



## **REGULATIONS FOR THE CONTROL AND CERTIFICATION OF ORGANIC PRODUCTS IN THIRD COUNTRIES**

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These regulations for certification of the Suolo e Salute s.r.l. Control Body were drafted by the department head, verified by the Quality Manager and approved by the Board of Directors. They are in force from 14 March 2016, and supersede any previous similar document and it is the only document that is actually operational.

THE R.AQ

THE PRESIDENT

## **REGULATIONS FOR THE CERTIFICATION OF ORGANIC PRODUCTS IN THIRD COUNTRIES**

### **01 Introduction**

Suolo e Salute s.r.l. (hereinafter referred to as the OdC) is a Control Body for organic agriculture which took over the certification business of the original Associazione Suolo e Salute.

The purpose of these regulations is to regulate the activities of control and certification of controlled operators who manage their activities under Regulation EC 1235/08, in equivalence to Regulation (EC) 834/07, as amended. Certification of conformity is issued after assessment of the activities through audits undertaken in accordance with a standardised procedural process drawn up by an OdC, and based on documentary evidence and assessment of the results of any analyses carried out on samples taken from the controlled companies. Certification of conformity to organic farming methods is applied to agricultural and food production of plant and/or animal origin, regardless of the various stages of the supply chain the beneficiaries operate in during the production, preparation, processing, marketing and import processes. "Organic product" means crop and livestock production obtained using an "organic method", in accordance with current national and international legislation relating to agricultural and industrial production. The OdC's activities are aimed at verifying conformity by controlled operators to the above legislation in order to provide, in the various stages of the supply chain, adequate guarantees for the inspection system and the end consumer. Suolo e Salute does not provide, either directly or through affiliated companies, any technical or management consultancy or support activities for the drafting of documentation required for product certification schemes.

### **Scope**

The scope of these regulations includes all firms in the other countries in the organic food supply chain. The OdC operates in conformity with the rules set out in Regulation (EC) 834/07, Regulation EC 889/08 and Regulation EC 1235/2008, as well as internal Technical Standards that are an integral part of the above-mentioned EC Regulations. Also, as an OdC accredited by Accredia, it operates in accordance with the ISO/IEC 17065:2012 which defines the requisites that product certification bodies must possess,

### **General requirements**

The OdC carries out audits, issues certificates of company conformity and certificates of inspection of products imported from other countries, as well as approval of the wording, in terms of conformity, of labels and the issuance of company certificates to all controlled entities which request them and meet all the requirements of the inspection system.

### **02 Definitions and Abbreviations**

**CONFORMING COMPANY:** a company that meets the requirements to start organic activities and therefore enter the inspection system.

**NON-CONFORMING COMPANY:** a company that does not meet the requirements to start organic activities and therefore enter the inspection system.

**CERTIFICATE OF CONFORMITY:** a document certifying the company's inclusion in the Suolo e Salute

inspection system for the specific notified activity.

**BIG PLOT:** a legally uniform group or aggregation of elementary plots or similar included in an administrative area.

**SAMPLE:** a quantity of sampled material, belonging to the same field or lot, divided into four parts that are similar to each other of a minimal amount sufficient to allow analytical testing to be carried out.

**Board:** Board of Directors.

**CTD:** Technical Deliberation Committee.

**TFC:** Technical Foreign Coordinator.

**CSI:** Committee for the assurance of independence.

**CERTIFICATE:** this is the document is issued to a company certifying that it has implemented production standards equivalent to those under Headings III and IV of Regulation EC 834/2007;

**CERTIFICATE OF INSPECTION:** a certificate defined by Regulation EC 1235/2008 authorising the release for free circulation in the Community of consignments of products imported under the system of equivalence referred to in Article 33 of Regulation (EC) 834/2007;

**CERTIFICATE OF TRANSACTION:** a document certifying that a specified amount of product, subject of a shipment from a third country to the European Community, has been obtained in accordance with current legislation in organic agriculture (Reg. EC 834/2007 art.33.1d and Reg. EC 1235/08 annex V). This authorizes the release for free circulation in the Community of a products batches imported under the equivalence regime in according to art. 33 of Reg (EC) 834/2007;

**FORMAL WARNING:** a written warning to remove a non-conformity.

**EXCLUSION FROM INSPECTION SYSTEM:** deletion of an operator from the inspection system; readmission must be preceded by the submission of a new application (first notification with the requirement, for an agricultural and zoo-technical company, to an under conversion return, respectively, of the allotments and animals).

**INFRINGEMENT:** a manifest breach, or a breach with a prolonged effect, of the obligations prescribed by Regulations(EC) 834/2007, 889/2008 and 1235/2008, both in documentary terms, and contravention of the additional obligations borne by the operator, including the failure to comply with Technical Standards and certification regulations, as well as contractual obligations.

**IRREGULARITIES:** failure to comply with formal documentary aspects, as well as failure to apply the provisions of the Regulations(EC) 834/2007 and 889/2008 and 1235/2008, without prolonged effects that can change the company's status.

**INSPECTOR:** an expert technician who carries out audits on operators.

**LABORATORY TESTING:** an analysis laboratory that operates in accordance with the UNI CEI EN ISO/IEC 17025 standard, which possesses ACCREDIA accreditation for its testing methods with measurement precision and uncertainty in the ranges required by the ODC

**TECHNICAL APPLICATION STANDARDS FOR COMPANIES UNDER AN EQUIVALENCY SYSTEM:** internal instructions on the management of operational aspects which are used to assess equivalence to Regulation EC 834/2007.

**NON-CONFORMITY:** an action or situation that does not comply with the regulations, contractual agreements and technical specifications for organic production.

**OdC:** Control Body

**OPERATOR:** a natural or legal person who produces and/or prepares and imports products of agricultural or animal origin from other countries for trade purposes, or who carries out conditioning, distribution and/or the exclusive sale of these products. Persons who individually harvest vegetable products are also operators.

**LOT:** a quantity of products covered by a single certificate of inspection submitted by the same means of transport and imported from the same country.

**PRODUCT UNDER AN EQUIVALENCY SYSTEM:** product imported from another country produced according to production standards equivalent to those under Headings III and IV of Regulation (EC) 834/2007 (Article 33);

**CONFORMING PRODUCT:** product imported from another country produced according to production standards that meet the requirements of Headings II, III and IV of Regulation (EC) 834/2007 (Article 32);

**TEST REPORT:** document describing the test results and providing additional on them. It normally concerns a document showing the results of analytical testing.

**C.M...**Certification Manager

**CLAIM:** means a dispute relating to control and certification activities with regard to actions taken by the OdC, concerning suppliers, and directly in relation to certified products.

**REMINDER:** a written invitation to remove a non-conformity.

**APPEAL:** a dispute brought by the supplier to adverse decisions taken by the OdC regarding disputes or decisions it has taken that concern the operator.

**INSPECTION SYSTEM:** organisation of all the activities and control processes related to conformity pursuant to Regulations (EC) 834/2007, 889/08 and 1235/08

**SE:** Headquarters/overseas branch

**SUSPENSION OF CERTIFICATION:** temporary withdrawal of certification for a maximum period of 12 months in relation to one or more allotments and/or production and/or preparation and/or import units, as well as individual production lines.

**PRECAUTIONARY SUSPENSION:** consists in a provisional prohibition to market in the organic supply chain a particular product as a result of founded suspicions on the compliance of the product or provisional inhibition in the use of the certificate of conformity, resulting in inhibition of marketing with the organic references products contained therein

**DELETION OF INFORMATION:** ban for the operator to use information related to organic production methods on its labels and documents in relation to lots or all its products.

**SUB PLOT:** parts of land that are uniform from an agricultural standpoint and which are part of a cadastral parcel of land (plot).

**Suolo e Salute:** Suolo e Salute S.r.l.

**T.I.:** Technical Inspector

**AUDIT:** visit to check an operator's activities.

### **03 References**

The following are the reference documents that are the basis of these Regulations: EU legislation and that of the foreign state regarding organic farming, the ISO/IEC 17065:2012 "Requirements for bodies certifying products, processes and services" ; the UNI CEI 70006 "General rules of an independent body for a standard product certification system"; the quality manual; company by-laws, articles of association, resolutions of the Board of Directors, and Accredia regulations, circulars and guidelines.

### **04 Organizational and operating structure**

The organizational and operational structure of the OdC for the organic farming method certification scheme is composed of the following:

#### At national level

- a Board of Directors (Board) which is responsible for all of the company's technical and administrative functions: Quality Department (UF.QUA); Deliberations Technical Committee (CTD); Technical Management (TM), Administration Directorate, Software Division, Marketing and Promotion Division.
- Committee for the handling of Appeals (CO.TRICO), the Committee for the Protection of Impartiality (CSI) which are independent bodies which support certification activities.

#### at a peripheral level

- Regional Directorate (DR) linked to the TM that is responsible for it. It is responsible for the operational management of the organic farming inspection and certification service in its area of responsibility;
- Overseas branches, linked to the TM, responsible for operational management of the organic farming inspection and certification service according to areas of responsibility.

### **05 Application for certification (entering the inspection system)**

An application to enter the inspection system concerns different types of operators: companies undertaking the production, preparation and packaging of food products, companies that only market products, and companies that import them.

#### **Production companies**

This category covers agricultural companies which produce crops and/or livestock, operating in accordance with current legislation regarding hygiene and other industry specifications. Applications must be formalised sending to SE a copy of the "Notice of production with an organic method". Operators who wish to submit to a prior audit must send an original copy to the SE and the relevant territorial Authority, where this is required by local regulations. Notification must be supplemented by copies of the following documents:

1. An identity document of the notification holder;
2. VAT number or tax identification code, or equivalent document.
3. Plans showing the declared surface areas/aerial photos which include the GPS coordinates required to facilitate the identification of the company's allotments;

4. Declaration of controlled areas (Declaration Form);
5. Programme for the use of zoo-technical fertilisers;
6. Livestock management programme;
7. Administratively defined plots list

***For companies that prepare, condition, or market food products, notification must be supplemented by the following documents in addition to points 1 and 2:***

1. Synoptic plans of buildings appropriately showing the dimensions and with evidence of their use and volumes;
2. Authorisations to trade issued by the relevant Authorities (except for operators who only market products without handling or storing them);
3. Specific contracts for processing performed by third parties.
4. HACCP Manual or equivalent.

Companies that carry out multiple activities (e.g. production and preparation), must include information in the notification that is specific to each type of activity.

Signing the contract is tantamount to acceptance of the payment of fees for the service defined by the Board on an annual basis, and an undertaking given by the inspected company to allow access to OdC staff or a party appointed by the latter to locations where products are produced, processed and handled Access must also be allowed for the formal verification of technical and administrative documentation concerning the activities subject to certification.

#### **06 Application proceedings and preliminary assessments**

The SE receives applications for entry into its inspection system from any persons who operate in the agro-food industry, without any limitations or discrimination. It assesses the documentation, and if it is correct, a first start-up audit is planned. If the documentation is incomplete or inconsistent, the SE must notify the party concerned of the entity of additions and/or measures necessary to overcome the highlighted non-conformities, indicating the timescales and deadlines. The entry process is considered to be suspended until the operator has completely complied with the OdC's requirements; the application will be permanently closed if will expire the allowed timing for the required documental integration.

Following the completion of the initial process, a person shall be appointed by the OdC to proceed with a start-up audit to determine the conformity of the application of the organic farming method, about in relation to the operator's environmental, operational, structural and management activities.

In particular, the audit assesses the state of conformity to the technical Suolo e Salute standards (IO 19.04E) adopted for production under the equivalency system.

The SE must acquire the controlled operator's entire file and send a copy of the documentation and audit report to the Foreign Office.

The TFC must assess the documentation it has received, and where it satisfies the requirements it must send it via internet to the CTD for its opinion regarding admission to the Inspection system. Once it has examined the file for conformity, the CTD must then state its opinion.

Where there is a favourable opinion the company is entered in the register of operators controlled by the SE and receives a certificate of company conformity to the OdC's inspection system.

Submission to the inspection system starts from the date of first notification with all the necessary documentation or, if documents are added after this date, the date the SE registers the missing documentation.

Where there is an adverse opinion, the SE must inform the company of the outcome and reasons that led to temporary ineligibility to enter the inspection system and any necessary corrective measures to overcome these deficiencies, indicating the maximum timescale for remedying them, on pain of the complete failure of the application.

The operator must send a declaration to the SE of the corrective actions taken within the defined deadline. These actions must be verified during the first audit. If no communication is received the application for entry shall be considered to have lapsed in accordance with the preceding paragraph.

## **07 Company documentation**

The documents listed below are sent by the SE and must be filed and kept up to date by the inspected company. The types of documents are different depending on the different types of companies:

### ***- Companies that produce crops and zoo-technical products***

**The raw materials file** is a tool used to record the origin, nature, quantity, and raw material produced by the company or from external sources.

**The crops activities file** is a tool used to record the productive use of technical means (protective products, technical resources, etc.) and the agronomic activities carried out by companies that produce crops.

**The sales file** is a tool used to record the nature, quantity, and reference to tax or accounting documents, of each product that leaves the company.

**Annual register of workstations (RAP)** is a tool for recording the status of beehives, requiring a fortnightly update and accompanied by adequate descriptive mapping. It is in a free format but must summarise the size and location of the beehives, their loading and unloading, the duration and mode of transportation, length of stay, conversion period and type of products obtained.

### ***- Companies that prepare and package food products***

Apart from the raw materials and sales files, the companies in question are obliged to correctly complete the **product processing file**, a recording tool which must contain the origin, nature, quantity and uses of all materials, raw materials, and the technical means used for processing.

### ***- Companies that that only market or store products***



These companies are obliged to complete the **raw materials** and **sales files**.

Companies engaged in multiple activities (e.g. production and preparation or preparation and import) are required to keep records for each specific activity.

Records may be kept on paper or computer files. In any case, during the audit updated copies of these records, duly completed in such a way as to allow the technical inspector, on the spot, to initial and/or sign them at the bottom of each page, must be available and must be printed on official paper signed and numbered that has been issued before to operator from the S.E.. The controlled operator is responsible for the filing and subsequent updating of the records on a systematic basis. The fiscal and contract documentation regarding purchases, sales and the performance of services must be kept on file and made available, together with the records, whenever necessary.

### **08 Analytical activities**

Representative samples may be taken by the Inspector in charge during inspection activities, based on the forecasts in the annual sampling plan drawn up by the TFC. They may instead be taken based on reasonable doubt or suspicion regarding the use of forbidden substances, or lastly, for monitoring purposes, in order to highlight risks related to possible sources of pollution that are external to the inspected company. The guideline criteria of the sampling plan is based on a risk analysis relative to the company, with particular reference to the more "sensitive" production supply chains, defined on the basis of scientific and technical considerations and statistical calculations using the historical data that has been collected. The number of samples in each SE, besides the risk assessment, is based on a minimum percentage of 10% of the total operators. Products subject to sampling can be either vegetable-based or animal-based originating from the company, as well as any other substances that are involved in the production process for various reasons. The OdC does not have its own test facilities. It delegates these activities to external analysis laboratories with which it has signed agreements.

The laboratories must be accredited in accordance with ISO 17025, or if there are no local laboratories certified in accordance with this standard, the analyses must be assured and assessed by qualified personnel. In countries where there aren't laboratories accredited to this standard, the SE shall use the analytical services offered by laboratories affiliated to the DT (Italia) of Suolo e Salute.

A specific report must be completed in relation to sample taking, signed by the Inspector and the operator. The operator must be given a set of four samples and the other three must be sent by the SE in a timely manner depending on the type of matrix and in any case not later than 15 days after they have been collected from an affiliated laboratory.

The sample set left with the inspected company must be properly stored by the operator in appropriate conditions to prevent its perishability.

When the laboratory receives the rates, provides immediately to the conservation of them.

In the shortest possible time they provide to the execution of analysis in one of the tree rates.

In case of positive result the laboratory brings forward that information sending an e-mail to the Foreign Office.

The Foreign Office communicates to the operator (in 7 days from receiving the analysis) the precautionary suspension which indicates the right of the operator to proceed with the counter analysis of the conserved rates in the accredited laboratory, specifying that the cost being met by the losing party.

The counter analysis has to be required from the operator in 7 days after the suspension received by e-mail,

fax, mail or registered mail.

In the case of positivity a cultivation is still in the field in others plots different from the one that one sampled, the Foreign Office provides immediately to the extension of the investigation also in the others plots designating an inspector and another sample taking.

Similarly if the positivity concern the stoked products, the Foreign Office extend the investigation to the stored material with different lots.

The way of management of the rates of the others plots and of their eventually positivity is the same as the first sampling.

Once received the report of the first rate sampled and if the operator doesn't request the counter analysis, the foreign technical coordinator issues a proposal of infraction in conformity with the dispositions expected to the procedure of no conformity and he sent the documentation to the CTD for the evaluation of measures to take following the no conformity.

If the operator has made use of the right of the counter analysis, CE awaits the results of the second analysis before proceeding with the proposal of infringement, keeping active the previously issued suspension. Meanwhile, the Foreign Office requires to the laboratory which analyzed the first rate to send 2 remaining aliquots to the laboratory chosen by the operator; investigations to ascertain the cause of the positivity of the analysis must be completed within 20 days from the communication of the precautionary suspension, unless there are technical problems related to the technical needs of the laboratory.

In the case in which the counter analysis of the sample are positive, Suolo e Salute brings together the CTD for the evaluation of the specific case.

If the second aliquot is negative, the Foreign Office asks immediately the laboratory that analyzed the first rate, and which is still in possession of the third sampled aliquot, to send the sample to a third accredited laboratory chosen by Suolo e Salute srl.

Once received the analysis of the third rate, Suolo e Salute brings together the CTD for the evaluation and if the result of the third report confirms the initial positiveness, decision will be issued as a result of the NC; if the result is negative, the suspension is canceled.

If a decision was issued, the operator has the right to appeal against the decision of Suolo e Salute availing of Co.T.Rico according to the provisions established by specific regulation.

The alerts about positive test results by third parties are managed as complaints and a extraordinary inspection activity procedure is activated, with an eventual sample taking. The maximum levels of tolerance of non-eligible are indicated in the operative instruction IO 19.01 which lists specific limitations relating to specific matrices sampled. These limits are not waived and affiliated laboratories must have adequate tools and methods that provide the analytical quantification limits equal to or below of those limits.

In order to evaluate the results of Multiresidual analysis, Suolo e Salute follows the official SANCO guidelines about the procedures for the analysis of foods and feeds, according to which shall be considered as definitive the value indicated in the analysis report minus the reported limit of uncertainty.

## **09 Audits**

The SE requires companies that carry out ordinary activities to be subjected to audits on the basis of the audits plan. Audits are carried out within 90 days of notification for companies in the start-up phase.

During the audit related to vegetable producers, the T.I. must collect the relevant satellite coordinates using the Inspection report attachment D1.

### **- companies in the start-up phase**

In the start-up phase, particular attention is paid to checking the correspondence of documentary material and what really happens in operational terms. A start-up audit is aimed at ascertaining eligibility to the inspection system, and therefore it must take into consideration the following aspects: technical know-how, the situation regarding the existing ecosystem and the extent of accidental and environmental risk factors.

In the case of producer groups, all the producers must be inspected during the start-up visit.

The audit must end with an opinion on eligibility by the T.I. and the date it will be carried out must be agreed with the inspected company.

### **- Companies subject to the control scheme**

Companies in the scheme are inspected at least annually in accordance with standard inspection plan drawn up by the TFC abroad with the approval of the Overseas Technical Division, in order to assess the application of the production method in accordance with Regulation EC 834/07 and the Technical Application Standards for companies in the equivalency scheme.

The number of audits and, in the case of producer groups, the percentage of producers to be visited during an audit are related to the value of company risk calculated using an objective method based on the use of a check list (Attachment 1 Risk Categories), which take into account the risk factors of the operators and the corresponding risk value associated to them. In the case of producer groups, the percentage of producers that undergo audits may be higher than that resulting from the risk assessment if it is deemed appropriate to do so by the TFC.

Monitoring visits are considered like announced audits, with the audit dates being agreed with the operators. Based on a decision taken by the TFC, if it is necessary for the evaluation of company conformity, extraordinary inspection visits can be carried out; furthermore on the basis of the operator risk and anyway on the basis of a minimum percentage of 10% of the total visits foreseen by the control plan, unannounced audits or audits at short notice (max 12 hours) are carried out.

During the different kind of inspection visits, the Suolo e Salute's technical inspector may be accompanied by external or internal observers with the role to verify the Control Body operations, coming from Accredia, public control authorities, the Suolo e Salute Quality Office, the CSI of Suolo e Salute srl (Committee for the Safeguarding impartiality), or by observers for the completion of the process of training for the staff of Suolo e Salute srl.

In these cases the operator, that is forewarned, have to accept these external observers giving them the full support and access to the facilities of the company.

The following are the identified risk factors:

#### ***Production of crops:***

main type of production;

production methods used;

company surface area (hectares);

non-conformities found in the last three years;

licensed operators.

#### ***Processors:***

Company Size (number of transactions/labels/export quantities per year);  
type of products prepared;  
non-conformities found in the last three years;  
number of certified/imported products;  
classification of operators;

Selection criteria have been identified for each risk factor, assigning a risk value to each of them in descending order according to their gravity. The combination of the risk factor criterion and the value assigned to it attributes a score for each risk factor. The sum of the values of each individual risk factor obtains the relative company risk value.

Since the company risk value is based on variable risk factors it may be subject to changes over time and consequently also a minimum number of audits per year per operator. Any changes in company risk must be communicated to S.E. in writing modifying of the annual control plan.

### **10 Issuance of certificates and approval of conformity wording**

If the exporter is controlled by Suolo e Salute, The Foreign Office will carry out a masse balance to verify the congruity: if this verification is positive the Foreign office will issue the certificates and the responsibility for their issuance is that of the Certification Manager.

After assessing applications from operators for the approval of a label, which requires the completion of Form RQ 16.13, where the operator describes the process and ingredients contained in its product, and provides a draft label, the TFC must approve the final label under its own responsibility. Approval only concerns the wording and logos related to organic production, in accordance with the requirements of Regulation (EC) 834/2007 on labelling.

On the basis of the certificate of company conformity, and after it has checked that the products are certifiable, the Foreign Office must issue, under the C.M.'s responsibility, the Certificate.

For sales made in the Third Country and / or between third countries, the SE, after the congruity's and sale's verification, when receives fiscal and other required supporting documents from interested companies, within 45 days of the transaction, could issue the Certificate of Transaction concerning if it is formally required by the company.

Suolo e Salute issues the following certificates:

- The **Certificate of Eligibility** is the declaration issued by Suolo e Salute, under the responsibility of the CTD, which indicates the products for which an operator is controlled. It is initially issued as the final step in the notification process.

### **11 Maintenance of certification**

Before 28 February of each year, the TFC must prepare a standard audit plan, which must be submitted to the C.M. for approval. Changes may be made to the plan, and in this case they must be authorised and approved in advance. For the companies already included in the inspection system, by 31 January of each year the SE acquires and send to the Foreign Office declarations of the surface areas under control (Declaration) and any variations. The TFC checks these declarations and in case of changes from the previous areas it can decide whether it is necessary to change the auditing plan. This change must be

authorized by the C.M.

The SE acquires notifications of changes from companies already included in the inspection system, retains the original documentation at its headquarters and sends a copy to the Foreign Office.

All notifications of change, will be reevaluated by the CTD and therefore should be addressed within 45 days from receiving by the SE to the Foreign Office in order to be evaluated and to have proposal for changes by the TFC. The TFC is responsible for the electronic transmission of the documentation to the CTD within 15 days of receiving them.

For all notifications of changes concerning the following aspects relevant to the operator's activities such as:

- an increase in the company's surface areas of more than 30% or in any case above 50 hectares;
- inclusion of new production processes;
- inclusion of zoo-technical products in the inspection system;
- inclusion of processing and/or new processing plants

Is required a specify audit.

Therefore, all the document must be sent to the Foreign Office for a consequent variation proposal. The TFC is responsible for (electronically) sending it to the CTD, in compliance with the previously described procedure.

## **12 Monitoring procedures**

The supervision of the operator commences after the issuance of the certificate of conformity, in order to ensure the maintenance of the general requirements set out by REGULATION (EC) 834/07 and the specific Technical Standards of the OdC for companies in the equivalency scheme, including all products that are marketed. During the monitoring audits, the operator must give access to all its land and company facilities to the personnel assigned by the OdC, and ensure they are given full cooperation.

Supervisory audits are announced before they are carried out, agreeing the audit date with the operator. Based on a decision taken by the SE, if it is necessary for the evaluation of company conformity, extraordinary inspection visits can be carried out; furthermore on the basis of the operator risk and anyway on the basis of a minimum percentage of 10% of the total visits foreseen by the control plan, unannounced audits or audits at short notice (max 12 hours) are carried out.

Samples may be taken under the conditions listed in paragraph 8 of these Regulations. A specific report must be prepared when samples are taken, signed by the Inspector and the operator.

## **13 Evaluation and certification of producers Group**

In some cases exist the possibility to verify and certify a producers Group. In this case a substantial part of the inspection work is carried out by internal inspectors in the framework of the internal control system set up by the group.

Suolo e Salute verifies and evaluates the effectiveness of the internal control system and certifies the group as a whole.

A group may be organised on itself, i.e. as a co-operative, or as a structured group of producers affiliated to a processor or an exporter. The group must be established formally, based on written agreements with its members. It shall have central management, established decision procedures and legal capacity.

The farms in the group must apply similar production systems and must be identifiable as "small farm". In this sense the considered parameters are the "geographical proximity" and the "size of the farm." In relation to the first parameter that is respected when the farms are located within the range of 50 kilometres. To assess "the size" of the farm are considered: the UAA (Utilised Agricultural Area) farm (which must be less than 10 hectares) and the cost of certification compared to total turnover of the farm (Example: a farm considered as "big" is one for which the cost of certification is less than 2% of the company turnover).

Suolo e Salute will inspect annually a minimum samples of this group according the criteria of Suolo e Salute procedure PRQ 19.

Processors and exporters can be part of the structure of the group, but Suolo e Salute will inspect them annually.

In case of producer group must be improved a documented internal quality system that includes a contractual arrangement with each individual member of the group- The producer group must design internal inspectors that must verify the efficiency of the group carrying our internal controls. These inspectors must ensure absence of conflict of interest; they must carry out at least one annual inspection visit to each individual operator including visits to fields and facilities. The internal control system keeps appropriate documentation including at least a description of the farms and the facilities, the production plans, the products harvested, the contractual arrangement with each individual member and internal inspection reports. The internal control system shall include the application of sanctions to individual members who do not comply with the production standards. It shall inform the Suolo e Salute of the irregularities and non-compliances found, as well as of the corrective actions imposed with agreed time for completion.

Suolo e Salute will evaluate the effectiveness of the internal control system, with the final aim to assess compliance with the production standards by all individual operators.

Suolo e Salute will carry out at least one annual inspection of the group and will carry out al least one annual inspection on the processors and/or exporters. According to the Suolo e Salute's risk assessment and related procedures, this Certification body will annually inspect a minimum sample of farmers included into the group to verify the compliance of the group and to evaluate the effectiveness of the internal control system.

In case Suolo e Salute will finds the internal control system to seriously lack reliability and effectiveness, this certification body will increase the number of farms subject to the annual inspection to at least three times the initial minimum sample of farms in the group.

#### **14 Exporting procedure**

In according to art. 13 of the Reg. (EC) n. 1235/2008, as modified by Reg. (EU) n. 1482/2016, the exporters and control bodies, for the management of their competence of the inspection certificate, use the integrated veterinary information system TRACES - Trade Control and Expert System, established by decision n. 2003/24 / EC of the Commission, subject to registration on the web portal.

All the batches of organic products exported, are accompanied by the original import certificate (inspection certificate) created through the TRACES platform and signed with an advanced electronic signature, in

accordance to art. 3 par.11 of the EU Reg. n ° 910/2014 of the European Parliament and of the Council or with an electronic signature that offers equivalent guarantees.

The operator who wants to export organic products in the EU must send to Suolo e Salute Srl a specific notice, 7 days before the expected arrival of the goods at the first receiving point, using the specific model RQ 27.01E "Communication for export of organic products".

With this communication the operator requires also the Certificate of Inspection for Import necessary for the introduction of the goods into the EU.

In the communication should be indicated the following information:

- the type of product and quantity marketed in the EU;
- the points of first reception and / or first product consignee;
- destination of the Certificate of Inspection;
- references of the courier used for delivery of the original copy of the Certificate of Inspection.

For the issuance of the certificate of inspection for imports the following documents must also be enclosed:

- Accounting document (invoice and / or delivery note) concerning the purchase of goods which have to be exported;
- If necessary, the supporting document of the supplier of the goods marketed in the EU;
- If necessary, the supporting document of the first recipient of the product, if different from the importer;
- Self-control analysis, if available, in, due to the batch exported, demonstrating the absence of substances not allowed under EC Regulation 834/07 and its implementing regulations and for the products such as soybean, corn and sunflower, also the absence of GMOs or substances obtained or derived from them. Such tests must be performed by an accredited laboratory, where present in the country of reference, in compliance with current regulations and recognized by the competent authorities of the third country.
- In the case of transport by ship, a copy of Bill of Lading

The exporter must send documents mentioned above before the beginning of loading operations, or transport, to the Suolo e Salute's Foreign Office at the following e-mail addresses: [estero@suoloesalute.it](mailto:estero@suoloesalute.it) and [estero@pec.suoloesalute.it](mailto:estero@pec.suoloesalute.it)

When Suolo e Salute srl will receive the documentation, it will make the necessary checks in order to issue the certificate.

Suolo e Salute will reserve the right to attend the boarding operations.

### **15 Changes to certification conditions**

The conditions of certification and the rules of the inspection system can, over time, vary due to legislative changes, resolutions passed by the Board of Directors and other changes of tools for the assessment of activity assessment.

If certification conditions are modified, the OdC must inform all the operators of the changes that have occurred, the corrective actions and the time within which they must be carried out. Failure to take these corrective actions shall result in the withdrawal of certification. A delay in implementing the corrective actions shall result in the suspension of certification.

### **16 Transfer to another Control Body**

If a controlled operator notify a withdrawal from the control system and the transfer to another CB, the

Foreign Office of Suolo e Salute operate in accordance with the following provisions. In particular, once received a notification for transfer to another CB, and once received the request from CB successor, the Foreign Office prepares a set of documentary checks necessary for the issuance of the transfer authorization that is issued as quickly as possible, in any case within 30 days of receiving of the request. If more time is needed to manage of the practice, Suolo e Salute have to formalize the reasons to the CB successor by the same deadline.

The CB successor accepts the operator under its own certification scheme providing the continuity of the control system using information received from Suolo e Salute.

The transfer authorization is the specific document which guarantee the continuity of the control in the case of transition of an operator to another CB.

The document contains the minimum information that are provided in the certificate. Those information are then extended with the following data: date of withdrawal from the control system and a list, if there were any, of non-conformities in the last three years with the related resolutions and sanctions issued to the operator.

Relying on company's risk assessment, Suolo e Salute could also plan an extraordinary audit necessary to retrieve all relevant information and which are essential for the proper acquisition of information provided by the transfer authorization.

If the involved company has some not conformance previously issued that is not still closed, Suolo e Salute will stop the transfer authorization until the company does not solve the non-conformities, issued by Suolo e Salute.

Suolo e Salute ensures to the CB successor, upon motivated request, the access to all information and documentation concerning the activity of control and certification in the possession of the operator relating to the previous controls.

Equally, if Suolo e Salute receives a notification from an operator for transfer from another CB, requires to the previous CB the same information contained in the authorization for transfer in order to ensure the continuity in the control system. If the requested information are not received within 30 days of the request or if these are not sufficient or satisfactory to ensure the status of corporate compliance, Suolo e Salute takes care of the notification of the operator without interruption and inserts it into the control system, for crop production and livestock companies with the qualification "in conversion to organic farming." Any and all pre-existing non-compliances will be charged by the Suolo e Salute which will require to the operator by written notice the resolution of non-compliances.

### **17 Sanctions**

On the basis of Community law there are two levels of non-conformity: infringements and irregularities, which are followed by sanctions whose type is graduated according to the capacity to affect the reliability of the inspection system.

The ODC has set out the procedure for the application of sanctions, in consideration of irregularities and infringements, in a specific procedure.

The following are the applicable sanctions:

- Recall



- Formal warning
- Deletion of information on organic methods
- Suspension of certification
- Precautionary suspension
- Exclusion of the operator

**Reminder:** this is a measure that has no effect on certification. The verification of corrective action is carried out during the next audit. Failure to comply with a recall leads to the application of a more significant sanction, i.e. a formal warning.

**Formal warning:** this is a measure that has no effect on certification provided it is remedied by the specified deadline. The verification of corrective action is carried out during the next audit. Failure to comply with a recall leads to the application of a more significant sanction, i.e. the deletion of organic information.

**Deletion of organic information:** the deletion of information entails the prohibition for the operator to include statements concerning organic farming methods on product labels and documents involved in the irregularity, relating to a lot or the entire production affected by the irregularity. Verification of the implementation and its effectiveness is carried out during the next audit. Failure to comply with the deletion of organic information leads to the application of a more significant penalty, i.e. the suspension of certification.

**Suspension of certification:** this is applied in the event that the reliability of the controlled operator is compromised, and it consists in the suspension of certification and return to the conversion period for the plot or animals affected by the measure. The suspension means that the operator is forbidden, for a defined period of time, from marketing products with indications referring to organic farming. This may refer to one or more processing areas or the entire company, as well as to individual processing lines. Verification of corrective action is carried out in accordance with the terms and manner prescribed by the relevant measure. Failure to comply with a suspension leads to the operator's exclusion.

**Precautionary suspension:** it is applied in all cases of founded suspicion and the other cases in which it appears prudent to protect the market and the consumer, in order to inhibit temporarily the commercialization with organic references of one or more products potentially non-compliant. The measure can concern only certain products or the entire activity, or all products present in the certificate. This is a provisional measure with a maximum duration of 30 days from the receipt of the measure. Suolo e Salute can extend the measure, for any valid and justified reasons, for further 30 days. At the same time, the operator has to provide, within 25 days from the date of receipt, to the Foreign Office of Suolo e Salute its findings and if required, it has to provide the relevant evidence to support a clarification of the doubts and circumstances that led to the measure.

**Exclusion of the operator:** this happens in cases of infringements of such a level that they compromise the reliability of the operator's management, and therefore inclusion in the inspection system, including when the commission of offenses is repeated, or if where the operator fails to fulfil the undertakings made to the

relevant Authorities and its contractual obligations to the OdC.

## **18 Contractual Obligations**

If an operator is excluded from the inspection system for non-fulfilment of contractual obligations, it may be readmitted to the inspection system after sending a proposal with appropriate reasons to the Manager of the SE. The proposal will be examined and may be accepted with a formal decision or document drafted by the Board and/or a delegate that has been assigned this responsibility. It is agreed that readmission will be subject to remedying the impediments that have generated them, with the restoration of the conditions and process defined in the first notification.

The certification body shall ensure its certification agreement requires that the operator comply at least, with the following:

- a) the operator always fulfils the certification requirements, including implementing appropriate changes when they are communicated by the certification body;
- b) provide all necessary facilities for carrying out the assessment, including those for the examination of documents and for the access to all areas assessed, to the records (including internal audit reports), to the personnel involved (for example, : in the activities of testing, inspection, evaluation, monitoring and reassessment) and to the resolution of complaints;
- c) the operator makes claims regarding certification consistent with the scope of certification and ensure that the certification documents are not used incorrectly;
- d) in making reference to its product certification in communication media such as documents, brochures, advertising, the operator complies with the requirements of the Certification Body be described in the IO 11:07 "Instructions for use of the logo" or as specified by the certification scheme;
- e) the operator complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity and on information related to the product;
- f) the operator does not use its product certification in such a manner as to bring Suolo e Salute srl into disrepute and does not make any statement regarding its product certification that Suolo e salute srl may consider misleading or unauthorized;
- g) Upon suspension, withdrawal or termination of certification, the operator discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme or by Suolo e salute srl (e.g. the return of certification documents) and takes any other required measure;
- h) If the operator provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;
- i) the operator keeps a record of all complaints made known to it, the results of the external or in self-control analysis and/or any other item relating to compliance with certification requirements and makes these records available to the certification body when requested. The operator must take

appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification and he must document the actions taken;

- j) the operator accepts as obligatory requirements for certification and applies them from the entry into force all the European and National regulations in the field of organic agriculture, as well as the Ministerial notes;
- k) the operator accepts the fact that non-compliance with legislative requirements prior to the conclusion of the contract can be provided for termination of contract;
- l) the operator signals without delay to the SE responsible for the area the results of any audits and measures taken by the public supervisory authorities;
- m) the operator covers the costs due for inspection and certification independently of the outcome.

## **19 Publications**

Every year Suolo e Salute compiles the following and update periodically the list of certified products and those of the companies that produce them.

## **20 Exchange of informations**

Suolo e Salute for the issuance of the certification according to art. 31 of Reg.EC 834/2007, requires information to other OdC and / or the Competent Authority to acquire useful information in order to verify the compliance of the controlled operators. In the same way Suolo e Salute on properly justified requests from other OdC, and / or from the Competent Authority is obliged to provide the requested information within 30 days from the formal request.

If a competent authority and/or other Member States and/or other Certification Bodies find a non conformance regarding a controlled company, Suolo e Salute, after specific investigation, will issue the sanction prescribed for the related non conformance on in other case Suolo e Salute will change the sanction if will be necessary.

In the same time if Suolo e Salute receive from Accredia or from another competent authority a notification of irregularity regarding the involved Company, will evaluate ix exit the possibility to suspend and/or cancel the certification.

As for the communication of sanctions following infringements the Foreign Office of Suolo e Salute provides promptly sending of the same by certified email to the SE of competence, to the European Commission and to the Mipaaf. The SE shall promptly notify it to the concerned operator.

## **21 Confidentiality and conflict of interest**

The OdC must ensure that all information acquired during audits is kept strictly confidential unless otherwise prescribed by legislation.

To this end all internal staff and assessors of the OdC, contracted to the company in various capacities depending on the situation and needs of the OdC, sign a formal confidentiality undertaking. This implies that all information on applicants and certified companies are processed as confidential information and all necessary measures are adopted to restrict access to company documentation.

Furthermore, in order to ensure impartiality and independence, all OdC personnel involved in auditing, deliberation are inhibited from carrying out any kind of consultancy activities for the operators they audit. Also, they may not carry out activities that are in conflict or contrast with the activities of operators.

## **22 Claims and appeals**

The appeals, against adverse decisions taken by the CB, is a right of the controlled operator .

Against the decisions of the CTD or any other structure of decision of Suolo e salute, individuals or companies who consider themselves damaged in their rights, of any nature, can appeal to the CO.TRICO

The appeals to the decisions and/or resolutions adopted by deliberative structure of Suolo e salute shall be instituted within a deadline of thirty days from the notification ( that could be sent by the postal service or by certified e-mail circuits) of the measure.

The appeals must be presented in two copies at the national head office of Suolo e salute s.r.l. (Fano, via Paolo Borsellino n. 12) where the CO.TRICO has his headquarter.

The appeal may also be sent by shipping with registered mail using the postal service: in this case it will be considered the date of award of the envelope to the Italian Post Office or other carrier qualified and authorized by law.

Suolo e Salute after appeal's reception, will verify that it is refer to the Suolo e Salute's Certification activity and in this case will inform the Co.T.Rico. about it. Suolo e Salute will inform the operator the appeal was received and that the starting of appeal's management.

The pronouncements of the CO.T.RICO. have an arbitral nature by virtue of the specific clause of compromise in the contract of subjection: the awards issued, therefore, are not subject to appeal except in the specific cases of the law and the competent court is the one of Pesaro with the exception of appeals concerning the productions DO which has the competent court in the place where the designation of origin is.

The CO.TRICO shall make his award within 30 days of receipt of the appeal, except in cases where, for reasons which will be mentioned from time to time, the decision will be taken within 60 days. From the pronouncement of the award, the CO.TRICO has 30 days to deposit motivations.

The award issued, duly documented and together with the justifications, is notified to the claimant at the domicile address.

The award issued contains the pronouncements on the condemnation to pay the costs by the losing party.

For the evaluation of the circumstances leading to the conviction or the compensation of costs refers to the rules in force in the Civil Procedure Code and as described in the rules for the handling of appeals.

The claims are related to abnormalities in the certification of Suolo e salute srl deriving from the controlled operators and from uncontrolled operators and / or from other stakeholders.

The claim must be filled on the form RQ 15:01 "Claims Submission Form" available on the official website of Suolo e salute srl , it must contain in detail the arguments of the compliant and submit the attached documentation to support the thesis, must consent to the processing of data by the claimant and must be formally sent by email or regular mail to the Office of Quality of Suolo e salute srl with the above rules,

otherwise the non-acceptance of the claim. There are no deadlines for the submission and forfeiture.

The Office of Quality within 5 days of receipt of the claim verifies the matters of complaint and confirms to the complainant the acceptance or rejection of the claim depending if it is referred or not to the activity of certification for which Suolo e salute srl is responsible. The answer with the outcome of the complaint process and any action taken for the resolution must be sent by the RAQ to the complainant within 30 days from the acceptance of the claim.

### **23 Revision notes**

These Certification Regulations for Other Countries of the Suolo e Salute S.r.l. control body, with code EM/REV 01:07, substitutes any earlier version with the same code.

The revision concerned the following:

points highlighted in grey, which identify the parts that have been changed.

**This document commits the parties (OdC and operator), and establishes their mutual rights and duties with regard to issued certification.**

These regulations are deemed to have been accepted and stipulated on the date the contract is signed

**THE R.A.Q**

**THE PRESIDENT**

**THE TECHNICAL MANAGER**

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