (RCS) is the function that evaluates claims received by ICEA. Based on the documentation provided by the claimant and on the documentation provided by the Certification Committee (CCERT), TCS, TC in relation to the procedures of the implemented certification schemes, the RSC (Responsible for the Scheme) evaluates:

- whether or not to accept the claim
- in case of non-acceptance, the claim is classified as unfounded, setting out the reasons for non-acceptance;
- if the claim is based on objective inadequacy of the activities carried out by ICEA, the RSC (Responsible for the Scheme), determines the actions necessary to satisfy the request of the claimant;

RAQ (The Responsible for Quality Assurance) informs the CSI of the progress of the Claims and of any findings relating to the reference standards and procedures.

16.1.2 Claims Management

ICEA takes charge of the claims from any entity (Operators, PA, Accreditation Bodies, customers of companies certified by ICEA, interest groups, etc.) that object to ICEA services, its way of acting or decisions relating to the certification process. The Claims is written and can be sent either by e-mail to: reclami@icea.biosia or by mail to the ICEA Quality Office at the Bologna Headquarters or by accessing the "Reports" service on the website homepage at www.icea.bio.
The Claim, in order to be evaluated, must include at least:

- name of the person submitting the claims;
- company or Entity name (if relevant);
- postal or email address;
- reference to service, office, area;
- reason and clear evidence of the claim.

Within **7 days** of receipt of the Claim, ICEA notifies taking charge of the same, activating the appropriate actions for its management.
ICEA ensures the management of the Claim by sending a written response on the outcomes, within **30 days** of taking charge of the same. In the case where further investigations are required, with Inspecting Verifications for the planned scope or involvement of other C.B., the answer will be sent within **60 days** from the date of the takeover of the same one.
The Responsible for Quality Assurance (RAQ) regardless of the actions taken for claims, assesses whether there are grounds for opening an internal NC and its subsequent management.

16.1.2 Confidentiality

ICEA is responsible for managing all information obtained or produced during the performance of the certification activities. With the exception of the information that the Operator makes publicly available, or when agreed between ICEA and the Operator, all other information shall be considered proprietary information and shall be kept confidential. ICEA must indicate to the customer, in advance, the information

that it intends to make public.
Information about the Operator obtained from sources other than the Operator itself (for example, the claimant or legislative authorities) shall be treated as confidential information.
The above does not apply to requests from supervisory and accreditation bodies.

16.1.3 Claims received by the Operator

Claims and/or appeals related to the conformity of the product received by the Operator must be immediately communicated to ICEA and, in any case, no later than 5 days. The operator must keep records of all claims and appeals received concerning the certified products. The Operator must also notify ICEA promptly, in any case no later than **5 days**, of the outcomes of controls carried out by the competent authorities in case of disputes of non-conformity.
These records, together with corrections and corrective measures taken by the Operator, must be made available during the Control phases.

16.1.4 Dispute during the Audit

The Operator, in the case that he does not agree with the assessment of the technical staff in charge, has the right to report and the obligation to sign in the Audit Report the reasons for its disagreement.

16.3 Appeals

The Operator may appeal against a decision of ICEA within **15 days** of receipt of the same, by sending the communication, in writing and by registered mail with return receipt or CEM to the address recursion@iceapec.info , to the Appeals Committee (CRR) stating the specific grounds on which the appeal is based and supporting evidence. Upon receipt of the Appeal, within **7 days**, ICEA informs of its taking charge and the consequent opening of the procedure in front of the Appeals Committee (CRR). Within **30 (thirty) days** from the date of taking charge of the Appeal by ICEA, the Appeals Committee decides upon the matter. The outcomes of the Appeal are communicated b ICEA, within **7 days** from the date of decision of the Appeals Committee. The acceptance of the appeal may entail the obligation for ICEA to review or annul the contested measure.
Following the receipt of the Appeal, RSC (Responsible for the Scheme) assesses the administrative compliance of the Appeal, communicating with the taking charge of the opening of the evaluation process by the CRR and its management timeframe. The take of charge notice is sent via CEM to the appellant, the CRR, the Certification Committee (CCERT)/TCS and the Competent Authority (ICQRF competent for the territory). The outcomes of the appeal are communicated by ICEA to

1. Appellant
2. CCERT/TCS
3. Competent Authorities: Ministry, Regions and Autonomous Provinces of Trento and Bolzano by uploading in "Supervisory Database"; pending the activation of the specifications in the Supervisory Database, the communication is sent via CEM to the ICQRF (Inspectorate for fraud repression and Quality protection of the agri-food products and foodstuffs) and Region responsible for the territory.

RAQ (Responsible for Quality Assurance), regardless of the actions initiated for Appeals, evaluates whether there are grounds for opening an internal NC and its subsequent management.

16.4 Litigations

ICEA registers the communications related to Litigations in the relevant section of the Claims & Appeals Register by activating the Board of Directors for the legal management of the case.

17. EXTERNAL ORGANIZATIONS

17.1 Testing laboratories

ICEA does not have internal laboratories. To carry out the sampling activity, ICEA can make use of companies operating in this sector upon signing a specific agreement.
The DIR is responsible for the qualification of External Organizations. The RSCs collaborate in the process.
The RAQ supports the DIR and RSCs in the evaluation, qualification and monitoring process.
The process is structured into the following phases: identification of laboratories, evaluation, inclusion of the list of qualified affiliated laboratories.
A prerequisite for identifying the laboratories is accreditation against the UNI CEI EN ISO/IEC 17025 standard in relation to the tests of interest and that they are included in the list referred to in the art. 2 of Ministerial Decree n. 2592 of 12 March 2014. If the laboratories qualified by ICEA do not provide tests on

specific matrices, the TCS identifies other accredited laboratories capable of carrying out the requested test, communicating this to the RSC.
At the conclusion of the preliminary evaluation expressed on the laboratory, the DIR formulates a summary judgment of the type:

a. Qualified
b. Qualified with reservations
c. Not Qualified

The judgment is the result of the numerical determination attributed to the individual parameter. This judgment is indicated at the bottom of the evaluation on the form
For the laboratories found to be Qualified, the RSC proceeds, if necessary, to:

1) draw up a specific Agreement which must be submitted for signature by the Legal Representative of the testing laboratory;
2) register the laboratory in the "Register of Qualified Affiliated Laboratories" and manage the list of accredited tests for each of them.

With each change to the Register, the RSC promptly updates the reference functions.

17.2 Specialized Service Providers

This category includes service providers, other than Testing Laboratories, to support the certification process. The Qualification Process follows the same criteria and operating methods as the Laboratories with reference to the satisfaction of specific requirements and parameters of the service being evaluated.

17.3 Evaluation Personnel - Subcontracting

The procedure for managing requirements relating to external resources is developed through:

- Selection of External Bodies (by the RSC):
  - Verify that the selected external bodies meet the requirements of the relevant international standards and other documents specified by the certification scheme.
  - For testing, ensure that external bodies comply with the requirements of ISO/IEC 17025; for inspections, of ISO/IEC 17020; and for management system audit activities, of ISO/IEC 17021.
  - Verify compliance with impartiality requirements for personnel involved in the evaluation.
- Management of Activities Outsourced (by the DIR):
  - Enter into a legally binding contract with the external body, including provisions on confidentiality and conflict of interest as specified in paragraph 6.1.3, c) of ISO/IEC 17065:2012.
  - Take full responsibility for all outsourced activities.
  - Ensure that the external body and its staff are not involved in a way that compromises the credibility of the findings.
  - Maintain an updated list of qualified entities for outsourced services.
  - Apply performance evaluation tables provided maintain documented information;
  - Implement corrective actions in case of violation of the contract or other requirements detected.
- Communications with the Customer (by TCS):
  - Inform the client in advance of any activity that will be outsourced.
  - Provide the customer with an opportunity to raise objections regarding outsourced activities.
- Continuous Monitoring (by the RSC):
  - Constantly monitor the performance of external bodies through periodic evaluations.
  - Implement corrective actions in response to any deviations from the certification body's requirements or expectations.
- Registration and Documentation (by TCS):
  - Maintain detailed records of outsourced activities, including assessments of compliance with relevant standards.

Maintain documentation relating to selections, contracts, corrective actions and monitoring for a period of 6 years (2 certification cycles).

18. CONTROL SYSTEM SCHEME