REGULATION FOR CERTIFICATION OF ECO-ORGANIC & NATURAL ANIMAL CARE PRODUCTS

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1. INTRODUCTION

The Institute for Ethical and Environmental Certification, hereinafter referred to as ICEA, is the non-profit Consortium made up of organizations operating in the field of activities related to sustainable, ethical and environmentally compatible development.
ICEA provides certification services according to the principles of independence, transparency, neutrality, impartiality and competence in order to increase the trust of suppliers and customers in the certified product by guaranteeing the compliance of the product with voluntary or binding product regulations.

The registered office of the Consortium is in Via Giovanni Brugnoli, 15.

ICEA obtains financial support from the proceeds of certification and training activities.

ICEA may establish other secondary offices, branches, agencies and representative offices both in Italy and abroad.

Control management is ensured by the Certification Scheme Responsible (RSC), the decision on certification is taken by the Certification Committee (CCERT), the decision on appeals is taken by the Appeal Committee (CRR) and the impartiality requirement related to ICEA activities is guaranteed by the Impartiality Safeguard Committee (CSI).

For inspection, testing and certification, ICEA can avail itself of qualified external personnel and/or organizations. ICEA also ensures the maintenance of the skills of internal and external personnel through education, training, and updating activities.

The contents of this Regulation are binding for ICEA and its clients (operators).

This Regulation constitutes an integral part of the Certification contract signed between the parties and must be considered in its entirety only. Its content may be subject to revision by ICEA in the manners provided for in the contract.

A copy of all documents and reference rules mentioned in this Regulation, including the Statute and the organization chart of the Consortium is available at ICEA offices and on the website www.icea.bio.

ICEA, on the national territory, carries out its activity (SdC) with staff and documents in Italian language. The documents that guarantee the certification are all issued in bilingual version (Italian/English).

To all the operators who guarantee the observance of the certification scheme governed by this regulation, ICEA authorizes the placing, on the obtained productions, of the conformity lettering and certification mark provided for by the reference legislation and/or standard.

a) ICEA guarantees the access of applicants to the certification schemes governed by this regulation without discrimination of any kind. In particular:

- no undue conditions of financial or other nature are adopted;
- access to assessment and certification is not conditioned by the size of the operator or membership in particular associations or groups.

b) ICEA undertakes to apply the procedures in force and the expense specifications, established on the basis of its national fee table in force, ensuring uniformity of application.

c) The request for inspection and certification does not imply for the concerned organization the obligation to use other ICEA services not

covered by this regulation.

2. PURPOSE AND SCOPE

This Regulation governs the conditions and procedures through which ICEA:
- issues, renews and/or modifies the Certification in favor of the Operator;
- carries out its own inspection activity towards the operator;
- applies to the operator, as a precautionary or final measure, the measures of Warning, Suppression of organic indications, Suspension, Exclusion provided for by the regulations in force in case of ascertained or suspected non-conformities in compliance with the regulations for which ICEA is authorized and accredited.

This Regulation applies to the Controlled operator (operator) who carries out activities at any stage of production, preparation, distribution of certified products that comply with the ICEA control system.

3. DEFINITIONS

Product: the result of a process.

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

Product specifications: documents that establish the requirements (hereafter will be defined as Standard).

Regulatory Body: public or private body which works with and publicly issues the regulations governing product specifications.

Organization: body, company, organism, enterprise or parts thereof, with share capital or not, public or private, with its own functions and administration, which participates in the production, marketing and supply of the product.

Applicant: organization requesting certification. In case the certification concerns a chain of products, the applicant is also the coordinator of the chain.

Licensed operator: organization to which ICEA has issued the conformity certification and which is, consequently, authorized to use conformity lettering and certification mark.

Operator: organization which has requested or obtained the certification.

Animal care products: products intended for pets to be applied on external surfaces (epidermis, hair system, teeth, etc.) in order to clean, scent, change the appearance, protect, maintain in good condition or correct smells. Cosmetic products, drugs, veterinary products and medical devices (disinfectants, insect repellents, etc.) are not included in the scope. Further details are given in the "Scope" of the ICEA DTR ABN Standard.

4. DOCUMENTS AND REFERENCE REGULATIONS

- UNI CEI EN 45020:2007 – Standardization and related activities - General vocabulary;
- UNI ISO EN 14024:2001 – Type I environmental labeling;
- UNI CEI ISO 17030:2006 – General requirements for third party compliance marks;
- UNI CEI EN ISO/IEC 17065:2012 – Requirements for bodies that certify products, processes and services;
- UNI EN ISO 19011:2018 – Guideline for management systems audits;
- ICEA operational manual;
- Standard for eco-organic & natural animal care certification.

The above-mentioned references are those in force at the time of carrying out the certification activity.

5. GENERAL REGULATIONS

5.1 General principles

The activity carried out by ICEA according to the Contract and this Regulation is inspired by the following general principles:

- the operator is responsible for meeting the certification requirements of the company under his control, his products and production and management processes, ensuring and maintaining full and systematic compliance with regulatory requirements and any other relevant regulation, at all times and for every aspect of his activity. The knowledge and correct application of the provisions of national regulations, as well as ICEA Regulations, is a certification requirement;
- ICEA is responsible for detecting, within the limits of the sampling nature of the controls, sufficient objective evidence about the conformity of the operator's production and management processes and products, on which to base the decision regarding certification. ICEA does not assume any obligation regarding the positive outcome of the controls carried out for the issue or maintenance of the certification.

5.2 The purpose of the inspection and certification activity carried out by ICEA is to give, through an initial assessment and subsequent surveillance inspections, an independent guarantee with an adequate level of trust that these products comply with the ICEA Standard of reference.
5.3 The certification system is based on the audit and approval of the management and inspection system of the production process, put in place by the applicant operator to obtain the production and type tests (when required by the standard); followed by continuous surveillance, carried out through periodic verification of the conformity of processes and quality system management, as well as control tests on samples taken both from the market and from the places of production and/or processing.
In particular, the quality system implemented by the organization must take into account the management and application of the following requirements:

- traceability and possible withdrawal of the product in case of

serious non-conformities;
- separation and identification of the certified and non-certified product;
- management of complaints received from customers;
- quality records management.

5.4 The request for certification can be submitted by any applicant organization whose activity is part of the production, branded distribution and import of such products. Certification is normally granted to the person responsible for marketing the product and/or holders of the trademark that distinguishes the product.

5.5 In order to obtain certification, the applicant organization must demonstrate that it complies with the Standard of reference and the regulations in force regarding that type of production. ICEA certification allows the applicant organization to apply the indication of conformity and the certification mark provided by this regulation on the label and/or other advertising and information material related to the product.

The certification mark "Organic and Natural Animal Care ICEA" is property of the Institute of Ethical and Environmental Certification and must be used in compliance with the provisions of this regulation.

5.6 In the case of certification projects involving several production units under the responsibility of a single entity, applications are submitted directly by the single responsible subject.
In this case the responsible organization must have legal personality and must:

a) have entered into written agreements with the other organizations participating in the certification project for the implementation of the provisions of the Standard of reference and this regulation;
b) have defined criteria for membership, participation and renunciation of the certification project of the participating organizations;
c) have procedures that allow the communication to each involved production unit, of the certification regulations and procedures and subsequent revisions, as well as the rights and duties related to the participation in the organic production program;
d) moreover, formally assume responsibility for the compliance of all involved organizations in the project, guaranteeing access to ICEA personnel and to that of the accredited bodies at all the involved organizations and production sites and to all the registrations, including fiscal ones, related to the certified product at any involved level of the chain.

5.7 ICEA does not provide any kind of consultation service to organizations; including methods to solve any non-conformities that prevent certification and direct promotion and information activities useful for the marketing of specific products of certified organizations.

5.8 ICEA, on the Italian territory, carries out its activities with personnel and documents in Italian language. For inspection and certification activities abroad, ICEA undertakes to operate (when

necessary) in English or, in any case, in the language known to the local population, reserving the possibility of using translators and interpreters accepted and deemed capable and prepared also by the controlled operator.

A similar principle is followed in the drafting and distribution to operators of the documents useful for requesting, obtaining and maintaining the certification (standards, regulations, registration forms, etc.).
Certification documents are normally issued in bilingual version (Italian/English). When the product is intended for use in countries where English is not a widely spoken and known language, ICEA undertakes to use the local language or another language known to the population.

5.9 In order to facilitate access to useful information for people interested in this certification scheme, ICEA undertakes to make all non-confidential materials and documents available directly upon request or through the website www.icea.bio. ICEA, moreover, in order to increase the transparency of the system, reserves the possibility to make public through the internet and other communication tools the non-confidential information related to its activity and in particular the licensees list, the inspection and certification fee table, the issued sanctions and the results of the type tests (analysis).

5.10 The application of this regulation is monitored by the Committee for Safeguarding of Impartiality (CSI), the body that guarantees impartiality and the good execution of certification activities, appointed by the Board of Directors of ICEA (CDA), which ensures the fair representation of the parties involved in certification. The delegates appointed by the interested parties in the certification activities of these types of products and processes are members of the CSI.

6 CONDITIONS FOR OBTAINING AND MAINTAINING THE CERTIFICATION

6.1 In order to obtain and maintain certification, the applicant organization must comply with the provisions of this regulation:
6.1.1 To implement and maintain a documented management system that provides evidence of compliance with the product and/or process requirements set forth in the reference Standard;
6.1.2 To have identified and kept under control the specified requirements, including those that are legally binding and regulated;
6.1.3 To have completed the documental evaluation and type testing (analysis) phase with positive results;
6.1.4 To take all the necessary measures to allow the proper conduct of the evaluation activities provided for in this regulation;
6.1.5 To maintain, throughout the period of validity of the certification, the conditions that allowed the issue;
6.1.6 To provide promptly communication to ICEA, as soon as it becomes aware of any irregularities about the product that affect its conformity, its downgrading and possibly the withdrawal of the product from the market;
6.1.7 To promptly notify ICEA of any changes to the organization;
6.1.8 In case of detection of non-compliance (NC) by ICEA, formulate proposals for corrective actions (AC), by filling in and signing the relevant forms, sending a copy by fax to ICEA within 10 calendar days

from the date of notice;

6.1.9 To meet all ICEA's requests for corrective actions within the agreed period of time;

6.1.10 To comply with the provisions of this Regulation;

6.1.11 To liquidate to ICEA the expected fees for the inspection and certification activity independently from its result. Any inspections, not included in the surveillance plan, that may be necessary following the finding of non-conformities, will be charged to the requesting organization according to the in-force fee table at the time of carrying out these inspections;

6.1.12 The fixed annual fee for maintaining certification is also due during any period of suspension;

6.1.13 To keep a record of all complaints received and documentation of the relative corrective actions taken throughout the period of validity of the certification; the applicant organization must also take into consideration complaints received by any other parties involved in the certification project and for which it assumes responsibility for the conformity of the product;

6.1.14 To notify ICEA of all cases in which it is involved in legal proceedings arising from product liability laws or, in any case, violations of applicable laws in relation to the obtained certification;

6.1.15 To accept that ICEA may exchange information and documents with other Certification Bodies regarding inspection and certification issues and possible sanctions against it;

6.1.16 To give free access to ICEA and accreditation body personnel to all company structures, records and documents deemed necessary for the proper conduct of the inspection.

6.1.17 To inform ICEA of the geographical location as certification may not be granted if technically impossible or risky for the people involved.

6.2 Certified organizations must ensure to ICEA personnel the maintenance and full availability of product related records.

6.3 These records must be regularly updated and kept in computerized form.
It is necessary to save this documentation in a way that ensures high levels of safety.
ICEA reserves the right to request a copy of these records.
Records involving products subject to conformity certification must be clearly distinguishable from those involving products not subject to certification.

6.4 ICEA's inspectors must also have access to all accounting, fiscal and financial documentation useful to cross-check the correctness and systematicity of the compulsory records.

6.5 Following the failure to comply with the above conditions, ICEA, in relation to the frequency and severity of the events, will take appropriate action up to the suspension and revocation of the validity of the obtained certification.

7 CERTIFICATION APPLICATION

7.1 To start the certification process, the applicant organization shall submit the ANIMAL CARE CERTIFICATION CONTRACT to ICEA by filling in the CON.ABN form.

In particular, the following information must be clearly indicated:

7.1.1 Company name and address of the registered office of the applicant organization;

7.1.2 Type of activity (production, packaging, subcontracting and distribution) and category of products for which certification is required;

7.1.3 other certifications obtained by the requesting organization, any denied certifications as well as any significant non-conformities and/or sanctions detected by the involved inspection and certification bodies.

7.2 By signing the CON.ABN form, the applicant organization accepts the contractual conditions proposed by ICEA (described in the form itself) and undertakes to comply with this Regulation in all its parts.

The following documentation must be attached to the certification request:

1. copy of receipt for payment of the fixed fee due to the inspection system according to the current fee table;
2. applicant organization's Chamber of Commerce Registration Certificate.
3. ICEA FEE TABLE FOR ANIMAL CARE INSPECTION AND CERTIFICATION (TAR.ABN) signed on the original for acceptance.

Afterwards, but in any case, before the first start-up inspection is carried out, the applicant organization must send the following documentation to ICEA:

1. INFORMATIVE QUESTIONNAIRE FOR ANIMAL CARE CERTIFICATION (MC.QI.ABN) with the description of the production process and involved production units, products composition and the identification of the organic certified raw materials.
2. Facsimile of label on the package;

ICEA will assess the compliance of the label with the relevant Standard and the correct use of the conformity indications, LOGO, and other functional statements indicated on the label and presentation of the product.

3. Organization chart signed by the director responsible for the production;
4. Quality plan of products to be certified, indicating measures implemented for monitoring and governing critical points;
5. Formula and other documentation proving the conformity of the product and the used raw materials;
6. Names of qualified organic providers and certifications attesting the conformity of organic ingredients;
7. When the applicant organization uses third-party processing companies, a copy of the contract signed with the processor must be sent, 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 unit and documentation.

And the applicant organization:

7.2.1 *undertakes to inform the processor of any changes and updates about this Regulation and the Standard of reference.*

8. PRE-CERTIFICATION INSPECTION

a) If the applicant organization considers it useful, it may ask ICEA to carry out a pre-certification inspection. The request shall be made in written form when filling in the application for certification.
The purpose of the pre-certification inspection is to determine and evaluate:

- the applicant organization's size, structure and activity;
- the extent of the applicant organization preparation to face the certification process and guarantee compliance with the ICEA Standard and this Regulation.

b) The pre-certification visit is optional and can be requested only once. The commitment and number of days required will be established on the basis of the organization's type and size. The date and schedule for the pre-certification inspection will be jointly fixed by ICEA and the applicant organization.

9. ASSESSMENT

Assessment is performed by ICEA with the purpose of verifying the conformity of the applicant organization's product and/or process with the requirements laid down in the Standard of reference. It includes:

1. evaluation of documents;
2. inspection at the facility of the applicant organization (and of any other organizations involved in certification);
3. type tests (when required by ICEA Standard).

The assessment phase starts only after the applicant organization has submitted the documents mentioned in chapter 6.

Non-conformity consists of failure to comply with the provisions of the technical specifications of the chosen certification scheme. The non-conformity is determined by conduct and/or negligence on the part of the customer or by events not directly attributable to the same.

Non-conformities are distinguished in MARGINAL NON-CONFORMITY, IMPORTANT NON-CONFORMITY (Minor), ESSENTIAL NON-CONFORMITY (Major).

The measures are applied proportionally to the importance, to the nature and to the circumstances that have determinated the occurrence of the non-conformity and to their non-resolution.

The detected non-conformities during the inspection, as well as the measures applied (also as a precautionary measure), are clearly referred to the points of the Reg. for the certification of the chosen certification scheme.

Marginal Non-Conformity

Marginal Non-Conformity is a small violation that does not compromise the conformity of the production process and/or the self-control system on the production method or of the management of the company documentation and it is characterized by not having prolonged effects over time and not determining substantial changes in the company "status" and/or compliance of products and/or customer reliability.

Marginal Non-Conformities do not imply the application of a measure but in case of reiteration in the subsequent inspection, they will be considered as important non-conformities.

Important Non-Conformity (Minor)

The Important Non-Conformity (Minor) is a non-compliance that compromises the qualification of the products but not the conformity of the production process and/or the self-control system on the production method or the management of the company documentation and is characterized by not having prolonged effects over time and not determining substantial changes in the company "status".

In case of non-resolution of the Important Non-Conformities, the suppression of the eco-organic indications is applied.

Essentials Non-Conformity (Major)

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

Essentials Non-Conformities that are not resolved involve the application of suspension of certification or revocation of certification.

ICEA classifies some observations (O) as recommendations that are to be considered as suggestions for improvement that the applicant organization must take into consideration.
When the documentation submitted by the applicant organization is complete, ICEA will make arrangements with the same for carrying out the necessary investigations in order to obtain the certification.

9.1 Evaluation of documents

9.1.1 Documents are evaluated by a qualified staff appointed by the Voluntary Certification Responsible (RCV), by filling the form DOCUMENT EVALUATION REVIEW (MV.RV.ABN) within 30 working days from receipt of document.
The appointed inspector shall evaluate all the documents submitted by the applicant organization to verify their compliance with the relevant standard, shall draw up a Document Evaluation Review and send it to the applicant organization.
ICEA reserves the possibility to ask for further 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 fulfilment of verification starts again from the

date of receipt of the new documents.

9.1.2 The assessment after the applicant organization's documentation evaluation, can be as follows:
9.1.2.1 **Approved**: if no NCs have been found;
9.1.2.2 **Approved on condition**: where ICEA's overall assessment of detected NCs does not prejudice the following evaluation phases (the NC solution can be presented directly during the start-up inspection.);
9.1.2.3 **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 solved.

9.1.3 If the operator does not solve the detected NCs and does not update the documentation within 60 working days, the application is lost (filing). A new application may be presented against new payment of the fees due to ICEA.

9.1.4 In the cases a) and b), a qualified inspector will be entrusted with the execution of the start-up inspection.

9.2 Inspections (start-up phase)

9.2.1 The purpose of inspections is to verify the conformity of the applicant organization, and of any other subjects participating in the project, with 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 risk analysis and will be equivalent, at least, to the square root of all the concerned production units. In the case of operations considered critical by the ICEA Certification Responsible to the scope of the standard conformity, the inspections will be carried out systematically.

In case the operator, in the start-up or surveillance phase, requests identical formulations to other already approved products and falling under the Certificate of Conformity of the contractor, the last inspection, already carried out at the contractor premise, can be considered valid.

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

9.2.2.1 An initial meeting with the applicant organization's Director (that is the Representative appointed by the Director) and with other significant persons included in the organization chart.

The purpose of the initial meeting is to introduce the ICEA Evaluator, or Evaluating Team, illustrate the inspection schedule and performance and underline that all ICEA evaluators are bound by a confidentiality agreement.

9.2.2.2 Accurate verification of compliance of all products to be certified with the provisions of the relevant standard and verification of correctness and reliability of the statements on the label and in the presentation of the product;

9.2.2.3 Verification through inspection of the correct management of the production process, analysis and control of critical points for product compliance and application of applicant organization's control plan;

9.2.2.4 Verification of quality plan implementation and effectiveness and relevant records;

9.2.2.5 A final meeting where the applicant organization's Director will be informed of the result of the inspection.

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

a) illustrate the contents of the INSPECTION REPORT (MV.VV.ABN), 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 observations written down in the NON-CONFORMITY REPORT FORM (MV.CN.ABN) and ask the organization to sign it for acceptance;

9.2.3 A copy of the INSPECTION REPORT filled in by the inspector is given to the organization.

A copy of the 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 inspection, completed with Corrective Actions (AC) and/or Non-Conformity Treatments (TNC), times and responsibilities of implementation.

The TNCs and the ACs proposed by the operator are verified by ICEA's coordinator within 20 working days from receipt. In case of serious NC, the review of the ACs will be carried out within 5 working days.

In case such TNCs and ACs are not considered sufficient or valid, the ICEA's coordinator shall give written notice to the operator indicating reasons.

9.2.4 In case of serious Non-Conformities, ICEA may arrange special inspections to evaluate the effective implementation of the approved treatments and/or Preventive Actions.

If irregularities concern documentation, it will be sufficient to regulate such documentation and send it to ICEA within a prearranged deadline.

9.3 Type Tests

9.3.1 To complete the 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 that may be needed in order to verify the conformity with the technical specifications included in the Standard of reference and the general reference regulation.

9.3.2 The tests shall be carried out (at the expense of the applicant organization) at accredited test laboratories, within the European certification system, in accordance with European rules governing laboratory accreditation.

Alternatively, in case it is difficult to find accredited laboratories for the execution of certain tests, such tests will be carried out at other laboratories, included the applicant organization's laboratory, after ICEA's previous evaluation of its competence and reliability.

ICEA undertakes to give the applicant organization advance notice of the type of analyses to be carried out.

When evaluating whether analysis is needed, also analyses reports produced by the organization will be taken into account if they are significant and carried out at accredited test laboratories in accordance with the above-mentioned criteria.

9.3.3 In case the tests show that the product does not comply with the reference Standard, general regulations and indications on the label and in the product presentation, the assessment will be suspended until the applicant organization, within an agreed deadline (which may not exceed 60 working days), restores the conformity of the product and request ICEA new type tests.

The samples for type tests may be taken during the start-up inspection.

10. CERTIFICATION DELIBERATION

a) The certification procedure will be submitted to the Certification Committee (CCert), appointed by the ICEA CDA only when the applicant organization has eliminated any existing NCs and/or has clearly and credibly committed itself to reaching full conformity within an established deadline and considered acceptable by the Committee. On completion of the evaluation, the Certification Committee will decide whether to grant or deny the Conformity Certificate.
ICEA undertakes to submit for evaluation the certification file to the Certification Committee or to the delegated Committee, within 30 working days from the date of elimination of the non-conformities found during the previous evaluation phases (documents, start-up inspection and type tests).
On completion of the evaluation, the Certification Committee will decide whether to grant or deny the Conformity Certificate.

b) In case of negative judgment (failure to grant certification), the applicant organization will be informed in written form of the decision and of the reasons for the decision.

c) If, within sixty working days, the applicant organization does not implement the necessary corrective actions, the application for certification will officially expire (office filing). A new application may be presented against a new payment of the fee due to ICEA.

11. ISSUANCE OF THE CONFORMITY CERTIFICATE

Following the Certification Committee’s positive opinion and deliberation to grant certification, ICEA will issue (within 15 working days) the CONFORMITY CERTIFICATE showing the following details:

- Certificate registration number;
- Name and/or business name of the applicant organization holding the certification;
- Operator’s code;
- Date of issuance (beginning of validity period);
- Validity expiration;

- Name of products subject to certification;
- Revision status of the document;
- ICEA Standard according to which conformity was granted.

The Conformity Certificate is issued with the signature of the ICEA President or his delegate.

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.

a) Use, validity and renewal of the Conformity Certificate

a) The validity of the Conformity Certificate is subject to the compliance with the reference Standard and this Regulation for certification.

b) During the validity period, surveillance inspections will be carried out in order to verify the continue compliance with the requirements.

c) The company's Conformity Certificate lasts three (3) years. At the end of these the Certification Committee shall, however, re-evaluate the applicant organization in its entirety and decide on the renewal of the Certification. The new assessment takes place according to all the elements that have emerged during the inspection activities carried out in the previous two years.

Once the applicant organization has obtained the certificate, it has the duty to provide, if requested, all documents concerning its own certificate.

Once the applicant organization has received the certificate, it is entitled to:

- advertise the obtained certificate;
- make the Conformity Certificate public;
- affix the conformity lettering and logo specified in this Regulation to the label of the certified products;
- use in the technical sheets and promotional material explicit statements referring to certified products, the conformity lettering and the provided logo.

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

The withdrawal from the inspection and certification for the purposes of compliance with ICEA standards has no effect on the provision of other services offered by ICEA.

b) Register of licensed operators

All organizations granted with the conformity certification and the authorization to use ICEA's trademark are entered in ICEA's operating

system with the following data:

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

The system is continuously updated and part of it is made public on the website: www.icea.bio.
ICEA may send it (also in electronic format) to any applicant who submits a written application and, if necessary, publish it on its own publications, information material and/or on its website www.icea.bio.

12. PROVIDED LOGO

Organizations that obtain from ICEA the Certification of conformity, in compliance with the STANDARD FOR THE CERTIFICATION OF ICEA ECO BIO & NATURAL ANIMAL CARE PRODUCTS in addition to this Regulation, may access the use of the following logos in accordance with the rules set out in the Regulation for the Use of the logo and Certification (Annex II Operating manual) of ICEA trademarks.

The different allowed graphic versions can be requested to the competent ICEA office.

ORGANIC ANIMAL CARE

NATURAL ANIMAL CARE

12.1 Support to protection initiatives

In addition to the ordinary surveillance activity, ICEA will check, at least once a year, whether the certification mark and conformity letterings are correctly used. ICEA personnel will also check 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. Checks will also be carried out by ICEA personnel at stores, supermarkets and other points of sale, trade fairs, websites, etc., as well as following proof and objective evidence provided 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 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 the ICEA RCV, who may avail himself of the support and collaboration of all ICEA

staff.

13. MODIFICATION OF CERTIFICATION CONDITIONS

a) Modification of Regulations and/or Standard

These changes are communicated to all certified organizations by means of a publication notice on the website www.icea.bio, indicating the deadline within which they must adapt to the new requirements or specifications.

The deadline to adapt the certified formulations based on the previous version of the Standard may not exceed 12 (twelve) months, starting from the date of the publication notice.

Once this deadline has expired, the applicant organization has the right to renounce certification. If it decides to maintain it, ICEA (by means of documentary checks or, when required, inspections and/or type tests) will check the compliance with the new requirements. The expenses for any inspections are to be borne by the applicant organization.

b) Modification of Certification Regulation

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

Once this deadline has expired, the certified organization is required to accept the new conditions provided for in the Regulation or, if not, to notify ICEA of the renouncement of certification (within 30 calendar days of the receipt of the notice).

13.1 Modifications of Certification request

If changes are made to the provisions contained in the Certification request, the new review will be communicated by email to the certified organizations at least 30 days (of calendar) in advance of the application starting date. ICEA will also publish the updated text of the Certification request on the web www.icea.bio.

Once this deadline has expired, the certified Organization is required to accept the new conditions set out in the Certification request or, if not, to notify ICEA of the renouncement of certification (within 30 calendar days of the receipt of the notice).

13.2 Modification of Fee table

In case of changes in the economic conditions provided for by the fee table, the new review will be communicated to the applicant organization at least 30 days (of calendar) in advance of the starting date of application.

The certified organization is obliged to accept the new fee conditions, otherwise, shall communicate to ICEA the renouncement of the certification (within 30 calendar days of the receipt of the notice). ICEA will also provide for the publication of the updated fee table on the web www.icea.bio.

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

the year.

14. SURVEILLANCE ACTIVITY

14.1 During the whole period of validity of the certification, ICEA will perform surveillance activities with its own qualified personnel, through inspections and type tests within a specific sampling plan.

In the case of multiple production units, these should be audited annually and the frequency of inspections at the different sites will be determined on the basis of the risk class.

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

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 inspector, during the 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 estimated cost.

In case samples are taken from processing and storage places subject to inspection, they shall be taken in the presence of the applicant for certification and/or the technical director or their delegate. If samples are taken from distribution points, wholesalers or points of sale, the organization accepts that such samples are directly taken by ICEA technical staff, also by simply purchasing them, provided that each sample is formed by three packages of the same lot.

Each package constitutes a sub-sample. One of this will be made available and, on request, delivered to the concerned organization in its original package.

14.2 Surveillance inspections may either be announced or unannounced.

In case of announced inspections, ICEA’s inspectors will communicate the date of the inspection directly to the applicant organization.

Announced inspections are scheduled at least once per year, in compliance with the surveillance plan.
In case of announced inspections, 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.
In case of brand owner companies, ICEA can reserve the possibility to conduct remote inspections (audit on desk).

The surveillance inspection schedule always includes:
14.2.1 evaluation of any changes in the applicant organization’s production processes;
14.2.2 verification of NC solutions and recommendations found during the previous inspections;
14.2.3 continue compliance with the requirements of ICEA Standards

and conformity to any occurred modification;
14.2.4 observance of Certification Committee's specific requirements and correct implementation (also within the deadlines of any granted derogations);
14.2.5 examination of customers' complaints;
14.2.6 verification of requirements laid down in this Regulation;
14.2.7 substantial changes in the production plan.

14.3 The procedures for non-conformity report and management are the same as the ones described in paragraph 8.2.

14.4 Unannounced inspections are scheduled, within the surveillance plan, on a specified sample of companies determined on the basis of statistical criteria or at ICEA's discretion, in order to verify the 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 guarantee the greatest collaboration to the staff appointed by ICEA. If the operator fails to communicate his absence on occasion of announced inspections, he undertakes to bear the cost of the inspection.

14.5 Procedure for dormant surveillance: in case of certified companies which have not carried out production activities in the last 12 months since the last surveillance inspection, it is possible to declare it to ICEA by sending a signed request, thus obtaining the status of "dormancy". During this period the company will not be subject to inspections and will not have to pay the related ICEA's fee. The production activities resumption will be notified to ICEA at least one month before this so that a proper surveillance inspection can be organized. This state can only be renewed once for a total of two years of "dormancy".

15 MODIFICATION AND EXTENSION OF CERTIFICATION SCOPE

15.1 The certified organization is entitled to request changes in the scope of certification.

These changes may concern:
15.1.1 change of business name and/or modifications of the organization;
15.1.2 modification or extension of production units;
15.1.3 modification or extension of products and/or processes subject to certification.

15.2 The procedure for requesting such changes is the same as the one indicated for submitting request of certification. The request shall refer exclusively to the aspects and/or products modified or extended.

The assessment may just be limited to a verification of documents and/or an inspection and/or a type test, without a Certification Committee's specific evaluation, only where such changes have no significant influence on the organization's activity or production process management, but just introduce new products into the same category.

15.3 The issuance and/or revision of the Conformity Certificate, keeping into account the modification and/or extension of certification scope, is subordinated to the positive fulfilment of the provisions laid down in Article 8 of this Regulation.

16 CONFIDENTIALITY

16.1 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.
ICEA's personnel involved in inspection and certification activities undertakes to treat as strictly confidential the data acquired, in particular as regards product process and formulation.

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

16.3 ICEA will not disclose 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.

16.4 The information which may be considered public and which can be disclosed 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 published on the website www.icea.bio.

17 VALIDITY OF CERTIFICATION CONTRACT

17.1 By signing this Regulation, a contractual relationship between ICEA and the applicant organization is constituted.

17.2 The hereby certification contract shall become effective starting from the day ICEA receives a copy of it signed by the organization. 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 be sent at least thirty (30) days before the expiry of the contract.

17.3 In particular, the validity of the contract is bound to the fulfilment of the following obligations:

a) Observe the current provisions concerning the production of animal care products.

b) Supply the required documentation for the application of the inspection system.

c) Fill in and constantly update the forms envisaged for the application of the inspection system.

d) Allow inspection personnel access to premises and documentation, as required by the inspection personnel.

e) Make available to inspection personnel all the products and raw materials useful for analysis as may be required for the purpose of inspection and certification.

f) Comply with the deadlines provided by ICEA, whether for the fulfilment

of the requirements of the inspection system or for the payment of any fees due to ICEA.

g) Notify any substantial change in the operator's situation or in any activity connected with the inspection system and product conformity, within the prescribed deadlines. In case the changes require a specific evaluation by ICEA, the operator shall wait for ICEA's conformity judgment before using the conformity lettering or logo for the concerned products.

h) Observe the provisions of the current regulations concerning product labelling and the Regulation for the use of the logo and ICEA certification, promptly reporting to ICEA any misuse, even by other operators.

i) Make comments about certification only when referring to the purposes for which the certification was issued.

j) Not use certification in such a way as to discredit the Certification Body and not make comments about product certification which may be considered not correct or not authorized by the Certification Body.

k) In case of suspension or withdrawal of the conformity certification, stop using all documents bearing indications referring to the certification and/or stop using advertising material containing such indications, in case of withdrawal of the certification. Return any certification document on Certification Body's request.

l) Use the certification only to indicate that the products have been certified in compliance with relevant regulations.

m) When referring to product certification in the media, such as documents, information material or advertising, behave in accordance with the Certification Body's requirements.

n) Accept, without prejudice to the possibility to file an appeal, the penalties applied in accordance with the provisions laid down in this Regulation.

o) Keep record of all received complaints regarding the products subject to inspection and certification.

p) Manage in a controlled way the distribution of ICEA's Conformity certificates to customers, recording for each distributed copy: number of the copy (to be indicated in the document too), date of delivery, and name of recipient.

q) Communicate any withdrawal or suspension of Conformity certificate to all subjects to whom such certificate had been distributed.

r) Accept that ICEA exchange information and documents with other Certification Bodies concerning problems related to inspection and certification and potential penalties.

s) Allow in charge ICEA personnel and accrediting body free access to all facilities, records and documents considered useful for proper conduct of inspection.

18 CERTIFICATION RENUNCIATION

The applicant organization may renounce certification: if it does not accept any changes made by ICEA to the certification conditions (see point 12) and, in any other case, following written request to be submitted with at least 30 calendar days' notice.

In any case, the organization shall remain subject to the inspection and certification system until all labels have been used (that is until packaging and labeling operations have been completed), and until no material showing conformity letterings and certification mark is left, bearing inspection and certification costs due to ICEA.
In any case, the placing on the market of the already packaged and labeled product must be stopped within 18 months from the date of withdrawal of certification.

In the event of a request for voluntary withdrawal by the operator, the exclusion and consequent termination of the right of all "inter-partes" agreements will proceed.
Through a resolution of the Certification Committee, ICEA communicates to the operator the exclusion from the certification system by sending the CD-M0608 form via e-mail and / or PEC.

19 PENALTIES

19.1 Suppression of eco-biological indications

The suppression of indications results in the prohibition for the operator to report, on labels and product documents concerned by the infringement, the indications concerning certification in relation to the lot or to the entire production concerned by the violation. The verification of the application and its effectiveness is carried out during the first useful inspection. Failure to comply with a suppression of the certification references may imply application of a more significant measure.

The measure is decided by the Certification Committee and communicated by sending the CD-M0605 form via e-mail and / or PEC, in which the reasons for the suppression will be specified, the conditions under which the suppression can be revoked and the deadlines within which the appeal can be presented.
Once the measure has been received, the operator can communicate in writing the reasons for dissent and send them by e-mail and / or PEC.

In the absence of dissenting communications within 15 working days of receipt, the measures, as well as the required corrective actions, will be considered accepted by the operator.

19.2 Suspension of certification

The measure of suspension of certification consists in the temporary suspension of the certificate of conformity with the adopted standard and is applied in case the detected non-conformities compromise the reliability of the controlled operator.

The suspension implies for the operator himself the prohibition, for the indicated period, to market the products with references to the applied certification.

The verification of the corrective action is carried out within the terms

and in the manner provided for by the provision itself. Failure to comply with a suspension involves normally the exclusion of the operator.

The suspension of certification is decided by the Certification Committee and communicated to the operator by sending the CD-M0610 form by e-mail and / or PEC specifying the reasons and deadlines within which it is possible to appeal (no later than 15 days from the date of receipt).
In the communication form of the measure, ICEA will specify the time period within which the corrective actions should be taken to eliminate the detected nonconformities. The measure will be revoked, with the same procedures provided for its imposition, only after a positive inspection carried out by the staff in charge by ICEA in order to detect the effectiveness of the corrective actions taken by the operator.

19.3 Certification withdrawal

The measure of withdrawal of certification applies in the event of violations that compromise the reliability of the operator in the management of the company and its permanence in the control system, including when there is recidivism in committing infractions, or in the event that the operator does not respect the commitments made towards the competent authority and the contractual obligations towards ICEA.

The following cases of non-compliance by the operator to the rules of ICEA adopted Certification Regulation will entail the withdrawal of the Certificate of conformity and will constitute a reason for the termination of the right of all the "inter partes" agreements:

- failure to implement corrective actions which should have followed measures of suspension of the certification referred to in Article 5.4 above;
- detection of ESSENTIAL NON-CONFORMITIES during surveillance inspections and violations of obligations provided for by the legislation in force and the Regulation for the applicable certification;
- opposition by the operator to carry out surveillance inspections;
- use by the operator of Conformity Certificate in violation of the terms of the related articles of ICEA applicable Regulation;
- serious or repeated violations regarding the correct use of the certificate and the conformity letterings;
- termination of the production activity of the organization;
- in case of lapses of the request for certification: if the operator fails to solve the detected NCs and update the documentation requested by the CB within 60 working days, the application lapses (filing) and can be resubmitted only with consequent new charge of the fee amount due to ICEA;
- exclusion in cases of arrearage: in case of non-payment of the fees due for the control and certification activity within the established deadlines and after two reminders of ICEA.

The exclusion of the operator, with the termination of the right of all the "inter-partes" agreements, is deliberated by ICEA, following the decision of the Certification Committee and communicated to the operator by e-mail and / or PEC by sending the CD-M0606 form, specifying the reasons and deadlines within which it is possible to appeal (no later than 15 days from receipt).

19.4 Restatement of certification

If case of proven non-compliance with certification requirements, whether from surveillance or other activities, ICEA considers and decides on the actions to be taken, which include:

- continuation of certification under conditions specified by ICEA;
- reduction of the scope removing nonconformity products and processes;
- suspension of the certification pending corrective action by the operator;
- withdrawal of the certification.

Each action includes evaluation, review or certification decision.

In case of withdrawal upon customer's request, suspension or revocation of certification, ICEA takes the actions specified by the certification scheme and makes all necessary changes to formal documents, public information, authorizations for the use of trademarks, etc., in order to ensure that the reduction of the scope is clearly communicated to the customer and clearly specified in the certification documents and public information.

If certification is suspended, the ICEA's scheme responsible/ ICEA's coordinator formulates and communicates the following to the client:

- actions needed to end suspension and restore certification in accordance with the certification scheme;
- any other actions required by the certification scheme.

If certification is reinstated after suspension, ICEA makes all necessary changes to formal documents, public information, authorizations for use of trademarks, etc., in order to ensure that all appropriate indications exist so that the product/process can continue to be certified.
If the decision to reduce the scope is taken as a condition for restating certification, ICEA takes the actions specified by the certification scheme and makes all necessary changes to the formal documents, public information, authorizations for the use of trademarks, etc., in order to ensure that the reduction of the scope is clearly communicated to the customer and that it is clearly specified in the certification documents and public information.

19.5 Notification of sanctioning measures of certification suspension and withdrawal

The sanctions are approved and signed by the ICEA President, following the Certification Committee's resolution and communicated to the applicant organization by e-mail and/or registered letter through the respective forms.

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 notice.
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.

20 CONSEQUENCES OF RENUNCIATION, NON-RENEWAL, SUSPENSION AND WITHDRAWAL OF CERTIFICATION

20.1 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 paper bearing indications referring to certification and ICEA trademarks;
- immediately stop using the provided conformity letterings and certification mark;
- upon ICEA's request, inform all the customers who had been advised of the certification.

20.2 In case the applicant organization uses the certification infringing the above-mentioned obligations, ICEA reserves the right to make public, 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.

21 INSPECTION AND TESTING ACTIVITY

21.1 ICEA, for the purpose of carrying out the inspection and testing activity, can avail itself of the services of external structures that have an agreement with it and/or are authorized for which it is the guarantor of competence, all in compliance with the requirements of the UNI CEI EN 45011 (in the future EN 17065) point 4.4 regarding subcontracting and without prejudice to the possibility of carrying out the same activity with its own national structures. ICEA, in any case, remains the sole owner and legally responsible for the issue, maintenance, extension, suspension or withdrawal of the certification.

21.2 The organization may express objections in advance, provided they are justified, regarding the use of a particular inspector, inspection body or test laboratory that ICEA decides to employ. ICEA, for this purpose, undertakes to communicate in advance to the organization the names of the professionals or bodies in charge. The organization must communicate these objections and their reasons, in writing, to the RCV (for the analytical tests it may request the indication of its request in the sampling report).

The RCV will have to decide whether to accept the request. The request is considered acceptable in cases where there is formal evidence of conflicts/disagreements, in place or in the past, between the operator and the professional or the appointed body by ICEA.
The operator's request and the consequent decisions of the RCV must be

communicated for information to the ICEA Quality Assurance Manager (RAQ).

22 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 Manager (RAQ) who will evaluate whether the complaint is justified and will give a reply within thirty 30 calendar days.

23 APPEALS

23.1 If the applicant organization considers, as a result of the decisions of the Certification Committee, or in any case decisions taken by ICEA, to be the victim of unjustified and/or discriminatory decisions, it may appeal to the Single Appeal Committee (CUR) of ICEA.

23.2 The appeal shall be filed in writing, stating reasons, within thirty calendar days from the date of notice of ICEA's decision.
Within thirty 30 calendar days, ICEA will convene the CUR, which will examine the appeal within 60 calendar days from the date of filing.
On occasion of such meeting, the applicant organization's representatives may request a hearing.

23.3 The decision made at this point will be unquestionable and irrevocable.

23.4 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 accredited laboratories within the European certification system, in accordance with European regulations concerning laboratory accreditation.

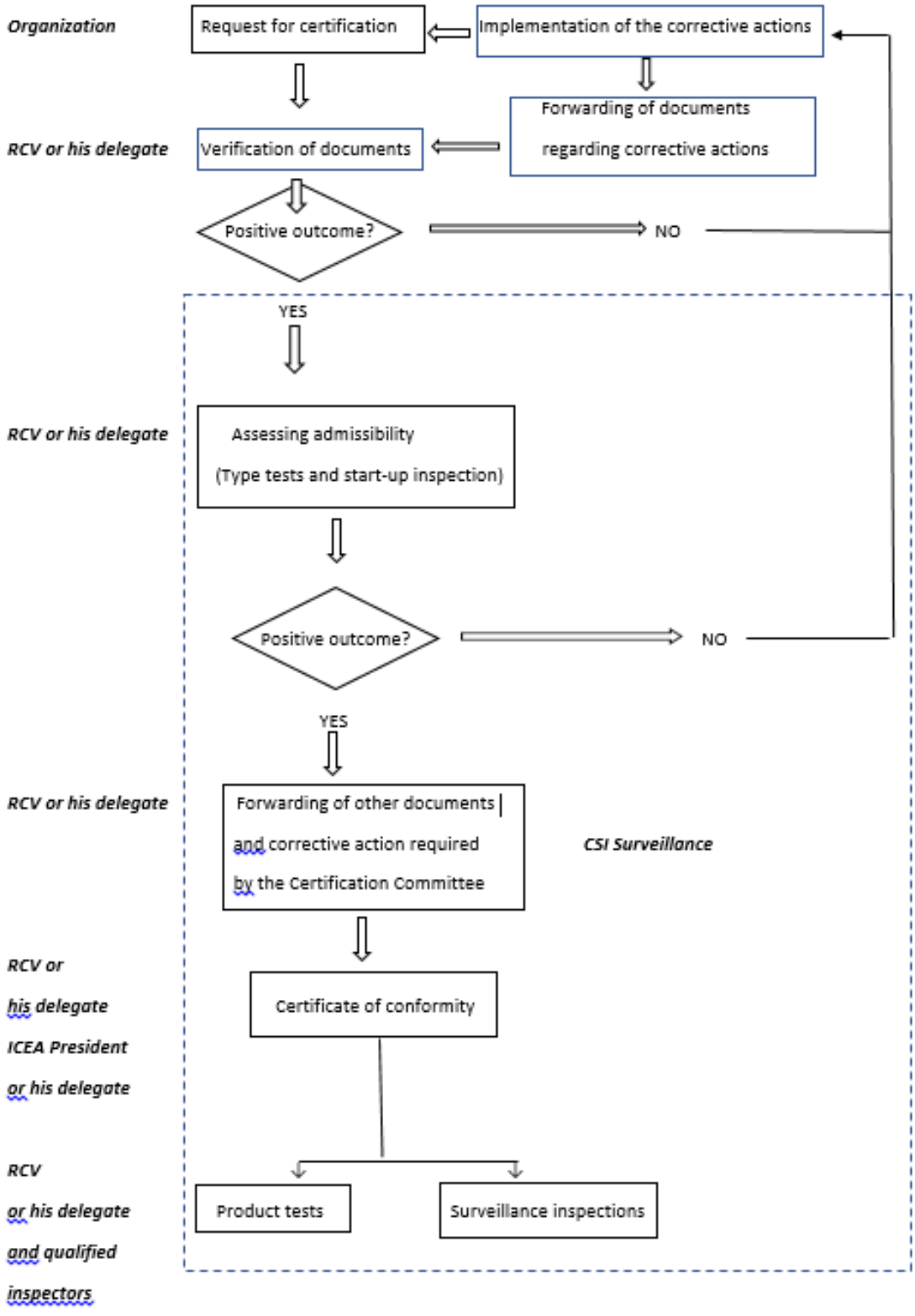
24 DISPUTES

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 when handling appeals, the competent and exclusive Court will be Bologna.

25 INTERNAL INSPECTIONS 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 Manager, carries out periodical internal inspections (VII) at the national office.
The results of the inspections will be reviewed by the Director in accordance with the procedures applied for all the other certification schemes.

26 INSPECTION SYSTEM CHART



27 ACCEPTANCE OF TERMS PROVIDED BY THIS REGULATION

(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 ICEA Organic e Natural Animal Care Regulation have been carefully read and accepted.

Date:	Stamp and signature

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.

Date:	Stamp and signature