CERTIFICATION REGULATION– FOREIGN SECTOR ANNEX

Referred to International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries

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1. OBLIGATIONS OF CONTROLLED OPERATORS

The Operator subject to control shall:

1. The Operator always fulfils the certification requirement, including implementing appropriate changes when they are communicated by ICEA;
2. If certification applies to ongoing production, the certified product continues to fulfill the product requirements;
3. Observe the provisions of national and Community regulations concerning organic farming (International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries);
4. Supply the documentation required by the control system;
5. Accomplish and constantly update the forms provided by the control system;
6. The Operator makes all necessary arrangements for:
   - 6.1. Allow ICEA's inspection staff to access production sites, mandatory records and supporting documentation (e.g. transport documents, invoices, VAT Registers, etc.), also when available in third parties' offices, as required by legislation in force. Moreover, accept, when required, the presence of an observers or Accreditation Body Witness Auditor, as part of the planned ICEA inspection;
   - 6.2. Investigation of complaints
7. Make available to inspection staff all the products and materials of crop/livestock origin and all the ingredients of agricultural and non-agricultural origin (including, therefore, water, additives, flavourings, etc.) for analysis as may be required, for the purpose of control and certification.
8. Keep the sub-sample delivered by ICEA staff after collection and store it properly for at least 15 working days from the date of delivery, except when indicated otherwise by ICEA fulfil the requirements of the control system and pay any fees due to ICEA for control and certification within the prescribed time limits.
9. Send notification of any substantial change in his situation or in any activity connected with the control system and product conformity, within the prescribed time limits. In case the variations that occurred require a specific evaluation by the CB, the Operator shall wait for ICEA's conformity assessment before using organic method indications.
10. Observe the provisions of the regulations concerning product labelling and the Procedure for Use of ICEA Marks, promptly reporting any misuse, even by other operators.
11. Make statements about the certification only when referring to the purposes, scopes, products and production sites for which the certification was issued.
12. Not use the certification in such a way as to discredit the Certification Body and not make remarks about product certification that may be considered not correct or not authorized by the Certification Body.
13. in case of suspension or withdrawal of certification:
    - 13.1. Stop using all documents containing references to the certification and stop using, in case of withdrawal of the certification, advertising material containing such references. Return any certification document to the CB.
    - 13.2. Communicate in writing the consequences of the sanction to the purchasers of the product, so that any indication referring to organic methods will be deleted from such product.
14. Use the certification only to indicate that the products have been certified in conformity/equivalence with regulations.

15. Behave as prescribed by the Procedure for the Use of ICEA Logos and Certification Publicity when dealing with media regarding product certification (i.e. documents, brochures or advertising).
16. Forward to ICEA one copy of the documentation accompanying the goods, no later than 5 working days from the transaction.
17. Accept, without prejudice to the possibility of filing an appeal, the sanctions applied in accordance with the provisions of national, Community and ICEA in force.
18. When requesting certification and submitting the Notification of production with organic methods and/or Application for Certification to ICEA:
    18.1. communicate the name of any authorized Certification Body to which the Operator has been previously subjected and any sanction applied by that Certification Body to the Operator;
    18.2. communicate whether the production unit is at the same time subject to another authorized Certification Body;
    18.3. provide evidence that the Notification has been sent to the competent Authority, where applicable.
19. After withdrawal from ICEA control system and/or submission of a new notification and/or application for certification, to another authorized Certification Body, communicate to the new Certification Body any sanctions applied by ICEA and still in force.
20. Record all complaints received regarding the products under control and certification and the related corrective actions (along with references of documents). Make these records available to inspection staff during the inspection visit.
21. Pay all the fees due to ICEA for control and certification activities, irrespective of the outcome.
22. To accept, in cases where the operator withdraws from the control system, that the control file is kept for a period of at least five years;

2. OBLIGATIONS DUE TO CERTIFICATION CESSATION

2.1. The Operator shall immediately cease the use of the Conformity and/or Equivalence Certificate, Unit Conformity Attestation, ICEA mark and advertising, in the following cases:
2.1.1. On expiry of the validity of the Unit Conformity Attestation;
2.1.2. In the cases mentioned at paragraph 13.2 and the ones following;
2.1.3. When the Operator fails to complete, within the deadlines, the corrective actions required as a consequence of amendments to the ICEA Control System regulations;
2.1.4. In all cases of the Operator's voluntary withdrawal from the Control and Certification system.
2.2. Should the Operator use the certification infringing the above mentioned obligations, ICEA may publicize, conveniently and without prejudice to any further action, that the Operator is no longer entitled to use the certification. The cost of publication will be charged to the defaulting Operator and so will any further damage.
2.3. If certification is terminated (by request of the client), suspended or withdrawn, ICEA shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, ICEA shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

3. GENERAL OBLIGATIONS

3. Responsibility:
   - 3.1. The Operator has the responsibility of fulfils the certification requirements as listed in the "International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries";
   - 3.2. ICEA has the responsibility to obtain sufficient objective evidence upon which to base a certification decision. ICEA performs evaluation activities with its internal resources or in outsource that meet the applicable requirements following standards:
     - 3.2.1. ISO/IEC 17025
     - 3.2.2. ISO/IEC 17021
     - 3.2.3. ISO 19011
     - 3.2.4. As specified by the certification scheme;
   - 3.3. Where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies, the control authorities or control bodies shall exchange the relevant information on the operations under their control.
   - 3.4. Where operators and/or their subcontractors change their control authority or control body, the change shall be notified without delay to the competent authority by the control authorities or control bodies concerned.
   - 3.5. The previous control authority or control body shall hand over the relevant elements of the control file of the operator concerned and the reports referred to in the second subparagraph of Article 63(2) to the subsequent control authority or control body.
   - 3.6. The new control authority or control body shall ensure that non-conformities noted in the report of the previous control authority or control body have been or are being addressed by the operator.
   - 3.7. Where the operator withdraws from the control system, the control authority or control body of that operator shall, without delay, inform the competent authority (information available in the ICEA website – updated operators' list).
   - 3.8. Where a control authority or control body finds irregularities or infringements affecting the organic status of products, it shall without delay inform the competent authority of the Member State which designated or approved it in accordance with Article 27 of Regulation (EC) No 834/2007(information sent to the Accreditation Body)
   - 3.9. That competent authority may require, on its own initiative, also any other information on irregularities or infringements.
   - 3.10. In case of irregularities or infringements found with regard to products under the control of other control authorities or control bodies, it shall also inform those authorities or bodies without delay.
   - 3.11. Upon a request duly justified by the necessity to guarantee that a product has been produced in accordance with this Regulation, the competent authorities, control authorities and the control bodies shall exchange relevant information on the results of their controls with other competent authorities, control authorities and control bodies. They may also exchange such information on their own initiative. The level of communication shall depend on the severity and the extent of the irregularity or infringement found.
   - 3.12. Where an operator runs several production units in the same area, the units for non-organic products, together with storage premises for input products must also be subject to the minimum control requirements. Where an operator runs several production units in the same area, the units producing non-organic crops, together with storage premises for farm input products shall also be subject to the general and the specific control requirements.

3.13. Formal certification documentation shall only be issued after, or concurrent with, the following:
- 3.13.1. the decision to grant or extend the scope of certification has been made;
- 3.13.2. certification requirements have been fulfilled;
- 3.13.3. the certification agreement has been completed/signed.

3.14. When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, ICEA shall consider and decide upon the appropriate action. Appropriate action can include the following:
- 3.14.1. continuation of certification under conditions specified by the certification body (e.g. increased surveillance);
- 3.14.2. reduction in the scope of certification to remove nonconforming product variants; suspension of the certification pending remedial action by the client;
- 3.14.3. withdrawal of the certification.
- 3.14.4. When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

3.15. If certification is suspended, ICEA shall assign one or more persons to formulate and communicate the following to the client:
- 3.15.1. actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;
- 3.15.2. any other actions required by the certification scheme.

3.16. These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications.

3.17. If certification is reinstated after suspension, ICEA shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified.

3.18. If a decision to reduce the scope of certification is made as a condition of reinstatement, ICEA shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

3.19. The ICEA requirement for EC 3rd country inspections is that at least 10 % of all inspections and visits carried out in accordance with Article 65(1) and (4) are unannounced, in accordance with the risk category are performed;

3.20. Even if ICEA M0202 section 10.f states, "the presence of an Accredia Witness Auditor, as part of the planned ICEA inspection" for EU equivalence it is intended IOAS Witness Auditor and/or any representative of the EU Commission. Indeed, Competent authorities delegating control tasks to control bodies shall verify that the staff of the control bodies has sufficient knowledge, including knowledge of the risk elements affecting the organic status of products, qualifications, training and experience with respect to organic production in general, and with the relevant Union rules in particular, and that appropriate rules on rotation of inspectors are in force.

3.21. ICEA shall take and analyses samples for detecting of products not authorized for organic production, for checking production techniques not in conformity with the organic production rules or for detecting possible contamination by products not authorized for organic production. The number of samples to be taken and analysed by ICEA every year shall correspond to at least 5 % of the number of operators under its control. The selection of the operators where samples have to be taken shall be based on the general evaluation

of the risk of non- compliance with the organic production rules. This general evaluation shall take into account all stages of production, preparation and distribution. ICEA shall take and analyses samples in each case where the use of products or techniques not authorized for organic production is suspected. In such cases no minimum number of samples to be taken and analysed shall apply. Samples may also be taken and analysed ICEA in any other case for detecting of products not authorized for organic production, for checking production techniques not in conformity with the organic production rules or for detecting possible contamination by products not authorized for organic production.

3.22. The result of the risk analysis provides the basis for determining the intensity of the unannounced or announced annual inspections and visits; additional random control visits carried out in accordance with Article 65(4) of at least 10 % of operators under contract in accordance with the risk category are performed.

3.23. ICEA implemented a catalogue listing infringements and irregularities affecting the organic status of products and corresponding measures to be applied by control bodies in case of infringements or irregularities by operators under their control who are involved in organic production (named M0609).

3.24. ICEA is under supervision of the competent authority and of the accreditation body. During the annual inspection, they shall, in particular, verify:

3.24.1. the compliance with the ICEA's standard control procedure as submitted by ICEA to the competent authority in accordance with Article 27(6)(a) of Regulation (EC) No 834/2007;

3.24.2. ICEA has a sufficient number of suitable qualified and experienced staff in accordance with Article 27(5)(b) of Regulation (EC) No 834/2007 and that training concerning risks affecting the organic status of products has been implemented; ICEA has and follows documented procedures and templates for the annual risk analysis in accordance with Article 27(3) of Regulation (EC) No 834/2007, preparing a risk-based sampling strategy, conducting sampling and laboratory analysis, information exchange with other control bodies and with the competent authority, initial and follow-up controls of operators under their control, the application and follow-up to the catalogue of measures to be applied in case of infringements or irregularities, observing the requirements of the protection of personal data for the operators under its control as laid down by the Member States where that competent authority operates and in accordance with Directive 95/46/EC.

3.25. In case of new certification projects in countries where ICEA is not yet recognized as in equivalence for EU, ICEA has the right to reduplicate the fee proposal in order to cover any eventual risks.

3.26. When the inspection plan is done, ICEA appropriate rules on rotation of inspectors states that the same inspector cannot run more than three complete inspections in sequence for the same operator.

4. CONVERSION RULES: PLANT AND PLANT PRODUCTS

For plants and plant products to be considered organic, the production rules as referred to "International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries" must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic farming, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.

In Third Countries (outside EU), where there is no competent authority, and in the absence of local rules about it, ICEA can decide to recognize retroactively as being part of the conversion period any previous period where:
(a) the land parcels were subject of measures defined in an official or not official programme. These projects have to be supervised by non governative or governative organizations (such as FAO, UNIDO, UNDP, NGOs, etc.), providing that the concerned measures ensure that products not authorized for organic production have not been used on those plots,
or
(b) the plots were natural or agricultural areas not treated with products not authorized for organic production.
The period referred to in point (b) can be taken into consideration retroactively only if satisfactory proof has been provided to ICEA, regarding the fact that the above mentioned conditions were satisfied for at least three years.
With the exception of particular conditions, where a derogation can be recognized by the ICEA Certification Committee (CCERT), the documents to be provided by the operator as sufficient proofs, are the following:

- Written operator's request (with date and signature) with a clear indication the surfaces under request, plot list and declaration about the land management of the 3 previous years; in particular, land could have been:
  - Not cultivated (except in case where cultivation of the land is not consequence of activities, such as deforestation, with a devastating environmental impact and that at least didn't happen in the last 10 years)
  - Managed with a method in compliance or in equivalence with "International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries" as amended;
- Third Party declaration to confirm the above mentioned declaration, regarding land management in the 3 years before the application to the CB.

Moreover, soil analysis results of the sample taken by the ICEA auditor, have to be included in the company dossier. The requested analysis will be different based on land situation, in particular:

- For land previously uncultivated – multi residual analysis
- For land previously cultivated – analysis for active principle classes mostly used for the crops under request; active principle classes have to be indicated by the ICEA auditor during the sample collection on the sampling collection report.

Decisions about conversion period reduction are defined as followings: In case of plots previously farmed with:
Perennial crops – from the application date, 12 months of conversion will be maintained

- Products collected during the 12 months of conversion cannot be certified
- Products collected after the 12 months of conversion can be certified as "organic"

Annual crops – from the application date, 12 months of conversion will be maintained

- Crops sowed before the application date, cannot be certified neither as "in conversion to organic" nor as "organic"
- Crops sowed during the 12 months of conversion, can be certified as "in conversion to organic"
- Crops sowed after the 12 months of conversion, can be certified as "organic"

In case of plots not farmed from at least the past 3 years:
Perennial crops – from the application date, the organic status of the plots is recognized

- The products harvested after the application date, can be certified as “organic”.

Annual crops – from the application date, the organic status of the plots is recognized.

- The products obtained from plants sown before the application date (provided that the seeds used comply with “International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries”), can be certified as product “in conversion to organic”.
- Products obtained from plants sown after the application date, can be certified as “organic”.

4.1. Other particular cases related to conversion period

In some cases, when the land has been contaminated with products not authorized for organic production, ICEA can decide to extend the conversion period beyond the period foreseen by the “International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries”
In the case of parcels which have already been converted to or were in the process of conversion to organic farming, and which are treated with a product not authorized for organic production, ICEA may shorten the conversion period in the following two cases:

a) parcels treated with a product not authorized for organic production as part of a compulsory disease or pest control measure imposed by the local competent authority;
b) parcels treated with a product not authorized for organic production as part of scientific tests approved by the local competent authority.

For the cases indicated in point (a) and (b), the length of the conversion period is established considering the following factors:

a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
b) the harvest following the treatment may not be sold with reference to organic production methods.

5. USE OF SEEDS OR VEGETATIVE PROPAGATING MATERIAL NOT OBTAINED WITH THE ORGANIC PRODUCTION METHOD

In Third Countries (outside EU), where there is no competent authority, and in the absence of local rules about it, where the conditions laid down in “International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries” applies,

a) seeds and vegetative propagating material from a production unit in conversion to organic farming may be used,
b) where point (a) is not applicable, and when organic seeds and vegetative propagating material are not available on the market, ICEA may authorize the use of non-organic seeds or vegetative propagating material, but only in case the use of organic seeds produced by the farm itself is not possible.

However, the use of non-organic seed and seed potatoes is managed in the following way:

- Non-organic seed and seed potatoes may be used, provided that the seed or seed potatoes are not treated with plant protection products, other than those authorized for treatment of seed in accordance with “International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries”, unless chemical treatment is prescribed in accordance with Council Directive 2000/29/EC (16) for phyto-

sanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the seed or seed potatoes are to be used.

- Authorization to use seed or seed potatoes not obtained by the organic production method may only be granted in the following cases:
  a) where no variety of the species which the user wants to obtain is available in the Third Country (or area) where the operator is based;
  b) where no supplier, meaning an operator who markets seed or seed potatoes to other operators, is able to deliver the seed or seed potatoes before sowing or planting in situations where the user has ordered the seed or seed potatoes in reasonable time;
  c) where the variety which the user wants to obtain is not available in the Third Country (or area), and the user is able to demonstrate that none of the alternatives of the same species are appropriate and that the authorization therefore is significant for his production;
  d) where it is justified for use in research, test in small-scale field trials or for variety conservation purposes agreed by ICEA
- In all the specific situations above mentioned, the documents to be provided to ICEA by operator are the followings:
  - Written request (ICEA form completed in all sections) to be sent at least 10 working days before sowing or transplant
  - Written request (and related answer, if available) to at least 2 local seed/plant producers about certified organic seeds/plants availability.

What previously stated is valid, with the exception of particular conditions, where a derogation can be recognized by the Certification Committee.
ICEA will answer for acceptance and/or for refusal within 10 working days from receiving the request (based on ICEA receiving protocol date). Copy of the ICEA answer has to be kept by the operator.

6. SEED DATABASE

Any variety which has not been registered in the database shall be considered as unavailable.
The updating of the database is made every time a new plant breeder and/or seed trader is included in the ICEA certification system, and however, every January with eventual information coming from other CBs.
ICEA has established a computerized database where the available varieties for which seed or seed potatoes obtained by the organic production method are listed for each Third Country where ICEA activities are present.

This database (propagating material) is based on all ICEA certified plant breeders and seed traders.
The list of certified plant breeders and seed traders is included in the same list of certified companies - see “http://icea.bio/biologico-extra-ue/ - in this page click on “Scarica qui la Lista degli Operatori certificati nei paesi terzi in regime di Equivalenza EU (REG CE 834/07, ART 33.3)”.
The database can be integrated with data coming from other CBs working in the same Third Countries.

The registration is automatically made whenever a new plant breeder and/or seed trader is included in the ICEA certification system, or upon request of other plant breeder and/or seed trader.

The information in the database is available through the Internet on the ICEA website (www.icea.info), cost free, to the users of seed or seed potatoes and to the public.
In case there are no ICEA certified plant breeders and seed traders, users can apply directly to ICEA office (icea@icea.bio) for specific information.

7. ORGANIC PRODUCER GROUP CERTIFICATION SCHEME APPLIED IN DEVELOPING COUNTRIES

7.1 Scope

This document defines the operating procedures and minimum requirements to apply for collective certification.
When intended for export, the marketing of the organic certified products must be carried out as a group and not as a single producer

7.2 Objectives

To overcome the economic problems related to inspections of small operators;
To allow internal inspectors to perform most of the inspections within the Internal Control System introduced by the group.
To have the validity of the Internal Control System verified and evaluated by the external control unit, and certify the group as a whole.

7.3 Definitions

Group members
Only small operators may be part of the group involved in the collective certification. The small operator is the person (picker, farmer or field producer) who works on his own or with his family's help.
The farmers or field producers belonging to the group must adopt similar production systems. Production units must insist on homogeneous territorial areas.
Exceptionally, the operators of big companies may also be part of the group (they pay less than 2% of the value of their business for the certification), and will be subject to annual inspections by the external control unit.
Processing and export companies may also be part of the group, and will be subject to annual inspections by the external control unit.

Small Operators Group (GPO)
The group may be organized in cooperatives or associations, or be affiliated to a processing or export company.
The group must be formally constituted through written agreements signed by all of the members. It must be formed by a central Board of Directors, and have decision-making procedures and capability to pursue legal actions.
The size of the group must be such, as to permit the application of a valid internal control system and a group coordination of sales and exports.

Internal Control System (ICS)
The Internal Control System of a GPO is a documented internal quality control system which provides for a contract signed by all of the members of the group.

7.4 Requirements

7.4.1 GPO requirements

7.4.1.1 Democratic organization

The GPO organization shall be structured democratically, on the conditions that:

- race, colour, sex, religion, political opinions, nationality or social class will not be discriminating factors for admission;
- there will be a General Assembly which guarantees every member the right to vote; within the General Assembly every member can vote;
- the General Assembly is the supreme decision-making organization;
- during the General Assembly the Board of Directors are elected and assigned their responsibilities;
- the General Assembly is formally summoned at least once a year;
- the estimated budget and the final balance are submitted to and approved by the General Assembly.

7.4.2 Internal Control System requirements

7.4.2.1 Internal Control System activity

Internal inspectors will perform at least an inspection once a year for every smallholder, verifying the lands and the plants. This provision is also valid for livestock producers and processing units.
Before accepting a new operator in the GPO, or substantial modifications of the company units, an inspection shall be performed.

7.4.3 Internal Control System operating personnel

7.4.3.1 Internal Control System Chief Executive Officer

The ICS shall be under the responsibility of a Chief Executive Officer.

7.4.3.2 Inspectors

Internal inspectors are nominated by the GPO to perform internal controls. They must have been adequately trained in organic farming and in internal control management. All the training activities shall be documented.
The inspectors must follow defined instructions which clarify their duties and responsibilities.
The ICS shall lay down strict rules to prevent or limit potential conflict of interests of the internal inspectors.

7.4.4 Internal Control System Documents

The ICS shall be illustrated in an exhaustive Manual, together with the procedures and the relevant forms.
This Manual shall indicate:

- The Legal status of the GPO;

- name, position, experience (CV) of every member of the Board of Directors and inspectors; a flow chart indicating the hierarchical structure, the responsibilities and the functional relations between the single executive bodies and the director;
- the procedure for the audit of the Manual;
- the administrative procedures, including documentation management;
- procedures for recruiting, selecting and training Inspectors and monitoring of their competence;
- procedures for the management of documents regarding operators;
- procedures for the preparation, execution and verbalization of the internal inspections; procedures for the management of nonconformities and assurance of the efficiency of the corrective and precautionary actions carried out;
- procedures for the management of sanctions and appeals.
- obligation, for the internal control system, to include the application of sanctions to individual members who do not comply with the production standards;
- obligation, for the internal control system, to inform the external inspection body of the irregularities and non-compliances found, as well as of the corrective actions imposed with agreed time for completion

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The ICS System Manual shall be regularly re-examined and updated, if necessary.

7.4.5 Operators documents

The ICS must assure the availability of adequate documentation relevant to operators, which shall contain:

- A written declaration between the GPO and every operator with at least: the description of the appropriate organic standards (the description could be contained in an attached document); a formal commitment to comply with the organic standards; the permit issued to inspectors for access to farm and plants; the sanctions in case of violations and the right to appeal;
- A basic document (operator's admission form) for each operator subject to certification. This should, at least contain: the description of all of the lands (including the conventional ones) and units, and the last day of application of prohibited products;
- A topographic map (city and community map) which indicates the position of each farm (with all the relevant lands) and the code of each smallholder;
- The production plan of each operator;
- A copy of each inspection report;
- The registration of infractions and violations;
- Documents which show that the director of the internal control procedures has examined
- the inspection report and all the notes about the violations indicated by the inspector.

7.4.6 Internal Control System implementation

Each smallholder must be subject to inspection, at least, once a year, for all activities.
All the new organic smallholders must be subject to inspection before being admitted to the GPO.
The inspection results must be indicated in the Inspection Report. This, must be dated, signed by the inspector and countersigned by the operator.

The Inspection Report must indicate, at least, the following information:

1. name of the operator, name of the operator's farm hands, identifying data of the operator, inspection date;
2. Description of the total farming area under the responsibility of the operator (distinguishing between conventional, organic and in-conversion lands), list of organic crops and relevant areas, indications about the crops of the past years;
3. Rotation Program for the year relevant to the inspection;
4. Description of all the aspects regarding organic standards (use of technical aids, land and fertilizer management, crop defence, use of seeds, separation and prevention from contamination during and after the harvest, breeding with organic method, etc.);
5. Cultivations in the neighbouring lands (including the observations on the use of products by the farmers involved);
6. Buffer zone between the land of the operator and those neighbouring;
7. Potential risks of contamination. Indicate on the map the areas where the risk of contamination is high, and specify why these are a cause of worry. (Can risk of contamination be reduced? What are the effects of the potential contamination on the land with time? Does a prevention program exist? What kind of counter-measures have been implemented?)
8. Cultivation phase at the time of the internal inspection;
9. Estimated harvest date and estimated yield;
10. Observations of the producer regarding the certification and GPO management.

7.4.7 Approved operators register

A Register of Approved Operators shall be instituted and made available.
The register shall include for each approved operator, at least the following information:

- Country/location;
- Name of the operator;
- Operator Code;
- Total surface area and organic cultivation areas, number of animals, etc;
- Approved internal status (organic, in conversion);
- Date of the first approval.

7.5 Small operators group evaluation

When a collective group of operators presents a new request for certification to ICEA, the ICEA Certification Committee (CCERT) has to:

- Decide whether to consider the project as a Collective Certification Project *(inasmuch as the requirements set by ICEA for the members of the group are respected).*
  Decide whether to require ICEA's control over 100% of the farmers or retain that the ICS of the group may give all the necessary information ICEA needs to evaluate the operators' conformity to the requirements and procedures *(inasmuch as the requirements expected by ICEA have been satisfied according to the ICS);*
- Evaluate the conformities to the selected standards *(Reg, (EEC) No 834/2007, NOP or International Accredited Certification Bodies Equivalent European Union Organic Production & Processing Standard for Third Countries, etc.).*
- Evaluate the procedures determined by the group aimed at:
  - Establishing conversion periods for the farm;
  - Accepting a new member and/or new land.

ICEA shall subsequently:

- define the frequency of the group inspections (at least once a year);
- accept or correct the evaluation of risks made by the inspector (who will be able to use the attached evaluation table) that is: Normal, medium-high or high;
- confirm the number of annual re-inspections (inspections by ICEA of the producer or sub-operator) considering the following calculation.

Square root of the operators according to risk factors (see example below)

MINIMUM NUMBER OF OPERATORS TO BE INSPECTED ANNUALLY BY THE CERTIFICATION BODY

Risk level	Normal	Medium	High
Minimum fee	10	12	14
Coefficient of risk	1,0	1,2	1,4

Square root of the operators according to the risk coefficient

Re-inspection fee for the no. of operators	100	10	12	14
Re-inspection fee for the no. of operators	200	14	17	20

Factors to define the risk should include:

a) factors related to the magnitude of the farms - size of the holdings, value of the products, difference in value between the organic and the conventional products,
b) factors related to the characteristics of the holdings - degree of similarity of the production systems and the crops within the group, risks for intermingling and/or contamination,
c) experience gained- number of years the group has functioned, number of new members registered yearly, nature of the problems encountered during controls in previous years and results of previous evaluations of the effectiveness of the internal control system, management of potential conflicts of interest of the internal inspectors, staff turnover.

In a continuative way, the ICEA CCERT shall:

- confirm/vary the frequency and the percentage of the re-inspections;
- confirm the evaluation of the ICS subject to inspection;
- confirm the conformity to organic standards;
- assure that the farms visited by ICEA must be predominantly different from one year to the other.

If the ICEA CCERT notes that the ICS is inefficient, inaccurate, incomplete or somehow inadequate, or has other pain points which invalidate project reliability, it can:

1. postpone the certification until the problem is solved. To solve the problem, the ICS shall:
    a. demonstrate that all the lands have been subject to internal inspections, by sending ICEA the compiled inspections reports;
    b. proceed to the correction of the documents (on the condition the company is substantially conforming, despite one or more minimal nonconformities) and re-qualify or dismiss the employees who made the mistakes. In this situation, ICEA will be able to execute a re- inspection to control the relevance of the corrections.
2. request that 100% of the group members be subjected to inspection by ICEA before going on with the certification.
    a. This option would imply that ICEA will send an inspector to analyse all the lands which have not been controlled during the annual inspection.
    b. the CCERT will evaluate again if the ICS can conduct inspections in the future.

7.6 Non compliances and sanctions

Considering the cases listed in Annex 1, the Certification Officer, at the first level, will apply one or more sanctions to the operator group and the CCERT will give its final decision.
Possible sanctions are:

- Various requests and specific corrective actions or conditions to be complied with (within an established time frame);
- Need of further inspections;
- Dismissal of operators;
- Suspension of the certification while certain types of problems have not been adequately solved;
- Return to conversion;
- Extension of the conversion period; Amendments;
- Withdrawal of the certification;
- Withdrawal from the market of the product or batch.

Serious nonconformities which may cause the withdrawal (and/or suspension) of the certification and/or the withdrawal of the product from the market are the following:

- Any kind of fraud;
- Failure to separate the “organic” products from the conventional or “in-conversion” (whether intentional or not);
- Continuous nonconformities and lack of improvement.
- Serious incapacity of the ICS to evidence nonconformities.
- Serious incapacity of the ICS to work correctly;
- failure to perform 100% of the inspections (for derogations or calamity);
- Lack of an updated list of the farm operators.

Generally, in case of nonconformities of an individual or a subgroup it would be necessary to sanction the entire group. However, if the nonconformities can be attributed to a subgroup (for example, a control technician) and the organic integrity has not been compromised yet, it is possible to deviate

from the principle of sanctioning the entire group and limit the sanction to the nonconforming subgroup.
It is important to underline that during the evaluation of possible cases of withdrawal of the certification, the control unit should always take the general context into consideration. Important factors to be considered are the following:

- History of the ICS (e.g. Has this situation happened in the past?);
- Has organic integrity been compromised?
- The intentionality of the event (e.g. Did the ICS know about the infraction? What measures have been taken?)
- Other relevant points.

Every nonconformity must be evaluated in view of the risk (low, medium, high) and the percentage of operators who have undergone re-inspection as a confirmation of such nonconformities. This percentage is defined as “re-inspection index.”
However, in case ICEA finds the internal control system to seriously lack reliability and effectiveness, ICEA shall increase the number of farms subject to their annual inspection to at least three times the square root of the number of farms in the group.

8. CERTIFICATE OF INSPECTION

ICEA shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has carried out a documentary check on the basis of all relevant inspection documents, including in particular the production plan for the product concerned, transport documents and commercial documents and, as appropriate according to its risk assessment, it has carried out a physical check of the consignment.

However, for processed products, ICEA shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has verified that all organic ingredients of such products have been controlled and certified by a control authority or control body listed in Annex III or IV or have been produced and certified in the Union in accordance with Regulation (EC) No 834/2007.

Where the operator carrying out the last operation for the purposes of preparation is different from the producer or processor of the product, ICEA shall only issue the certificate of inspection and sign the declaration in box 18 of the certificate after it has carried out a documentary check on the basis of all relevant inspection documents, including transport documents and commercial documents, it has verified that the production or the processing of the product concerned has been controlled and certified by a control body or control authority recognized for the products concerned and the country concerned in accordance with Article 33(3) of Regulation (EC) No 834/2007 and it has carried out, as appropriate according to its risk assessment, a physical check of the consignment.

As a general matter, for all cases, all the necessary evidences will be required to applicant, before to issue the certificate of inspection, in order to have all available information.
Time needed to issue the certificate of inspection will also depend on time necessary for the operator to provide all required evidences.
Application for the certificate of inspection shall be done at least 10 days before shipment of the related lots in order to permit to carried out, as appropriate according to its risk assessment, a physical check of the consignment.

At the request of the Commission or of the competent authority of a Member State, ICEA shall make available without delay the list of all operators in the organic production chain and the control authorities or control bodies under whose control those operators have placed their operations.

The certificate of inspection shall be made in one single original.

The certificate of inspection shall be issued by ICEA, endorsed by the relevant Member State's competent authority and completed by the first consignee on the basis of the model and the notes set out in Annex V and using the electronic Trade Control and Expert System (TRACES) established by Commission Decision 2003/24/EC.

The original certificate of inspection shall be a printed and hand-signed copy of the completed electronic certificate in TRACES or, alternatively, a certificate of inspection signed in TRACES with an advanced electronic signature within the meaning of Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council or with an electronic signature offering equivalent assurances with regard to the functionalities attributed to a signature by applying the same rules and conditions as those laid down in the Commission's provisions on electronic and digitized documents, set out in the Annex to Commission Decision 2004/563/EC, Euratom.

When the original certificate of inspection is a printed and hand-signed copy of the completed electronic certificate in TRACES, control authorities, control bodies, relevant Member State's competent authorities and the first consignee shall verify at each stage of issuing, endorsement and reception of the certificate of inspection that this copy corresponds to the information indicated in TRACES.

To be accepted for endorsement, the certificate of inspection shall have been issued by the control authority or control body of the producer or the processor of the product concerned or, where the operator carrying out the last operation for the purposes of preparation is different from the producer or processor of the product, by the control authority or control body of the operator carrying out the last operation for the purposes of preparation as defined in Article 2(i) of Regulation (EC) No 834/2007.
That control authority or control body shall be: (a) a control authority or control body listed in Annex III to this Regulation for the products concerned and for the third country in which the products have their origin, or, where applicable, in which the last operation for the purposes of preparation has been carried out; or (b) a control authority or control body listed in Annex IV to this Regulation for the products concerned and for the third country in which the products have their origin or in which the last operation for the purposes of preparation has been carried out.