

Operational Manual for Certification of organic products

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DATE	REV.	EDITION	REASON OF THE REVISION

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1. FOREWORD

The certification scheme for products of organic farming in accordance with the rules on organic farming, is part of a certification system of regulated product, which imposes the respect of these standards and the standard ISO/IEC 17065 norm first.

The certification system is based on the following principles:

1. the quality of the product is the result of a process that includes the phases of production, verification of the activities, and the results achieved. Only the assessment of the whole process can give sufficient guarantees that the product conforms to specified requirements;
2. BAC does not substitute the operator, to which belong the primary responsibilities to respect the procedures of production and verification, self-control: 1^{er} level control, be the product in accordance with the requirements of certification and always respect the clauses and commitments determined by the contract and by the rules and procedure of the certification, agreed with BAC;
3. the Mission of BAC is to verify which is the ability of the operator to continuously respect all as indicated in the previous point, control by third parties: 2nd level control,
4. the operator should give objective evidence of compliance with the established requirements;
5. the requirements to monitoring should be expressed in measurable and verifiable terms.
 - Surveillance, (3^{er} level control), about the certification system and the activity carried out by BAC, is exerted by:
 - The competent authority in the territory;
 - The ACCREDIA accreditation body , on the basis of the standards ISO/IEC 17065 norm.

The system of certification carried out by BAC is composed of the following items among those expected of the standard ISO/IEC 17065 :

- ✓ Assessment of the project and, if possible, of the business management system;
- ✓ The validation of the process: verification of the ability of the process to regularly produce compliant products to specified requirements (the certified product is the result of a cycle in which predominantly is the production process aue is subject to assessment,)
- ✓ Tests conducted on samples taken directly from the market or the operator controlled, to improve the evaluation of the process and to identify fraudulent; behaviors
- ✓ monitoring on the product, on the process and, if possible, on the enterprise management system.

2. REASON FOR THE REVISION

This manual has been written as a new edition, in order to cover different organic certification schemes, to an International level, and to be in compliance with ISO 17065. Implemented requirements according to the ISO 17065 are in blue color.

As provided by art.12(1) (a) (b) of EC Reg.1235/2008 each time this manual is subject to amendments BAC will submitted to European Comission in real time.

3. OBJECTIVE AND FIELD OF APPLICATION

The present operating instructions Manual, OM, describes the requirements and the procedures laid down by BAC for the program of certification of products from organic farming on the basis of the regulations on organic agriculture.

Concerning the EU Regulation, this manual is applicable only in Third Countries for the certification in equivalence.

The OM is related with the MQ and operating procedures and refers to other documents, such as: regulations for certification; operating instructions, technical standards and registration forms.

4. STANDARDS AND REFERENCE DOCUMENTS

- Codex Alimentarius - International Food Standards;
- ISO/IEC 17065;
- UNI CEI EN ISO/IEC 17025;

- UN CEI EN 70006;
- UN CEI EN 45014/99
- Reg. CE 834/07 and successive integrations, as well as regulations concordant and national, regional and provincial regulations adopted on the basis of those regulations;
- The IFOAM Standard for Organic Production and Processing, Version 1.0.;
- National Organic Program (NOP);
- Guidelines of organic products: composition and labelling of organic food for Canadian Standards;
- Equivalence agreement between NOP/USDA Standard and the Organic Product Regulations of Canada (OPR 2009);
- Regulations of organic farming in the Ecuador;
- LPOMEX (Mexican law for the organic productions);
- BAC EU Equivalent Organic Standard 09/07/2009 v1.1 20/12/2012 rv. 1 24/11/2014;
- Bioagricert Standard for production of Inputs to be used in organic farming

5. DEFINITIONS AND ABBREVIATIONS

Definition or abbreviation	Description
CA (AC)	Competent authorities - Competent Authority - monitoring on the control system and the maintenance of records of organic operators. Local governments, for the territory within its competence which maintains registers of producers and processors.
ACCREDIA	It is the national system for certification, which covers the accreditation of certification and registration bodies in a proper registration.
Evaluation activity	Documentary examination or inspection or tests carried out by Bioagricert to obtaining certification.
BAC	Bioagricert Srl, with head office in Via Dei Macabracchia, 8 - Reno Casalecchio (BO)
CC Certification Committee	Bioagricert Certification Committee: technical organ that has competence to deliberate the certification.
Certificate of inspection for import	Document provided by the Reg certification scheme. CE 834/07, which certifies that there has been an amount defined product, from a third country to the community, in compliance with current standards of organic farming.
Certificate of organic products	It is the document where products for which BAC has authorized the licensee to make declarations in accordance with the regulations on organic agriculture are listed (Documentary evidence. The declarations of conformity granted by the licensee are represented by the labels on packaging for products destined for consumption and by transaction documents of for products destined to other controlled operators.
Transaction certificate	Document certifying that there has been a definite quantity of product, subject to a commercial transaction, in accordance with the regulations of organic agriculture
Final consumer	the consumer of a foodstuff who will not use the food as part of any operation or commercial activity in the food industry.
CRI	Appeal Committee – BAC Appeal Committee
CSI	Safeguard of Impartiality Committee - Bioagricert impartiality safeguard Committee: organ representative of all the involved parties, which has jurisdiction to determine the fairness of the processes of certification and control, in which are represented equally: consumer associations, associations of agricultural producers, associations of processors, distributors, technicians and scientific bodies.
Certificate of Conformity according to the Bioagricert Inputs Production Standard	Certificate of conformity based on the international regulations for the production of INPUTS for organic farming.
Declaration of the State of control	Document that is issued to the operator, which states that the company is in process of certification (or recertification). It is not a certificate of product and can not be used for the selling of organic products.
Distribution	Storage, or exposure for sale, offering for sale, selling, delivery or any other mode of trade organic products.
Transaction document	Document by which an operator says in writing that a batch of identifiable and traceable production, object of transaction to a customer, complies with the requirements specified in the certificate of conformity.

Agricultural company Agricultural Firm / Farm	Organization, or part thereof, that has as main objective the cultivation of the soil, livestock and related activities, which are the preparation and sale of agricultural products from the same company.
Certification scheme	Certification system regarding certain products and processes, to apply the same rules, the same particular rules, and the same procedure .
Evaluation	Examination of documents and/or inspection and/or testing by BAC for certification
Small Farmers Group- SFG	Association of producers, who must comply with the following features: homogeneity of the products, of the agricultural surface and the production methods used; same geographical area; easy and frequent contact between the members of the Group; low average income of agricultural activity.
Licensee or licensee company / Firm	Operator to which BAC has issued and maintains a valid organic products certificate. This operator has the responsibility to ensure that products for which the certification is issued meet continuously the requirements in the same certification is based them and, in general, any requirement of the law.
Guideline	Documentation for the application of reference standards, which define the rules of production, the characteristics of a product or process. These rules come from the standards of reference, which the operator must comply in the event of discrepancies between the lines guides and regulations.
List of licensees (LdL)	List of licensees and related products with directions to standards in accordance on the basis that they are certified. LdL can be achieved with a simple request to BAC.
Corrective action	Action taken to eliminate the causes of existing nonconformities or other situations in order to prevent unwanted recurrence
Preventive measure	Action taken to eliminate the causes of potential nonconformities or other situations not desired in order to prevent its recurrence
INPUTS	Product used for Defense and nutrition of plants in agriculture
MO	Operative Manual - operating instructions of the certification scheme
Sample	Representative Sample - amount of material for your sampling, which belongs to the same property or production lot, divided into four similar proportions among them, of a sufficient for analytical determination minimum amount foreseen.
Non-conformity	Lack of satisfaction of a requirement. Based on Community legislation, will feature two levels of non-conformity: irregularity and breach, who apply the consequential sanctions whose type is graduated according to the ability to put the safety of the control system.
OdC / CB Operator	Control and Certification Body - Control and certification body Physical or legal person who produces, prepares exports or imports organic products according to organic agriculture regulations, which has responsibility for ensuring that certified products always meet the requirements of base of the certification system, and, in general, in accordance with any other requirement of the law.
PDC	Annual Control Plan (ACP)
Risk	potential that an operator who Produce, Process or markets products do not comply with the rules of organic agriculture, causing damage.
Organic System Plan	Paper prepared and updated by the operator, which contains: <ul style="list-style-type: none"> - the description of the / the site (s), of activity of the operator, of the products to be certified and accounting information; - Description of the procedures adopted, based on a systematic identification of critical process phases, the implementation of these procedures should ensure at all times the processed products meet the organic production regulations; - the prevention plan with a description of the measures to reduce the risk of pollution substances or unauthorized products and the description of the preventive measures for prevent products not organic are put in the market with indications to organic production; - commitment of the operator and acceptance BAC certification procedure
Procedures and Operational Manual Processors	Prescriptive documents used by Bioagricert and managed in a controlled manner food Processing enterprise (of their or other companies products), places of storage, commercial company (selling to the wholesale or to the retail), producers of feedingstuffs, structures for the preparation of food for restaurants and canteens.
Primary production	the production, rearing or growing of primary products including harvesting, milking and the breeding of animals, slaughtering. It also include the harvesting of wild products but exclude the hunting and fishing .
Head of sector BAC (RS) BAC (RS) Responsible sector	Member of the Bioagricert Certification Committee having competence for the deliberation of certification.
Risk	consideration of a possible danger situation.
Sub-licensee	Operator that makes part of a process for another controlled licensee.

Traceability the possibility to find and follow the trail, through all stages of production, processing and distribution, of a food, a feed, an animal destined to food production or a substance intended to be incorporated into food or feed or likely to be so.

6. CERTIFICATION REQUIREMENTS

Requirements, which the operators have to follow:

- in the regulations of organic farming and its successive variations in related regulations and adopted national, regional and provincial regulations in accordance with such regulations and the Codex Alimentarius;
- guidelines and operating instructions;
- in Bioagricert certification Fees Doc.TB01 price table.

These documents are provided to operators that have subscribed the acceptance and receipt of documents.

6.1 BAC REGULATION FOR CERTIFICATION

The BAC regulation for certification describes:

- the conditions and procedures for granting, monitoring, extension, suspension, resignation, renewal and revocation of certification;
- the requirements and procedures of evaluation and certification;
- rights and duties of who applies for certification;
- the rules for the use of conformity mark, the precautions to be taken in the advertising and the modalities to correctly refer to certification;
- procedures to treat complaints, appeals and disputes;
- the efforts made by the licensee.

The regulation is approved by the CSI.

6.2 GUIDELINES

GuideLines are application documents of the standards of reference, that define the rules of production and the characteristics of the process of the organic product. The Technical Committee, appointed by the CC, issue the guide lines and elaborates the technical document after a careful analysis of the legislation of reference. This document is subject to the approval of the CC. Provides for the review the same cycle redaccion-verificacion - approval, and if there are no changes are confirms the previous document. All requests for clarification and/or interpretation of the BAC guidelines should be submitted in writing and directed to the CC, detailing the reasons of the application. After the changes, the operators can benefit from a adaptation period of one year.

6.3 CONTROL AND CERTIFICATION FEES

The fees charged to applicants for certification are defined in the Doc. TB01 Bioagricert Fees Table elaborated and approved by the Board of Directors, BoD/CdA and subordinate to the validation of the safeguarding of impartiality Committee, CSI.

The calculation of the Fees as follows:

- for the companies of production, a fixed fee and a variable fee per hectare on the basis of the type of crop and a fee per head of cattle, based on the bred species;
- flat for processing companies, a fee based on the size of the company and
- for exporting companies add a variable fee based on the value of exported organic products.

Only the Presidency, under the CdA delegation, can apply discounts on the Fees table to a simplification of the control activity.

6.4 MODIFICATION OF THE CERTIFICATION REQUIREMENTS

Amendments to the certification requirements may be based on the standards of reference, the regulations for certification fees. Where variations are provided to technical standards or regulations for the certification, new documents were sent to the licensees within three months from the date of approval. Process enterprises and the livestock one should apply the amendments made within 6 months from the date of adoption; plant production companies should apply the changes from the next production cycle. In the case of modifications of the legislation that may invalidate the conformity of products, operators are duly informed. The licensee may adapt to the new requirements, within the terms stated above or give up to the certification. In the case of maintenance of certification, BAC find compliance with the new requirements.

Variation fees, these are communicated to the licensees that may accept them or renounce the certification by means of a communication to BAC.

7. OPERATING INSTRUCTIONS AND COMPETENCE OF STAFF

Bioagricert staff has manuals and procedures to carry out its business with competence and adequacy. Bioagricert staff must maintain the confidentiality of the information acquired and, in this regard, it signs a declaration every year (Master 40) which also includes the communication of any conflict of interest.

The procedure for staff training, qualification, management and evaluation is *Pro. 004 Training of Personnel and performance evaluation*.

7.1 TECHNICAL INSPECTOR

Responsibility: perform inspection and sampling activity according to the requirements of the Standard, BAC operating manual, to the control plan and the contractual agreements with BAC (*Protocol of professional assignment, M041 Protocol rev. 00 - Assigment Protocol of Inspector*).

Areas of qualification: on the basis of their specific skills, curriculum, courses and training, technical inspectors are qualified for inspection activity in the following sectors: crop production/natural harvesting, livestock production, food processing.

Working tools

Qualified inspectors receive the following tools:

- ✓ *Operating instructions*, procedures, forms and standards.
- ✓ BAG mobile software for the consultation of operators' documents and information, including previous recommendations and non-conformities, certificates of conformity etc.
- ✓ Stamp with inspector's BAC code.
- ✓ Equipment needed for sampling and for the shipment of samples to the laboratories.
- ✓ Control plan which includes the list of companies to be controlled and the period period (quarter) in which they should perform the inspections and the sampling activity, where indicated.

7.2 TECHNICAL EVALUATOR

Responsibility: evaluators are responsible for reviewing the documentation relating to each operator, including the results of the analyses, any non-conformities, recipes, labels etc. for the purpose of the certification proposal to be submitted to the Certification Committee for ratification and subsequent issuance of the certification. The evaluators conduct their activities in compliance with the requirements of the Standard and in accordance with Bioagricert procedures.

Working tools

Qualified evaluators receive the following tools:

- ✓ *Operating instructions*, procedures, forms and standards.
- ✓ Personal access to BAG software for the consultation of operators' documents and information.
- ✓ List of companies to be controlled.

8. ACCESS TO THE CERTIFICATION SCHEME: POLICIES AND PROCEDURES

8.1 POLICIES

BAC ensures:

- ✓ Free access to the certification scheme to all operators whose activity is considered within the scope of the certification and who are in possess of the applicable requirements;
- ✓ Non-discrimination of any kind and in particular: are not taken incorrect conditions of a financial nature or otherwise; access to assessment and certification is not influenced by the dimensions of the operator or membership of particular associations or groups;
- ✓ Treatment without discrimination of applicants and in particular the evaluation of the requests for access are still numbering Protocol on entry and not accepted requests are subject to the validation of the CSI.

BAC offers applicants the following documentation, that is send to applicants by mail or email:

- ✓ Certification procedure
- ✓ The request forms and instructions, including: application for certification , organic system Plan / management plan, recipe, list of suppliers, e.g. for labelling
- ✓ Operating instructions,
- ✓ Records Registers
- ✓ Guidelines or documents for the interpretation of the regulations
- ✓ Regulation for certification
- ✓ Fees

The evaluators and BAC Heads of sector are available to answer any questions and interpretative differences about the documentation sent to applicants.

8.2 PRELIMINARY INSPECTION

The operator may request a preliminary inspection. Once we receive the documents, technical secretariat records the operator BAC management system and assigns a number of Protocol in entrance, Coordinator of the inspectors assign the competent inspector for preliminary inspection, during which:

- ✓ visit the totality of the company and expresses an opinion on the possibility of applying the method of organic production;
- ✓ evaluates the documentation;
- ✓ indicates the errors found;
- ✓ records the results in the inspection report, signed by the operator.

For this inspection is charged to the company the cost corresponding to an additional inspection, according to the fees.

8.3 CLASSIFICATION OF OPERATORS

Controlled operators are classified in the following categories: producers, processors, mixed companies and importers.

Crop operations are the operators who develop primary production and/or conduct agricultural enterprise.

Handlers are operators carrying out activity of secondary production, using the primary production to processing, marketing or export.

Mixed are producers associated primary production to processing and/or marketing activity.

Importers are operators, natural or legal person importing products from organic agriculture with the aim of introducing them to the local market and practice the “ free circulation”, on their behalf or a representative.

Following, detailed the classification of operators in categories, clarifying the coding and the activities:

Definitions of the activities:

A producer

B processor

C importer

AB - producer - processor

BC - processor - importer

BC - producer - importer

ABC - producer - processor - importer

Additional definitions for producers (categories A, AB, AC, ABC):

z - producer with livestock production

a - producer of aquaculture

r - collector of wild products

v - vegetable production

Additional definitions for the operators:

s - producer of seeds

e - exporter to other countries organic product

p - beekeeper

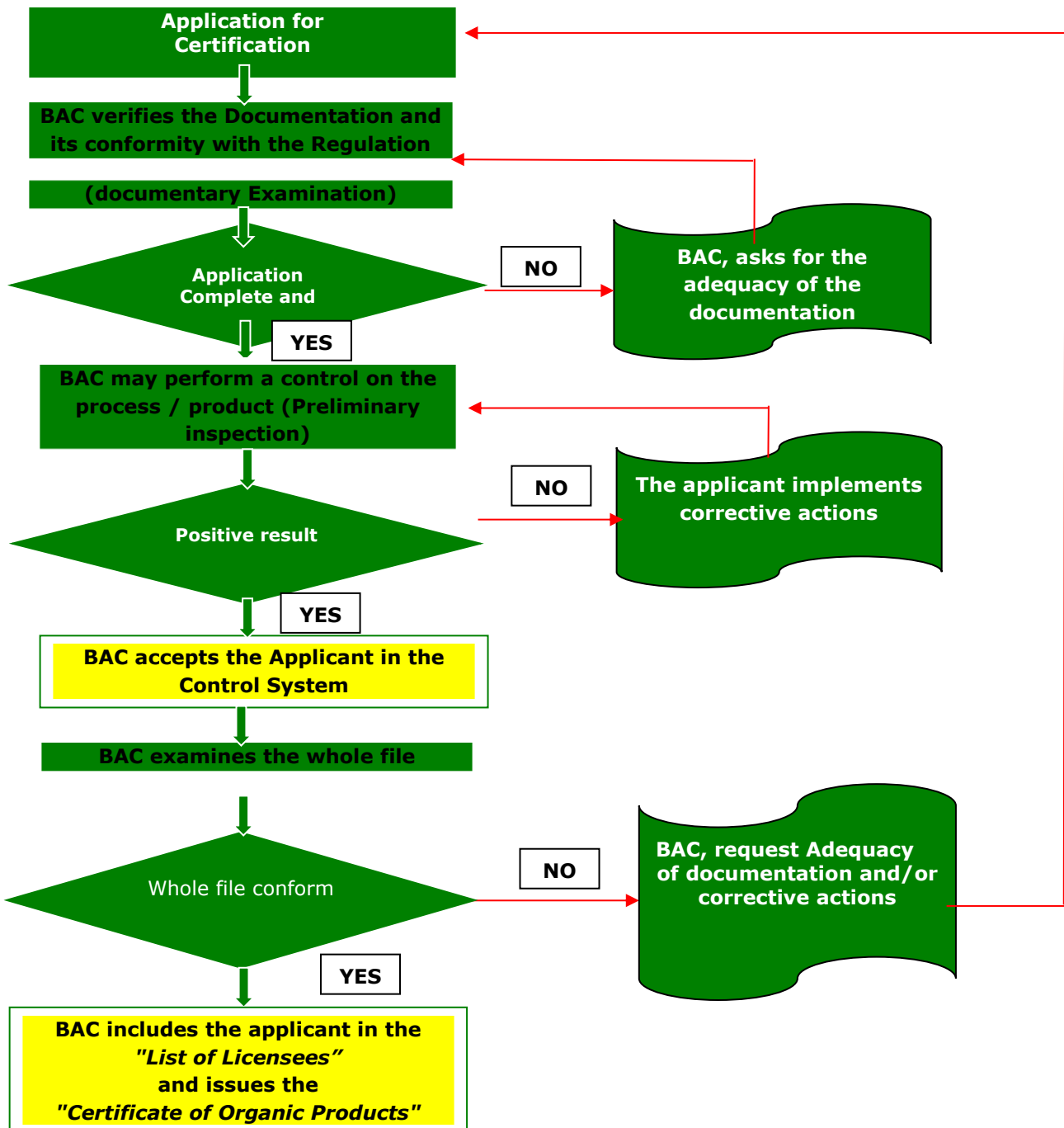
t - trader

g - wholesaler

8.4 PHASES OF THE CERTIFICATION PROCESS

Access to the certification scheme consists of two phases:

1. issuance of a declaration of the "state of control" that indicates the operator requesting its registration for the list of licensees is in process of certification;
 2. issuance of the "Organic Products Certificate", according to all the standards.
 For process enterprises the two phases may coincide, while for production operators registration in the BAC list of licensees is achieved only after the completion of the minimum period of conversion to organic farming. During this period the production company is subject to surveillance, as referred to paragraph 9.



Between the application and the issuance of the certificate, there is a period of maximum 90 days

8.5 REQUEST OF ACCESS TO THE CONTROL SYSTEM

The access system depend on the different types of companies.

8.5.1 Crop Operation

The request to access is done by using the following documentation:

1. Application form:

Description of the company, used agricultural surface (SAU) kind of activity and business structures;

2. Management plan /Organic System Plan (OSP), which includes:

- production units and concrete measures adopted to ensure compliance with the requirements to apply;
- description of the total activity of the company, specifying the organic activity;
- production units (plots, harvesting areas, process and packaging areas), the preventive measures imposed (areas of respect, hedges, green areas) and the date of the last application of not compliant products ;
- Rotation plan adopted to maintain fertility and the organic activity of soil with duration in years and crops used;
- Management plan indicating cultivation techniques adopted for fertilization, pest and weeds control;
- mode of harvesting, storage and transport of products, specifying the measures taken to ensure the identification of the organic product and to avoid that these lots are mixed or come into contact with conventional ones;
- procedures for the maintaining of records;
- commitment of the producer (part 7)

3. Certification Request, in which the company indicates products to be included in the organic certificate. In this form, it is also described the annual production plan, where the company reports the estimated quantities for each field. This document has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations.

4. Other attached documents:

- ✓ Map of the farm, production unit, at minimum 1:10 000 scale, with boldface of the farm / unit boundaries;
- ✓ if applicable, the mappings of structures and premises for the storage, conservation and processing, etc.;
- ✓ documents of possess or rental of the unit;
- ✓ certificates relating to plots and buildings in possess or availability of the operator and related production;
- ✓ copies of documents that attest the previous activity in the event that the company already apply the organic method ;
- ✓ documents identifying the owner or the legal rapresentative.

8.5.2 Wild harvest Operator

The request to access is done by completing the following documentation:

1. Application form:

- the documentation required for the plant production companies.
- Where the land in which the harvest takes place are not owned by the operator, He/Her must provide the map of the area of interest and to harvest authorisations granted by the competent authorities, forestry, common, etc....

2. Organic Sysytem Plan (OSP) /Management plan, which includes:

- the total activity of the company, specifying the activity of organic;

- description of harvesting areas and the measures imposed to ensure respect of the organic standards indication of the presence of areas of respect, hedges, green areas, and in particular of the risk factors that can contaminate the area of harvest;
- description of the modalities of harvest and storage of products, specifying the measures taken to ensure to maintain the balance of the natural habitat, specifying the measures taken to ensure the identification of the organic product and to avoid at this stage that batches are mixed or come into contact with conventional products.
- commitment of the producer (part 7)

3. Certification Request, in which the company indicates products to be included in the organic certificate. In this form, it is also described the annual production plan, where the company reports the estimated quantities for each field. This document has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations.

8.5.3. Animal Husbandry operators

The request to access is done by completing the following documentation:

1. Application form, containing:

- the documentation and information provided for companies in plant production, together with the description of livestock productions: address of exploitation, number of head of livestock in breeding, relationship UBA / ha SAU and any activities related to livestock production.

2. Organic System Plan (OSP) / Management plan (technical report) have to describe:

- the total activity of the company, specifying the organic activity;
- production unit: stables, pastures, areas free, open parks, etc; if applicable, the premises for storage, to the process of animal products and structures for the storage of animal manure;
- the distribution plan of the dejections, together with the full description of the surfaces intended for crops, indicating any pasture area agreements necessary to not exceed the maximum limit of 170 Kg of N / ha SAU/year of dejections;
- the feed ration, next to the definition of a plan of rationing that envisages:
 - use only organic food, for the respect of the nutritional requirements of the animal;
 - for the herbivore species, the origin from the same company for at least 50% of s.s. (dry substance) annual ration and areas of rangeland managed according to an appropriate rotation program;
 - the list of the raw materials used in feed integration, according to the limits laid down by the legislation of reference;
- the origin of the animals: the races in the company, management plan of the mounts (open or closed cycle) and the measures taken in the event of introduction of extra business animals;
- health measures: write a health care plan that, in case of illness of the animal, envisages the use of homeopathic or herbal remedies, limiting to a minimum and only in case of severe suffering, the use of medicinal allopathic, and in this case duplicate the suspension time;
- stable structures: premises for the accommodation of the animals which, in addition to satisfying the requirements of the animals in the field of ventilation and lighting, respect a useful surface, (indoor and outdoor), enough to allow each animal freedom of movement needed to develop a natural social behavior.
- the identification of the animals, the concrete measures taken for the permanent identification of animals, (individually for the large mammals and lots for small mammals and poultry);
- methods of collection, storage and transport of products, specifying the measures taken to ensure the identification of the organic product and to prevent, during these phases, batches are mixed or come into contact with conventional;
- registrations: the methods of conservation of all records, always available in the company;
- commitment of the producer (part 7)

3. Certification Request, in which the company indicates products to be included in the organic certificate. In this form, it is also described the annual production plan, where the company reports the estimated quantities for each field. This document has to be sent to BAC at the time of the first notification and

following each year together with the documentation for the recertification, or during the year, whenever there are variations.

4. Other attached documents:

- plan of the stables, breeding, milking etc...;
- if applicable, the mappings of structures and premises for the storage, conservation and processing, etc.;
- documents of possess or rental;
- certificates relating to plots and buildings in possess or availability of the operator and related production;
- copies of documents that attest the previous activity in the event that the company already apply the organic method ;
- documents identifying the owner or the legal rapresentante

8.5.4. Beekeeping

The request to access is done by completing the following documentation:

1. Application form, containing:

- Description of the category of activity, reason and firm headquarters, representative;
- description of beekeeping production: total number of colonies, production units, of the type of production, any activities related to organic; organic bee productions

2. OSP /Management plan (technical report), has to describe:

- production units and measures concrete taken to ensure compliance with the requirements;
- the total activity of the company, specifying the organic activity;
- areas of nectar collecting (specifying the possible pollution risk factors), the areas of wintering and the plan of travel (if practiced nomadism);
- materials used for the construction of pictures and hives;
- the origin of the bees and identification form ;
- plan search of feed, with an indication of the food used for the nutrition of bees during winter or in the event of extreme weather conditions;
- the program of general prophylaxis and veterinary; cures
- for honey extraction and measures for the storage and transportation of products, specifying the measures taken to ensure identification of the organic product and to avoid mixing or contamination;
- the Organization of documentation with respect of: all veterinary treatments, operations, honey extraction, acquisition of raw materials etc. and the Registers to record the different operations;
- commitment of the producer (part 7)

3. Certification Request, in which the company indicates products to be included in the organic certificate. IThis document has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations.

4. Other attached documents:

- copies of documents which attest the previous activity, in case that the company already apply the method of organic agriculture;
- the bees annual production program (PAP-bees), where the planned annual production is declared and has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations;
- the management of the raw materials (Master 052-EN);
- the beekeeping prophylaxis (Master 054-EN);
- "Number of apiaries per year" Records (Master 055-en)
- Cartographic inventory , at the appropriate scale, of the places of installation of the hives.

8.5.5. Processing Operators

The request to access is done by completing the following documentation:

1. Application form, containing:

- Description of the category of activity, reason and social headquarters, representative;
- Description of the process and/or marketing activity;

2. Organic system plan (technical report) should describe:

- production units and concrete measures taken to ensure compliance with the requirements to be applied;
- the total activity of the company: field of activity, structures and production lines, organizational chart and number of employees;
- the organic process, flow chart, average production and additives and/or processing aids eventually applied ;
- cleaning and sanitizing procedures to ensure the correct use of the structures, machinery and equipment and to avoid possible contamination;
- procedures to ensure the identification and separation of the lots of organic products and kind of storage to avoid mixing or contact with conventional products;
- procedures to ensure the identification and transport to prevent that organic products are contaminated, replaced, mixed or come into contact with conventional products;
- the evaluation of suppliers: measures to determine compliance of the suppliers and supply, based on the organic regulations;
- procedures for the identification and traceability of products in entrance, during the process and of the output of the company;
- processing control and the sampling plan to ensure the safety and compliance of products to the regulations of reference;
- procedures for the management of non-conformities and complaints and products that do not comply;
- procedures for the maintenance of the records;
- commitment of the operator (section C)

3. request of certification, in which the company indicates the products that should be included in the organic certificate, the estimated production quantities and if such products are marketed labelled for final consumption or in bulk. This document has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations.

4. other attached documents:

- ✓ map of each structure containing the equipment and lay-out;
- ✓ sanitary authorization and other authorizations of the sector;
- ✓ list of organic products qualified suppliers;
- ✓ recipe with a list of all the ingredients used to obtain 100 Kg of product, additives and processing aids used (attaching their data sheets), packing material and a brief description of the methods of preparation of the recipe;
- ✓ any procedures and operating instructions of the company , should be attached at the Organic System plan;
- ✓ specimen of labels and advertising projects.

Note: In case the company ask for declaration of equivalence NOP-COR, the dossier must include:

- application for approval of labels/indications of organic products destined to Canada in equivalence NOP/COR
- verification of the conformity of the products to market in Canada in the scope of the agreement of equivalence Canada-USA and its restrictions, for suppliers certified by other organisms of certification based on standard NOP/USDA;

8.5.6. Mixed Operators

The request to access is done by completing the following documentation:

1. Application form

2. Organic System plan, that includes:

- Description of the activity of primary production and processing activity;
- commitment of the producer (part 7 and section C)

3. Request of certification, according to the procedures foreseen for production (crop, livestock and beekiping) and processing companies.

An exceptional case is considered the licensee who makes primary production activity associated with a first manipulation, first storage or labelling of product by the same company. In this case, the request of access is made similarly to production companies by adding the application and other documents, specimen of labels and sanitary authorization, if foreseen by law.

8.5.7. SubContractors and activities Sub contracted to third parties (subcontractors)

The activities carried out by third parties, are subject to the control system. Therefore, the licensee who wants to request an activity to a third party, describes this activity in its Organic System Plan. The performer of the activity (subcontracted company) is not a licensee with its own certificate of organic products but must comply with the rules of organic farming and organic productions and it should subject its activity to control system, based on the written contract between the licensee and the performer of the activity (contract of subcontracted work between contractor and subcontracted company).

The company that outsources some activities to third parties, in its organic system plan will include:

- 1) a list of the subcontractors with a description of their activities and certification bodies which they are controlled;
- 2) the contract of subcontracted activity which shall be subjected to control;
- 3) all the measures, including an adequate system of accounting records, to ensure, where appropriate, the identification of suppliers, vendors, recipients and purchasers of products that licensee put on the market;
- 4) authorization from the contractor and companies subcontracted to the exchange of information between certification bodies in reference to the operations subjected to the control.

In case that the outsourced company is subject to control under the regulation on organic farming, the licensee will have to save the certificate of the subcontracted (provider) organic products.

The processing company which only carries out activities for third parties, to undergo the control, need to submit to BAC the same documentation provided at point 8.5.5.

8.5.8. Small Farmers Groups - SFG

The small producers Group or "Small Farmer Group" - SFG, applies when there are areas in development or on marginal farmers , in situations of obvious poverty areas etc... Constitution and control of a group, aims to simplify the control activity and the fulfillments of the farmers and firms, reducing costs of certification of operators belonging to the group. Characteristics for belonging to the group are:

- the producers refer to a processor or an exporter that is responsible for the project generally acquires or collect the product of the small producers, and supports the costs of certification. The small farmer group may be organized on itself as co-operative or as structured group of affiliated to a processor or an exporter. When intended for export, the marketing of the products must be carried out as a group.
- the production areas are homogeneous and in geographical proximity. In particular generally marginal areas, crops practiced do not have a great diversification, they have a homogeneous management (more or less the same modality of cultivation); operators are in geographical proximity
- operators are generally small or very small producers or harvesters of wild products. Small means it has to annually selling value less of around \$5000. Companies that invoice more, should not be part of a group and should be controlled as individual companies, with all the obligations and the documents of the individual companies. Larger farms, whose turnover is higher than \$5000 but the external cost for individual certification is lower than 2 % of their turnover, can also belong to the group but have to be inspected annually by Bioagricert. Processors and exporters can be part of the structure of the group, but have to be inspected annually.

- The group must be established formally, based on written agreements with its members. It shall have central management, established decision procedures and legal capacity.

In the field of small producers, SFG, groups are distinguished producers with internal Control system (Internal Control System ICS) and groups without ICS.

SFG with Internal Control system (ICS)

The processor or exporter, that has responsibility in the chain of control, adopt a system of internal control, that is a documented internal quality system that includes a contractual arrangement with each individual member of the group. Internal inspections must be conducted by an "internal" inspector (not of the certification body - CB) who is designated by the group. The inspector must receive suitable training. The internal quality system sets out rules to avoid or limit potential conflicts of interest of the internal inspectors. The internal inspectors carry out at least one annual inspection visit to each individual operator including visits to fields and facilities and have to determine compliance with all regulatory requirements by all small producers (small farmers). The system has to be documented in a MANUAL of internal control (also can be called differently) which includes all the regulation requirements, the management and planning of the controls, the application of sanctions to individual members who do not comply with the production standards. This manual should explain in detail, how the control activities work, with which periodicity, as registrations and documents of all the producers are kept, etc...

The Group has to send to BAC:

- ✓ application form;
- ✓ list of producers belonging to the group, which has to include the name of the group, name of the farmer, name of the plot, total and certified surface of each plot, the crop, estimated production and the status (organic (O) or conversion (V)) and facilities;
- ✓ all the necessary documents such as maps, contracts with the group, titles of possession of land, ownership certificates, identification documents, etc...;
- ✓ list of producers suspended or resigned;
- ✓ Internal Control System - ICS;
- ✓ inspections made by the internal inspector of the ICS;
- ✓ irregularities and non-compliances found, as well as the corrective actions imposed with agreed time for completion
- ✓ Organic System plan;
- ✓ Request of certification;
- ✓ letter of the Authority to reduce the conversion period.

Bioagricert evaluates the effectiveness of the internal control system, with the final aim to assess compliance with the production standards by all individual operators.

SFG without Internal Control system, ICS

In the case in which the Group of producers does not have an internal audit system, the companies that are part of the project have to be controlled all and not randomly.

The group will have to send to BAC:

- ✓ application form;
- ✓ list of producers belonging to the group, which has to include the name of the group, name of the manufacturer, name of the plot, total and certified surface of each plot, the crop, estimated production and the status (organic (O) or conversion (V));
- ✓ all the useful documents such as maps, contracts with the group, titles of possession of the land, allotment certificates, identification documents, etc...;
- ✓ list of producers suspended or resigned;
- ✓ Organic System plan;
- ✓ Request of certification;
- ✓ letter of the Authority to reduce the conversion period.

8.5.9. INPUTS Operators - MT

The request for access is made up of the following documentation:

1. Organic System plan for INPUTS companies, which includes:

- ✓ *Notification of activity of production of INPUTS*, suitable for use in organic agriculture;
 - Description of the category of activity, reason and Company's headquarters, representative;
 - description of the activity of processing / marketing of prepared INPUTS;
- ✓ *Organic system plan (technical report, that may be filed with the BAC Form document or a business document that includes all the necessary information) and should describe:*
 - production units and concrete measures taken to ensure compliance with the requirements to apply;
 - the total activity of the company: field of activity, structures and production lines, organizational chart and number of employees;
 - process of INPUTS , flowchart, additives and/or processing aids employed;
 - list of the raw materials used and suppliers;
 - analysis of the product;
 - impact of the INPUTS in the environment;
 - procedures for the identification and traceability of products in entrance, during the process and of output of the company;
 - management of records and documents;
 - labelling and sale;
 - the company's commitment

2. request for certification, in the which the company indicates products which, if compliant, want to be inserted in the certificate, the estimated production quantities and if such products are marketed labelled or in Bulk. This document (81MTS -) has to be sent to BAC at the time of the first notification and following each year together with the documentation for the recertification, or during the year, whenever there are variations.

3. other documents to attach:

- ✓ map of each structure containing the equipment and lay-out indications;
- ✓ sanitary authorization and other authorizations of the sector;
- ✓ list of qualified suppliers of organic products (M_27-s);
- ✓ Composition of INPUTS (M 081-MTR-EN), with a list of the raw materials used, the the processing aid used, list of products and packaging that are made with the same formulation, indicating if is the case also the name of the company for which the product is made;
- ✓ any procedures and business operating instructions attached to the organic system plan ;
- ✓ specimen of labels and advertising projects based on "Guidelines and criteria" indicated by the production and evaluation of means compatible with organic farming.
- ✓ "*Sub Licensee Contract to regulate the use of the IFOAM Accredited seal together with Bioagricert seal*", contract sub-licensee to regulate the use of the logo "IFOAM Accredited" together with the logo of Bioagricert.

8.6. Evaluation of the Request

Once received the request, the BAC local office proposes to Bioagricert in Italy sector Manager, the inspector, to perform the inspection at the company, based on specific competencies (training of the technician, used language), the geographical position of the company and the absence of conflicts of interest. The BAC sector Manager assigns a technical evaluator for the assessment of the dossier and the inspector.

The technical evaluator in charge, assisted by the technical secretariat, evaluates the documentation, the presence of all the information and the means available to continue in the certification process. Then he communicates to the operator and to the inspector the approval or eventually the failures and adjustment required. The TI and TV assignees will also ensure that it is resolved all differences of understanding between the certification body and the operator, including the agreement on standards or other normative documents.

In case that the CC considers not to have sufficient capacity to carry out the activity of certification in relation to the scope and location of the operations of the applicant, do to a particular requirement as for example the language used, communicated to the same applicant the rejection of the application for certification.

In the event that the applicant for certification is subjected to the control of other CB, BAC will ask the CB of provenance, documents and following information:

- "not obstacles" for the registration of the company in the BAC control system;

- Date in which the activity of control over the company is finished;
- Communication of possible sanctions or non-conformities raised;
- Stock in the warehouse of raw, organic semi-finished and finished products;
- Other useful information, such as issued certificates, analysis, etc...

8.7. FIRST INSPECTION

The inspector in charge, within 90 days of the receipt of the initial documentation, performed the first inspection.

All the documentation relating to the inspection, including possible evidence acquired during control, must be delivered to the local office of Bioagricert, within the 10th of the next month of the date of inspection.

8.7.1. Inspection at crop operations

The technical inspector responsible inspect the farm, both the organic and non-organic part, and find out the details of the organic system plan:

- ✓ Control the description of the production unit, organic and not organic part, the places of storage and production, plots or the harvest area, stables, grazing land, breeding system, the INPUTS and, if the case, places in which processing or conditioning operations are carried out
- ✓ control measures that producer has activated or must be activated in the business unit to ensure the respect of the requirements;
- ✓ records the results of the previous control in the space provided in the M 080-EN;

The inspector, using the inspection report, evaluates the company, its Organic System Plan and the production, indicates the requirements of standard not respected, communicates possible non-conformities and takes samples for analysis. The inspection results are formalized in the relevant form signed by the operator (or who by him), which receives a copy of the summary of the inspection results with signatures (For NOP certification, the inspection report will be approved and delivered to the company together with the certificate). The sampling is formalized in the sampling report, nonconformities in non-conformity reports, signed by the operator (or who by him), that receives a copy. In the case in which the inspector cannot indicate to which accredited laboratory should be sent the sample, he can indicate in the sampling report, signed by the operator, that the sample will be sent directly by the local office.

At the end of the inspection, the technical inspector gives to the operator the following documentation, (if the operator not have yet), and give the information on the following steps and on the follow-up to the certification process:

- ✓ Operator (Farm) Register and other register to be used, if there are other activities related to production;
- ✓ Procedure for BAC certification;
- ✓ Documents for the interpretation of the regulations.

Note: if controlled operator provides its organic products to a company requesting the Declaration of equivalence NOP-COR, the inspector will have to fill in the form: verification of the conformity of the products to market in Canada in the scope of the agreement of equivalence Canada-USA and its restrictions, for the suppliers, according the standard NOP/USDA-certified by Bioagricert.

8.7.2 Inspection of processing operators

The technical inspector responsible to inspect the company, both the organic and non-organic part, and verify the organic system plan details. The Inspector records the control results in the appropriate space on the organic system plan.

The inspector, by using the inspection report, evaluates the company and its organic System plan and production, indicates the requirements of standard not respected, communicates possible non-conformities and takes samples for analysis. The inspection results are reported in the relevant form signed by the operator (or who by him), which receives a copy of the summary of the inspection results with signatures (For NOP certification, the inspection report will be approved and delivered to the company together with the certificate). The sampling is reported in the sampling report, not conformities in the not-conformity reports, signed by the operator (or who by him), that receives a copy. In the case in which the inspector cannot indicate the name of the accredited laboratory to which send the sample, will indicate in the sampling report, signed by the operator, that the sample will be sent directly by the BAC local office.

In addition, the inspector:

- ✓ acquires the necessary documentation to complete the control and the Inspection Report;
- ✓ deliver the missing BAC documents (records) etc.,
- ✓ install the BioAgriCert software (if requested by the company) and trains the staff to use it;
- ✓ verify and document:
 - input of organic products;
 - organic products in exit;
 - mass balance of organic products;
 - the conformity of processed products;
 - the identification and traceability of animal products;
 - The compliance with the requirements of the IFOAM-IFS/Bioagricert International standard for production and processing companies;
 - The compliance with the requirements of the NOP/USDA standard;
 - The equivalence and restrictions between the NOP/USDA and the COR standard;
 - the handling of complains and external notifications on operators;

8.7.3 Inspection of small farmer group - SFG

✓ SFG with ICS:

The Bioagricert inspector should carry out at least one annual external inspection of the group. The inspection has to be done in the presence of the person responsible for the group. The BAC inspector verify the plots, the requirements and the application of the manual of internal control, checking that all requirements are respected, inspecting the part organic or not organic and finding out the organic system plan details.

The inspection results to each producer are reported in the inspection report signed by each producer (or who by him), which receives a copy.

After controlling the defined number of producers, the technical inspector report all results in a single inspection form (Audit Report) signed by the head of the Group (or who by him), which receive copy of the summary of the results of inspection with signatures (For NOP certification, the inspection report will be approved and delivered to the company together with the certificate).

The sampling is reported in the sampling report, not conformities in the not-conformity reports, signed by the operator (or who by him), that receives a copy. In the case in which the inspector cannot indicate the name of the accredited laboratory to which send the sample, will indicate in the sampling report, signed by the operator, that the sample will be sent directly by the BAC local office.

How to calculate the risk and number of farmers to be inspected

Bioagricert assesses the risk considering the following factors:

- Risk Factors related to the crops:
 - value of the products
 - difference in value between the organic and the conventional products
 - farming practise/intensity in the growing area
 - Risk of use of forbidden products
- Risk factors related to the characteristics of the SFG
 - size of the SFG
 - risks for intermingling and/or contamination
 - The complexity of the group's production system(s);
 - degree of similarity of the production systems and the crops within the group
 - Group with split operations (organic and conventional)
- Risk factors related to ICS
 - number of years the group has functioned (experience)
 - 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.

Each year Bioagricert defines and justifies a risk-orientated sample of farms subject to their annual inspections. The number of farms subject to annual inspection cannot be lower than 10. For a normal risk situation, it shall be calculated as the square root of the number of farms in the group. The number of inspection for medium risk situation, in any case cannot be lower than 12 and shall be calculated as 1.2 square root of the number of farms in the group. For high-risk situations in any case it cannot be lower than 14 and shall be calculated as 1.4 square root of the number of farms in the group.

Minimum number of farmers to be inspected by the BAC inspector			
Number of group members = n	Normal risk factor 1	Medium risk factor 1.2	High risk factor 1.4
Minimum	10	12	14
n	Square root of n	1.2 Square root of n	1.4 Square root of n

The farms visited by the BAC inspector must be different from one year to the other. The inspector should also consider the following aspects:

- Larger farms, processors and exporters shall be inspected annually.
- From new members should be inspected the 2 square root of new members.
- If BAC finds the internal control system to seriously lack reliability and effectiveness, it 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.

If Bioagricert finds that the internal control system to lack reliability and effectiveness, it shall apply sanctions to the group as a whole, including, in case of serious deficiencies, the withdrawal of the certification of the group. In any case Bioagricert will apply sanctions described at 10.1 of this manual.

Bioagricert must perform witness audit(s) of internal inspectors. Bioagricert inspector reviews the information maintained in the inspector records and decides who the internal inspectors to be witnessed are.

✓ SFG without ICS:

In the case of a group of small producers without ICS, the technical inspector has to control to all producers, inspecting the part organic or not organic and verify the details of the organic system plan:

- ✓ Control the description of the production unit, places of storage and production, plots and the harvest area, stables, grazing land, breeding system, the INPUTS and, if the case, places in which processing or conditioning; operations are carried out
- ✓ control measures that producer has activated or must be activated in the production unit to ensure the respect of the requirements;
- ✓ records the results of the previous control in the space provided in the organic system plan;

The inspector, by using the inspection report, evaluates the company and its production, indicates the requirements of standard not respected, communicates possible non-conformities and takes samples for analysis. The inspection results they are reported in the inspection report signed by the operator (or who by him), which receives a copy of the Summary of the inspection results with signatures (For NOP certification, the inspection report will be approved and delivered to the company together with the certificate). The sampling is reported in the sampling report, not conformities in the not-conformity report, signed by the operator (or who by him), that receives a copy.

At the end of the inspection, the technical inspector gives the operator the following documentation, (if not available yet), and reports on the next steps and the follow-up of the certification process:

- ✓ Operators (Farm) Registers and other registered used, if there were other activities related to production;
- ✓ Procedure for BAC certification;

- ✓ Documents for the interpretation of the regulations.

8.7.4 Inspection of INPUTS companies - MT

The technical inspector responsible inspect the company and controls the production equipment, checking that everything that has been indicated in the Organic System plan for technical maens is ascertainable in the company. Records the control results in the space provided in the Organic System Plan.

The inspector, by using the inspection report and its annexes, evaluates the company and its organic System Plan and production, indicates the requirements of standard not respected, communicates possible not conformities.

The inspection results are reported in the relevant form signed by the operator (or who by him), which receives a copy of the Summary of the inspection results with signatures. Not-conformities are indicated in the not-conformity report, signed by the operator (or who by him), that receives a copy.

In addition, the inspector:

- ✓ acquires the necessary documentation to complete the control and the inspection Report, indicate to the Operator if necessary, modifications of the process necessary to be in compliance with the regulations applicable. It also formalized the procedures for maintenance of the documentation of control and registration for the following BAC administrative control;
- ✓ takes samples of the product for analysis;
- ✓ deliver missing BAC documents (Registers for records) etc.;
- ✓ install the BioAgriCert, software (if requested by the company) and train staff to use
- ✓ verify the
 - input organic products;
 - Output of organic products;
 - Mass balance of organic products;

8.8. FINAL EVALUATION AND DECISION FOR CERTIFICATION

The final evaluation and decision for certification are divided into two parts:

1. Acceptance of the operator in the control system and issuance of product certificate

8.8.1 Acceptance Of The Operator In The Control System

The operator documents, together with the inspection, sampling and not-compliance reports are evaluated by the evaluator, includes verification of the presence and accuracy of the Organic System Plan that contains the acceptance and signing of the Bioagricert rules

Note: For NOP, the evaluation will be performed in two steps – see Pro_010 NOP Certification Procedure

8.8.2. Issuance of organic products Certificate

To obtain certification of organic products, the crop operation has to have completed the period called "in conversion to the organic farming", based on terms laid down by the applicable rules. The starting date for the calculation is the presentation of the application form and the Organic System plan. Before the expiration date of the entire period of conversion and only for vegetable productions, the product will be certified as "in conversion".

Derogation:

Reotractive recognition of conversion period: In certain cases the period of conversion of the company ca be recognized retroactively.

In order to get the conversion period recognized retroactively prior to the date of the application, the operator has to submit:

-A written request addressed to BAC with a detailed description of the fields and agricultural practices during the previous three years.

-An official statement issued by a local competent authority declaring the statusof the farm concerning the use of chemicals products during the last three years.

-Any other supporting evidences (analyses, technical reports...)

During the first available inspection, the BAC inspector will verify the congruence of the information and will give a feedback on the inspection report.

Non Organic seed: In order to get derogation for the use of Non organic seed the operator must state on the OSP the use of Non Organic no treated seeds because Organic seed were not available on the market.

The search and procurement methods used to source organic seed and planting stock varieties, including:

-Evidence of efforts made to source organic seed, including documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock.

Sources should include companies that offer organic seeds and planting stock.

-Records may include, but are not limited to: letters, faxes, email correspondence, and phone logs from seed suppliers and companies; seed catalogs; searches of organic seed databases; receipts; receiving documents, invoices, and inventory control documents

For other kind of derogation, relevant documentatation will be required case by case.

Certification Proposal : The operator to access to the BAC LoL and to get the certificate of organic products will have to present the request enclosing (if applicable) the recipes, the list of qualified suppliers and the labels. The evaluator completes the evaluation documented by the M201; if the evaluation is positive, the evaluator makes the proposal of certification to the BAC sector manager for the issuance of the document attesting the conformity to the applicable standards.

In case of derogation, the evaluator review the request submitted by the operator and the onsite inspection and propose the acceptance of the derogation.

Deliberation of certification : the evaluator submits the certification proposal to the sector manager (which is also a member of the CC), if he accepts it, he can deliberate the issuance of certificate of organic products.

In the case of non-compliance or deficiencies that compromise the release of the certification, the CC requires the operator to apply corrective actions and the integration of the documentation, establishing a time for the adjustments. If within the specified time the operator proves that he carried out the appropriate corrective action, eliminating the deficiencies that were found, BAC will only repeat the necessary parts of the evaluation and the CC decides for the certification. Otherwise the CC communicates the operator the final denial of certification.

In case of derogation request the CC issues the notification of granted derogation on the basis of Certification proposal by the evaluator.

With the deliberation of the sector responsible or of the Certification Committee, can be decided to:

- Organic Products Certificate – EC Reg. 834/07 and EC Reg. 889/2008;
 - Product Certificate according to the NOP Organic Agriculture Rules - NOP/USDA Standard;
 - Certificate of Conformity to the Organic Agricultural Method - IFOAM Basic Standard;
 - US - CANADA organic equivalency certification - NOP-COR Equivalency Certification
 - Certificate of Conformity according to the Bioagricert Inputs Production Standard - IFOAM INPUTS
- ✓ the issuance of certificate of inspection for imports into the European Community of organic products, only for exporters (only EC Reg. 834/07)
 - ✓ the registration of the operator in the LoL for the products certified;
 - ✓ approval of the packaging labels and the authorisation to use of recognized conformity logos;
 - ✓ the granting of transaction documents for organic products.

The certificate of organic products is the document where are listed the products for which BAC has authorized the licensee to make declarations in accordance with the regulations on organic farming. The declarations of conformity granted to the licensee are represented by the labels on packaging for products destined for consumption and by the transaction documents for products destined to other controlled operators. The certificate of organic products is issued and signed by the CC of Bioagricert.

9. SURVEILLANCE ACTIVITY

9.1. Policy

Surveillance aims to find out that the compliance of the requirements is maintained continuously.

Surveillance is developed on the product, on the production process, the proper employment of certified organic products and, if applicable, on the organic system plan of the operators. All operator sites which are

subjected to BAC control, must be open to the technical inspector to carry out control, also without prior notice, at any time during working hours and must be always present at least one employee who can provide the necessary cooperation.

Inspections are conducted on the basis of an annual programme that ensures that:

1. during the year each operator receives at least one complete control of all applicable requirements;
2. the balance controls of raw materials, registration and certificates of organic products, are made during all inspection visits, except for inspections outside of the operational headquarters of the licensee (for example in supermarkets) and agricultural parcels without prior notice;
3. the inspector is assigned based on the specific competence (the inspector training), the geographic position of the company and the absence of conflicts of interest.

To avoid the risk of "familiarity" between inspectors and operators, BAC can decide to interrupt the continuity by a thorough inspection carried out by a different inspector. If comparing the results of two inspectors do not leave significant differences, the previous inspector can be commissioned to conduct a new round of inspections to the operator.

9.2 ANNUAL CONTROL PLAN

In February of each year, sector responsables prepare the Control Plan (PDC) for controlled operators. Based on the level of risk of not compliance with the regulations on organic farming, the minimum number of inspections per year is established, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

The risk analysis procedure shall be designed in such a way that:

- 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 of at least 10 % of operators under contract in accordance with the risk category are performed;
- at least 10 % of all inspections and visits carried out are unannounced;
- the selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk

The standard number of inspections and sampling that should be done for each risk class is indicated in the table below, in accordance with the provision laid down in Regulation (EC) No 392/2013, amending Regulation (EC) No 889/2008:

Risk class		N ° of announced inspections / year	N ° of unannounced inspections / year
1	LOW	1	0
2	MEDIUM	1	1
3	HIGH	2	1
Additional requirement		+ 10% per year of operators in risk class 2 or 3	Unannounced inspections must represent at least the 10% of the yearly total

Once decided the level of risk, for each operator, it is defined:

- ✓ the inspector;
- ✓ the technical evaluator or the person in charge of the dossier;
- ✓ the number and type of inspections and analytical tests during the year;
- ✓ the period in which must be carried out controls (quarter); the choice of the moment in which to place controls is related to the time of the year (or stage) more criticism, based on products and the annual program of production.

Each inspector endorses, for acceptance, his annual PDC with the Declaration of absence of conflict of interest with the operators who have to control.

Each operator in the reserved area of the website www.bioagricert.org can see the number of inspections and surveys established in the year for your company

Calculation of the risk level:

The assessment of risk for each operator is made as following (The total score places the operator in the relevant risk class):

Risk class		Score	Announced inspections	Unannounced inspections	Sampling
1	Low	From 4 to 7	1	0	0
2	Medium	From 8-11	1	1	1
3	High	From 12	2	1	1

Table 1. Risk analysis for crop operations

Risk factor		Score		
		3	2	1
1	Yield	high	medium	low
2	Kind of production	Covered crops; Nursery - seeds; Fruits (↓);	Vegetable (↓↑); Medicinal plants; Industrial crop; Crops not for food; Olives (↓), Wild harvest	Cereals; forage; grazing. Cactus, legumes
2	Adopted production method	Mixed companies		Only organic farming
3	Surface	More than 50 ha	From 15 to 50 ha	Less than 15 ha
4	Not conformities detected in the previous year	Companies with important infringements	Companies with low infringements	Companies with significant irregularities
5	License	Licensee		Not licensee

Table 2.- Risk analysis for livestock

Risk factor		Score		
		3	2	1
1	Yield	High	Medium	Low
2	Kind of production	Milk (↓); Eggs (↓); Meat (↓); Beekiping (↓)		Reproduction (↑)
3	Adopted production method	Mixed companies		Only organic farming
4	Size of livestock (in UBA)	More than 30 UBA	From 18 to 30 UBA	Less than 18 UBA
5	Not conformities detected in the previous year	Companies with important infringements	Companies with low infringements	Companies with significant irregularities
6	License	Licensee	Not licensee	

Table 3.- Risk analysis for processors

Risk factor		Score		
		3	2	1
1	Yield	High	Medium	Low
2	Size of the company: turnover, nr of transactions, etc	Amount of the contract \geq 900 €		Amount of the contract $<$ 300 €
3	Kind of processed products	Milled, canned vegetables, canned, feed preparation, sausages, steaks, canned meat, fruits and vegetables. Ice cream and frozen food distribution, storage and trading of cereals, milk and dairy products (U)	Preparation of pasta and bread, alcoholic and not alcoholic beverages, flaking, extraction of oil fat, candied, seeds, beekeeping products, eggs and products with eggs.	Packed fresh products
4	Nr of certified products	5 or more products	From 2 to 4 products	One product only
5	Classification of the operator	Processing / Trading, Export	Processing, Trading	Processing of own agricultural products
6	Not conformities detected in the previous year	Companies with important infringements	Companies with low infringements	Companies with significant irregularities

Table 4.- Risk analysis for companies with nurseries and seed production

Risk factor		Score		
		3	2	1
1	Yield	High	Medium	Low
2	Kind of production	Nursery of horticulture	Seeds	Nursery of orchards
3	Adopted production method		Mixed companies	Only organic farming
4	Size	Amount of the contract \geq € 700	Amount of the contract from 500 to 699 €	Amount of the contract $<$ 500 €
5	Not conformities detected in the previous year	Companies with important infringements	Companies with low infringements	Companies with significant irregularities
6	License	License		Not licensee

Legenda: (U) = risk value classifiable according to the specific characteristics of the company, evaluated case by case;

(↑) = value of risk may increase depending on the features of the company, to be evaluated case by case.

The Plan is periodically revised to insert new operators, visits and additional analysis and variations relating to the plan of operators.

Note: In each country could be necessary to have different parameters to calculate the risk to have their own criteria to calculate the risk level, in this case the parameters used to calculate the risk must respect minimum requirements (EU Reg. 889/2008 art.65 point 4) and should be approved as specific instruction for risk assessment.

9.2.1 MONITORING OF THE ANNUAL CONTROL PLAN

The correct and timely implementation of the control plan is verified by the RVAP by means of IT utilities of the BioAgriGest management system, in order to extract analysis about:

- ✓ n ° and percentages of inspections and sampling carried out and feedback with what was planned;
- ✓ n ° and percentages of inspections and sampling not carried out;
- ✓ period of carrying out the checks: n ° and percentages of activities regularly carried out, those in advance and those late, compared to what was planned;
- ✓ operators for whom surveillance has not been planned (e.g. operators who entered during the year).

Monitoring is carried out at least two times per year.

The IT tool is also used by:

- ✓ IT for self-control and to facilitate the definition of the calendar of activities to be performed;
- ✓ VISs for assessing the performance of inspectors;
- ✓ the TS for the acceptance of inspection reports;
- ✓ the RS and RR for the verification and acceptance of changes to the pdc requested by inspectors or headquarters;
- ✓ The RVAP on an annual basis for the verification of the amount of inspections / day per inspector.

9.3. INSPECTIONS

The following types of inspection are provided for:

- **announced inspections (VA)** communicated in advance to the licensee;
- **unannounced inspections (VN)**, scheduled without prior notice, to producers they consist mainly of the observation of the State of crops in field and the of the animals and for sampling; for companies of process consist in observation, at the headquarters of the licensee, of the processes in course, the mass balances controls in the warehouses and the sampling and also, in places of sale, on the verification of the conformity of labels, the use of the marks, the information for the consumer and sampling;
- **complete inspections**, in the processes organic and not. Inspections are usually announced and each operator should receive by the least one full inspection per year. Concern all applicable requirements and all the areas/activities submitted to the control;
- **partial inspections**, addressed to operator areas/activities more critical and, most of the time are unannounced inspections;
- **additional visits** provided for in the following cases: extension of certification; request for the reduction of the conversion period; new products or amendments affecting the product or the process or management, that may affect conformity certified products; non-conformities, complaints and information related to operators which, during the inspection, show a capacity of conform to the requirements of certification continuously; requests of certification based on different standards.

The inspector creates the inspection report based on the requirements applicable to the operator (producers, processors and INPUTS) and verifies the documents, non-conformities, the certificates delivered to the operator, of which have copy.

Inspection reports have to be filled out completely and thoroughly, including date and time of entry – and of exit and they have to be signed by the operator (or delegate) only at the end inspection and never before.

All the documentation relating to the inspection, including possible evidence acquired during control, must be delivered to the local Bioagricert office, within the 10th of the next month the date of inspection.

The operator at the end of the inspection has the right to receive a copy or a summary of the inspection report. In the case of the summary must contain at least the overall result of the inspection, the description of not-conformities and/or recommendations, prescriptions, the name and surname of the inspector and the operator and the signature of both parties.

In case of disagreement on the findings of the inspection, the operator may not sign the report, in this case, the same copy has to be sent to the licensee by certified mail.

The result of the inspections is considered confirmed by BAC if the operator does not receive different communication within 60 days of the date of the inspection (not applicable for NOP certification).

9.3.1 Inspection Of Producers

The surveillance system establishes that crop operations (both organic or not) are fully assessed to the conformity by completing the inspection reports. The inspection lets BAC to verify and update in relation to modifications involved (the Organic System Plan verification) and treatment of not-conformities and recommendations.

The inspection process is as follows:

1st step: observations in the field and condition of crops, of young animals, of the stables premises, of the bees and wild harvesting areas.

Control in the field concerns the animals, all plots, business cultures and wild harvesting areas (is advised to take a position to have a complete overview for comparison with maps of the company).

The objects of evaluation are:

- ✓ extensions of the areas declared;
- ✓ status culture: vegetative development, presence of weeds and conformity to declared techniques;
- ✓ suspected signs of treatment or fertilizers, for example the presence of white spots on the leaves, yellowing for phytotoxicity, weeds yellowish even if they are not at the end of its development (possible use of herbicides), presence of grains of fertilizer, displace soil surface;
- ✓ nutritional status: how are the plants (development and color of the leaves) evaluate them in relation to the declared fertilizers, previous crops and rotations performed;
- ✓ technical problems of crops (fertility, pests, etc.) and compared to those who are generally present in the area. In this respect it is advisable to consult others technicians in the area;
- ✓ risks of accidental pollution, noting the location of boundaries (conventional crops), the presence of barriers, source of irrigation water, promiscuous use of equipments for treatments;
- ✓ consistency of the animals and the type of management of the same (freedom of movement, availability of grazing, access to feed and water, etc.);
- ✓ structures used by for the stabling and paddocks area;
- ✓ composition of the ration and documentation for the conventional feed quota of GMO-free declaration(if applicable);
- ✓ health management plan and precautionary measures to avoid diseases dissemination (e.g. quarantine of animals acquired);
- ✓ consistency of the hives and type of use of the same and the suitability of the agricultural area ;
- ✓ plan and type of nutrition and origin of feed in winter (if applicable);
- ✓ plan of displacement (in the case of nomadism);
- ✓ conformity of the area (in the case of harvesting of wild products).

2nd step : administrative and Storage / warehouse controls

In the company, will evaluate:

- *plant production Register records; evaluate if* are registered the operations during field observation, if have been indicated by the operator or deducted by the inspector to evaluate and assess technical consistency(for example, unregistered fertilizers, leafy appearance and traces of wheels, etc.) and the presence of the supporting documents provided for in the rules on Agriculture organic;

- *stable, records* evaluate the ration food, veterinary, interventions correct registration of entry and exit of animals, registration of sale of products and the presence of the supporting documentary evidence foreseen by the organic Agriculture regulation;
- invoices for purchase of INPUTS (including bait, feed, veterinary drugs), whose employment is declared (in the report indicate the references to the document) finding that the amount acquired is compatible with the real requirements;
- *stores*, assess whether they are actually used the products listed in the records, and if they are present not-compliant products or empty containers. If the company is mixed (organic/conventional), indicate if there are separate storage unit;
- *documents of transaction*, only for the licensees, find out they are filled completely, indicating also the number of the last document used and the quantity of documents used in the time of reference; calculate totals marketed by culture/breeding and assess the compatibility with the unit/farm production; check a minimum of 10% of transactions, finding out the correspondence between the transaction document and accounting documents;
- handling of complaints.

3rd step: collection of sample and sending to the laboratory for analytical testing (Master 32)

Sampling in the field, in the offspring or in warehouses, soil, fruit or parts of plants, zootechnical feed products obtained in the unit, if foreseen by the inspection plan or in the case of suspect.

4th step: inspection report

The inspection results are reported in the relevant inspection report signed by the operator (or who by him), which receives a copy with signatures of the outcome of the inspection results (For NOP certification, the inspection report will be approved and delivered to the company together with the certificate).

9.3.2. Inspection Of The Processors

The stages of the Inspection of the processing are:

1st step , at the offices of the company:

- a) setting the agenda of the visit;
- b) verification of non-conformities and previous recommendations;
- c) management of complains that the operator receives;
- d) verification of the updating of the Organic System plan;
- e) verification of conformity of the organic products in entry/ input;
- f) verification of the sales;
- g) mass balance verification of organic products and labels;
- h) verification of conformity with the requirements of the IFOAM-IFS/Bioagricert International standard for production and processing companies;
- i) verification of compliance with the requirements of the NOP/USDA standard;
- j) verification of equivalence and restrictions between the NOP/USDA and the COR standard;

2nd step , in the storage:

- a) verification of the checks at entrance of organic products and list of qualified suppliers;
- b) verification of inventories of raw materials, semi-finished products and finished products and labels;
- c) verification of the labelling of the products in exit.

3rd step , in the production area:

- a) verification of the measures of prevention and good manufactural practices in the different areas of the processing, through verification of documents of each stage and direct interviews to the people in the company involved and relevant with the points of control;
- b) verification of identification and traceability of meat and eggs.

4th step: sample collection and delivering to the laboratory for analytical testing, by using the sampling report

5th step inspection report: the inspection results are reported in the relevant inspection report and possible not conformities in the report of not-conformity signed by the operator (or who it), which receives a copy (For

NOP certification, the inspection report will be approved and delivered to the company together with the certificate). Each inspection report must always report the date, the signature and the stamp of the inspector. Complete inspections relate to all applicable requirements and all areas/activities subject to control.

Partial inspections provided for by the PDC, can be done for:

- verification of previous not-conformities and recommendations;
- the control of mass balance, the registrations and the certification of organic products;
- sampling and verification of notifications and complains.

9.3.3 Inspection Of The Mix Companies

For the mixed companies are used the applicable parts of the operating instructions and of the documents available to producers and processing companies.

9.3.4. Inspection Of Small Farmers Group - SFG

The SFG inspection is performed according to the same information described in section 8.7.3. of this manual.

9.3.5 Inspection Of Inputs Companies - MT

Stages for the inspection of INPUTS operations are the same provided for processing enterprises. However, surveillance is planned on a triennial basis, with minimum inspection in the triennium. In any case in the course of the triennium should be identified all activities relating to certified productions. In the event that in the course of the three years involved variations on processed products, if they involved significantly in the activity of the company, at the discretion of Bioagricert, additional inspections can be arranged.

9.4 ANALYSIS

The sampling plan foreseen the analysis on the product to:

- ✓ improve the evaluation of the process, with the double aim of having an index of control of the correct application of the organic farming method by the operator and the verification of the conformity of the products;
- ✓ identify operators fraudulent behaviors ;
- ✓ validate BAC certification (having an index control effectiveness).

The choice of products and the number of samples that undergo analysis is based on the characteristics of the process and the probability of getting not-compliant products (risk). The analysis of the historical data of the tests, each year develops a sampling plan, with the definition of the processes/products "at risk".

Possible causes of risk are:

- ✓ use of chemicals products for defense, herbicides or other INPUTS not accepted in the organic;
- ✓ use of veterinary drugs, steroid anabolic hormones or other INPUTS not allowed in breeding;
- ✓ employment of acaricides and antibiotics forbidden in organic beekeeping;
- ✓ employment of preservatives, fumigants, or other additives not allowed in organic post-harvest and processing, including treatment with radiation;
- ✓ employment of products containing organisms genetically modified, or that derived from them, not admitted in all the stages of the organic process;
- ✓ pollutants and accidental pollution.

The amount of samples subjected to analysis must be sufficient to achieve a certain probability of identifying fraudulent and compatible with economic sustainability approach. On the basis of the level of risk of not-compliant production, the annual sampling plan has to foreseen as a minimum the following analytical tests (In any case, the number of samples to be taken and analysed every year shall correspond to at least 5 % of the number of operators under control):

Risk class	Level of risk	N ° sample for testing
1	LOW	0 + possible sample if a not-compliance is suspected
2	MEDIUM	1 sample to 20% of the operators + possible sample if a not-compliance is suspected
3	HIGH	1 to 100 % of the operators

Samples are taken:

- ✓ in the production sites of the operator, production or warehouse, and have to be statistically representative of the lots, subject to control;
- ✓ in distribution, supermarkets or wholesale to the retail, without prior notice to the licensee.

The choice of samples and sampling time, has the following objectives:

- ✓ increase the incidence of surveys of sensitive parts (e.g. leaves) during the critical times of the process of production;
- ✓ sampling in advance to avoid the introduction on the market of not-compliant products.

It can be perform additional sampling in the following cases:

- ✓ request of the operators;
- ✓ applications for retroactive conversion;
- ✓ complaint and notifications from a third parties;
- ✓ treatment of NC;
- ✓ suspect, during inspection, use of INPUTS not consistent (signs of treatment, the presence of non-compliant INPUTS, etc.) with the aquired elements.

In these cases, samples are taken considering the suspect, the complaints, the NC, and not necessarily the statistical representativeness of the batch of product.

The analysis must be accredited based on ISO 17025 and accompanied by data of uncertainty of measurement (if available) and generally performed by laboratories in agreement with BAC. For this reason in case the inspector cannot be established to which accredited laboratory must be sent the sample, it will put on the master M32, signed by the operator, that the sample will be sent directly by the BAC local office.

In the case of positive results, rises a NC to the operator to which will follow the suspension of the certification of the researched batch. If to support the decision end (for example, turned in conversion) necessary deepen the ongoing investigation could be undertaken additional analysis for investigate the cause of the NC (in case of accidental pollution and/or employment of not-conforming substances). This can happen especially with agricultural producers and when the level of residues which are found in the first analysis is close to the analytical limit quantification.

The method of sampling, packing, storage and transport of samples, analytical requirements for the different products to be analyzed are defined in operating instruction (IO_03 Method of sampling).

9.5 EVALUATION OF THE DOCUMENTS

The evaluation of documents corresponds to the control of papers and certificates accompanying the goods, of records and the correspondence between the goods and the information reported on these documents (approval of labels and monitoring of transactions).

9.5.1 Approval of labels

For products labeled, listed in the certificate of organic products, the licensee have to get approval of labels prior to market them. The approval of labels carried out in agreement with the standards of reference and with the BAC guidelines and applies to the following aspects:

- correspondence between the name (description) of the product on the label and the name (description) of the product on the certificate of organic products;
- terms employed which refer to the organic production (e.g., organic product, in conversion to organic farming, made with organic ingredients, , etc.;
- references to the licensee: company name, headquarters of the establishment;
- references to the certification: " Organic Certified by Bioagricert s.r.l.", the certification body code and control code of the licensee;
- identification of the product;
- list of ingredients;
- use of the BAC logo
- use of the logos as provided by the applicable standards;
- reference to the place of origin of the raw materials;
- in the labels of the organic products are not allowed the reference of the term GMO Free and statements that suggest to the consumer that the indications in accordance with the method of organic farming are guarantee of superior organoleptic, nutritional or healthy proprieties.

They are excluded from the field of application all the other instructions placed on the label, in reference to which BAC provides non-binding recommendations to the licensee.

Among the aspects not included in the application, they are:

- the name (description)of the marketing of the product, which is not subject to direct verification by BAC;
- "claims"
- use of logos of other organizations (eg. Demeter) or associations (eg. Kosher etc.), other OdC logos relating to other certificates (e.g., corporate quality system), which have to be approved by owners of logos.

Compliance labels with regulatory requirements not included in the scope of the approval of labels by BAC is under the sole responsibility of the licensee.

Respect of the graphics requirements and mandatory wording that needs to be put on the labels are described in the "Composition and labelling" Guidelines.

9.5.2 Applying for Transactions on DTPB platform

The system for issuing transaction documents or certificates is called DTPB. This platform is directly connected to the "Organic Product Certificate" specific for each scheme (EU, NOP) to avoid transactions of non-certified products.

The Transaction documents are issued by the operator on a web platform and are published on the websites www.bioagricert.org and www.trasparente-check.com. Lot certificates of inspection must be validated by BAC and published on DTPB.

The difference between each kind of certificate:

- **TRANSACTION DOCUMENT:** this document is issued only for domestic transaction and it must accompany the goods during their trip from the seller to the receiver. It can be issued and released by the operator directly and it is valid only during the validity period of the certificate of organic products. No documents are required from Bioagricert.
- **LOT CERTIFICATE** (*choose **lot certificate** from the menu Other Certificates*): it is issued for transactions to countries different from the operator one (USA, Taiwan, Japan, etc...). This kind of certificate is completed by the operator but released by Bioagricert after the submission of the request of release and technical review for accuracy and validity.
Supporting documentation and minimum control points:
 - a. Commercial invoice
 - b. Packing list
 - c. Booking confirmation from the shipping company or B/L draft
 - d. Certificate of origin and/or phytosanitary certificate

- e. Exporter declaration
- f. Updated mass balance report

As for this last point (f), the mass balance report must be kept updated by the operator and submitted to Bioagricert every time they apply for a lot certificate.

Documents should be uploaded to DTPB in the specific section “Accompanying documents”, but BAC asks that operators also send them by e-mail, because sometimes BAC cannot open them from that area.

9.5.3 Applying for Transactions on TRACES platform

CERTIFICATE OF INSPECTION (choose import certificate from the menu Other Certificates): this certificate is applicable only for products sold to EU. The operator must complete it with all the information required and, once finished, the request of release must be submitted. Bioagricert, after checking the correctness of the information reported, releases it. The original is sent to the European importer directly and a scanned copy is provided to the exporter. Please refer to the attached guideline “Certificate of Inspection”.

1. COIs must be signed by Bioagricert before the goods leave the Country of export. BAC recommends that operators submit COIs at least 2 or 3 days before the departure, in order to be able to validate them on time.
2. According to the provisions of the EU Commission, the definition of Exporter is the last operator performing the last operation of preparation (including packaging and labelling). This means that traders cannot be mentioned on the COIs.
3. Minimum required documents for COI validation:
 - a. Commercial invoice
 - b. Packing list
 - c. Booking confirmation from the shipping company or B/L draft
 - d. Certificate of origin and/or phytosanitary certificate
 - e. Exporter declaration
 - f. Updated mass balance report

As for this last point (f), the mass balance report must be kept updated by the operator and submitted to Bioagricert every time they apply for a COI and/or a lot certificate.

Documents should be uploaded to TRACES in the specific section “Accompanying documents”, but BAC asks that operators also send them by e-mail, because sometimes BAC cannot open them from that area.

9.5.4 Equivalency export arrangements (NOP)

Requirements for export of U.S. organic raw and processed agricultural products to Taiwan:

All products exported to Taiwan must respect the terms of the arrangement.

<https://www.ams.usda.gov/sites/default/files/media/USDATECROLetter.pdf>

<https://www.ams.usda.gov/sites/default/files/media/FAQTaiwan.pdf>

Export certificate to Taiwan:

- **TM-11 CERTIFICATE** (choose **TM-11 certificate** from the menu Other Certificates): it is issued for transactions to Taiwan. This kind of certificate is completed by the operator but released by Bioagricert after the submission of the request of release as for Lots and COIs described above. The

certificates are also used by port of entry officials in both the United States and Taiwan to document organic production.

Requirements for export of U.S. organic raw and processed agricultural products to Japan:

All products exported to Japan must respect the terms of the arrangement

- Equivalence Arrangement (2013) – Plants and Plant-Based Processed Products
<https://www.ams.usda.gov/sites/default/files/media/NOP%20Japan%20Letter%20to%20U.S..pdf>
- Equivalence Arrangement (2020) – Livestock and Processed Products Containing Livestock Ingredients
<https://www.ams.usda.gov/sites/default/files/media/JapantoUSLetterOrganicLivestockEquivalenceDe termination.pdf>

Export certificate to Japan

- **TM-11 CERTIFICATE** (*choose **TM-11 certificate** from the menu Other Certificates*): it is issued for transactions to Japan. This kind of certificate is completed by the operator but released by Bioagricert after the submission of the request of release. The certificates are also used by port of entry officials in both the United States and Japan to document organic production.

9. 9.6 CROSS CONTROLS WITH THE OTHER CBS

The cross-checks are intended to verify the guarantee of the origin of the organic products and the exchange of information between CB to manage specific issues of the sector, to ensure a better management of the control of the production line.

Cross Control over certifications issued by others CBs consist of request to others CBs to recognize the validity of certificates delivered to BAC to guarantee the origin of the organic product.

10. NOT-CONFORMITIES AND SANCTION SYSTEM

10.1 Not Conformities

A NC is any condition of not compliance to the requirements to the standards of reference. The NC can be caused by the actions of the operator, by its negligence, as by events not directly attributable to its responsibilities.

Based on the rules of reference, during the activity of control of the licensees, will provide for three levels of violations of the requirements of the regulations, described in the following table:

Kind of not conformities according to NOP STANDARD:

Classification of NC	Definition	Example
Willful violation	it concerns an intentional violation of law or simple indifference to their requirements.	
Minor non-conformity	is defined as a violation that can be corrected, does not affect the integrity of the organic system or organic product, and prevents certification or to the continuity of the certification of a producer or a certified organic processor.	lack of presentation of information within the terms ,or temporary lack of update of Organic System Plan, and lack of maintenance of records.
Major non-conformity	is defined as violation of the organic standards affecting the integrity of the organic system or organic product and prevents the certification or continuation of certification of a producer or processor.	application of a banned substance, contact between organic and non-organic products, contamination of organic products with prohibited substances, and the lack of correction of one minor not conformance.

The distinction between non-conformity "**minor**" and "**major**" is particularly relevant in the assessment of civil penalties.

The **Organic integrity** refers to the qualities of a product, a production or a system of organic process that are obtained through the fulfillment of the requirements of the regulations on organic agriculture and which must be maintained from the production through the process to the point of final sale so that the final product can be labeled or marketed as organic.

Kind of Not Conformities according to EU Regulation:

Classification of NC	Definition
FAILURE	It is a minor not compliance that does not compromise the compliance of the production process and /or the self-control system on the production method or the management of the company documentation and it is characterized by not having long-lasting effects and does not determine substantial changes in the company "status" and /or product compliance and /or reliability of the operator. The detection of the failure involves the issue, by Bioagricert, of a formal warning.
IRREGULARITIES	it is as a major not compliance that compromises the qualification of products, but not the conformity of the production process and/or the self-control system on the production method or the management of the company documentation and it is characterized by not having long-lasting effects and does not cause substantial variations of the "status" of the company. The detection of the irregularity involves the issue, by Bioagricert, a notice of suppression of the organic mentions.
INFRINGEMENT	it is a meaningful non-fulfilment that compromises the conformity of the production process and /or the self-control system on the production method or document management or the respect of contractual obligations agreed with Bioagricert and it is characterized by having prolonged effects such as causing the substantial variations of the "status" of the company and /or product compliance and /or reliability of the operator. The detection of an infringement involves the issue, by Bioagricert, of a notice of suspension of certification or exclusion of the operator from the control system.

10.2 CONTROL AREAS

Both operational aspects and of the controlled company can producing irregularities and offences. however you can define different areas in which may occur non-conformities:

- general area;
- documentary area;
- agricultural production area;
- livestock production area;
- aquaculture production area;
- processing area;
- imports / export;
- specifications of products and certification documents area;
- non-observance of the sanctions area ;
- the repeated NC area .

You can define two levels of control areas in which occur not-conformities: operating level, against the market, and contractual level, against BAC.

Operational level:	Contractual level:
documentary area	area of non-compliance with sanctions
agricultural production area	the repeated NC area

livestock production area	
process area	
imports/ export	
area of product specifications and labelling	

The commercial life of many products subject to control is relatively short and the withdrawal of the certificate of sanctioned products is often not enough to guarantee the effectiveness of the system; Therefore, the warranty and the credibility of the certification scheme have to also consider the concept of **reliability of the operator**. The central elements located to assess the reliability of the operator are the reiteration of the NC and not-compliance with the sanctions. These two elements have been inserted as specific areas of control of the sanction system.

Failure to treat the NC within the terms provided brings to a higher level of not conformity, than the previous raised, and consequently the application of the relevant sanctions

The **repetition** of a NC within the same control area of an irregularity or infringement (major not conformity) brings to a higher level of not conformity, than the previous raised, and consequently the application of the relevant sanctions, unless the irregularity has not been determined by events not directly related to the operator.

10.3 PROCEDURE FOR THE MANAGEMENT OF NOT-CONFORMITIES ACCORDING TO THE NOP/USDA STANDARD

10.3.1 New Operators (APPLICANTS)

(A) Notification of not-conformity (NONC - Notice of Noncompliance) and issuance of the letter of NONC

Under §205. 405 (a), if the evaluation of the application and the management plan reveals that the applicant to certification is not able to comply or does not comply with the requirements of legislation, BAC (TV) will send a written notification of non-conformity (NONC) to the applicant (Template A).

The NONC includes (Template A):

- The description of each not-compliance;
- The facts in which is based the NONC, and
- The date on which applicant must refute or correct each NC and submit supporting documentation for each correction where correction is possible.

In accordance with § 205.405 (b), receiving notice of not compliance, the applicant may:

- 1) fix non-conformities and file a description of corrective actions taken with supporting documentation to the OdC;
- 2) correct nonconformities and present a new application to other CBs: provided that the applicant must include a complete application including the notification of NC raised by the previous CB and a description corrective actions taken with supporting documentation; or
- 3) present information in writing to the issuer CB for refute the NC described in the NONC.

Immediately response to the evaluation of to the NONC, BAC send a letter to the applicant (Template B: Letter of approval for certification - approval letter for certification).

In accordance with § 205.405 (c) after the issuance notice of non-conformity, the CB must:

- (1) assess corrective actions taken by the applicant and documentation presented support or the refutation in writing to carry out an inspection in the company If necessary, and
 - (i) when the corrective action or refutation it is enough so that the applicant can be qualified certification to the applicant certification approval according to § 205.404, or
 - (ii) when corrective action or refutation is not enough to the applicant be qualified for the certification, BAC will send to the applicant written notice of the denial of certification.
- (2) issue a written notice of denial of certification to the applicant who does not respond to the NONC.

(3) notice of approval or refusal to the administrator, in accordance with § 205.501 (to) (14).

(B) Denial of certification

(ii) when corrective action or refutation is not enough for the applicant to be qualified for the Certification, Bioagricert issue to the applicant a written notice of denial of certification (Template C: Letter of certification denial, Applicant -letter denial of certification, new operator).

In accordance with § 205.405

(d) notification of the denial of certification should indicate the reason for denial and the right of the applicant to:

- (1) send again the certification request in accordance with §§ 205.401 and 205.405 (e);
- (2) request a mediation pursuant to § 205.663 or, if applicable, in accordance with a State organic program, or
- (3) present appeal to the denial of certification pursuant to § 205.681 or, if applicable, in accordance with the State organic program.

(C) Combined Notification of NC and denial of certification

If BAC has reasons to believe that the applicant for certification has intentionally made a false statement or otherwise has misinterpreted the compliance with certification requirements, it may issue a combined notice of NC and denial of certification

(without issue before a NONC) - (Template D - Letter combined NONC denial and certification without NONC Applicant - notification combined CN and denial of certification without NONC, new operator).

10.3.2 Certified Operators

(To) Notification of not-conformity (NONC - Notice of Noncompliance) and issuance of the letter of NONC

When an inspection, review, or investigation of a certified operator reveals NC respect the law or standard, Bioagricert, pursuant to § 205.662 (a), will send a NONC to the certified operator (Template E - letter Notice Of Noncompliance (NONC)).

All notifications (NC, proposal of suspension or revocation, combined notification, and notification of suspension / revocation) issued to a certified operators follow the procedures of conformities and appeal specified in § 205.660-205.662 and 205.681 (a).

The NONC includes (E Template):

- The description of each non-compliance;
- The facts on which are based the the NONC, and the relevant sections of the NOP/USDA standards, 7 CFR Part 205, that are in violation.
- A statement that indicates that a response in writing must be received, to correct the violation or refute the alleged violation.
- The deadline for responding to the NONC. In general, the response must be sent within 30 days from receipt of the NONC. Response time can be changed in exceptional circumstances, such as when the organic integrity is threatened.
- Notice that if a written response is not received within the required time period, it may implement additional actions including the proposal of suspension or revocation of certification.

Evaluation of the answer to the NONC

The corrective actions proposed are evaluated to determine if they corrected the violation. Additional documentation and inspections may be needed to verify that corrective actions have been implemented. The rebuttals are evaluated to determine if sufficient information is provided to reconsider issuing the NONC. In the case of the refutation, the additional documentation or inspections may be needed to verify that there has been no violation.

Resolution of not-compliance - § 205.662 (b)

When a certified operator shows that the violation is corrected (or refutation verifies that there was no violation), BAC will send to the certified operator written notice of the decision on the NC. (Template E_1 Letter of resolution of NONC-NONC resolution chart).

The operator must send a response in writing to correct the violation or refute the alleged violation. The operator must refute or correct every NC and submit documentation in support of each correction when correction is possible.

If a written response is not received within the required time frame it may be implemented additional actions including the proposal of suspension or revocation of certification.

Corrective actions should correct the violation (additional documentation and inspections may be needed to verify that corrective actions have been implemented)

The rebuttals are evaluated to determine if sufficient information is provided to reconsider issuing the NONC. In the case of the refutation, the additional documentation or inspections may be needed to verify that there has been no violation.

(B) Notice of proposed suspension (NOPS) or revocation (NOPR)

When the refutation is not successful or the correction of non-compliance is not completed within the prescribed time, Bioagricert will send the certified operator, in accordance with **§ 205.662 (c), written notice of proposed suspension (NOPS) or revocation (NOPR)** certification in one or more areas of production or process, particular production or process lines or the entire company on the basis of the applicable to CN. (Template F - letter of NOPS or NOPR Proposed suspension or revocation - letter of NOPS or NOPR, proposal of suspension or revocation).

NOPS and NOPR include:

- The reasons for proposal of suspension or revocation;
- The facts underpinning the notification (NOPS or NOPR), and the relevant sections of the standards NOP/USDA, 7 CFR Part 205, that are in violation.
- The effective date proposed for suspension or revocation of certification (a minimum of 30 days from the date of notification of the proposal, plus the time of the mail);
- The length of the suspension in the NOPS;
- The impact of the suspension or revocation on the future decision on certification, and
- The right to request mediation in accordance with § 205.663 or to lodge an appeal pursuant to § 205.681 - resources, time for the request, and contact information.

To implement the proposal of suspension or revocation, BAC follows the criteria established in the NOP 4002 - date of issue: April 23. 2010:

- Notice of proposed suspension (NOPS)

It is issued when the NC is still considered correctable. A NOPS intends to give the operator time useful for working on the NC, achieve compliance, and be reintegrated.

- Notice of proposed revocation (NOPR)

It should be used when the NC is considered non-correctable, due to the nature of intentional and blatant violation or the consequent impact on the operator organic integrity.

(C) Notification of combined not conformity (NONC) and proposed (NOPS) suspension or revocation (NOPR)

In accordance with (§ 205.662 (c), when the NC correction is not possible, or when the violations are egregious or intentional, Bioagricert may issue a combined notice NONC and NOPS or NOPR (Template G - letter of combined NONC and Proposed Suspension (NOPS) or Revocation (NOPR) - Letter from NONC combined and proposal (NOPS) suspension or revocation (NOPR).))

Examples of said violations include selling conventional products like organic, use of prohibited substances, use of conventional feedingstuffs and the denial of access to pasture.

Notification combined non conformity (NONC) and proposed (NOPS) suspension or revocation (NOPR) includes:

- A description of the non-conformity;
- The reasons for the proposed suspension or revocation;

- The facts underpinning the notification (NOPS or NOPR), and the relevant sections of the standards NOP/USDA, 7 CFR Part 205, that are in violation.
- The effective date proposed for suspension or revocation of certification (a minimum of 30 days from the date of notification of the proposal, plus the time of the mail);
- The length of the suspension in the NOPS;
- The impact of the suspension or revocation on the future decision on certification, and
- The right to request mediation in accordance with § 205.663 or to lodge an appeal pursuant to § 205.681 - resources, time for the request, and contact information.

(D) Notice of proposed suspension or revocation, without an initial notice of not-conformity - intentional violation (§205. 662 (d))

If BAC has reason to believe that a certified operator has intentionally violated the law or the standards contained in this part, BAC will send the certified operator a notice of proposed suspension or revocation of certification in one or more areas of production or process, particular production or process lines or the entire company on the basis of the applicable to the NC.

When it is evidence of intentional violation, Bioagricert can directly issue a notice of proposed suspension or revocation, without an initial notice of non-conformity. (Template H letter of NOPS and NOPR Proposed suspension or Revocation - letter of NOPS and NOPR proposal of suspension or revocation).

(E) Partial suspension or partial revocation

Then to intentional violations or refutation or correction without success, Bioagricert may issue, in accordance with § 205.662 (c) and (d), a partial suspension or partial revocation (Template 2)

To apply the partial suspension or partial reversal, BAC follows the criteria established in the NOP 4002 - issue date: April 23, 2010:

Partial suspension: it can be issued by the CB to suspend a part of the process or production company, based on the applicable to the NC.

For example, a partial suspension may be applicable when an operator is certified for two or more areas of production (crops, wild crops, livestock and processing) and when an area of the company committed a violation not correctable or a refutation or correction without success to a not-conformity.

Partial revocation: can be issued as a result of an intentional violation or of having made a false statement under the Act to the official employee of the State responsible for the State's organic program, or the CB (§ 205.662 (g) - Violations of Act).

The partial revocation is rarely applicable and the CB must consult with the NOP before issuing a proposal for partial revocation. There are very few circumstances that justify the partial reversal, and each case must be determined on an individual basis.

(F) Notification of suspension or revocation (§ 205.662 (e))

Suspension or revocation:

(1) if the certified operator does not correct the not-conformity, to resolve the problem through mediation or refutation, or to appeal the proposed suspension or revocation of certification, BAC will send, in writing, the certified operator a notice of suspension or revocation.

2 BAC should not send a notice of suspension or revocation to a certified operator who has requested mediation in accordance with § 205.663 or an appeal pursuant to § 205.681, while the final resolution is pending.

Eligibility:

1. a certified operator whose certification has been suspended pursuant to this section may, at any time, unless otherwise stated in the notice of suspension, submit an application to the Secretariat for the reinstatement of their certification. The request must be accompanied by evidence supporting the

correction of each not-compliance and corrective measures taken to comply and remain in compliance with the standard NOP-USDA.

2. a certified operator or a person with responsibility related to an operator whose certification has been revoked will not be eligible to receive the certification for a period of 5 years from the date of the revocation, except, that the Secretariat can reduce or eliminate the period of disqualification, when in the best interest of the certification program.

Bioagricert issued a notice of Suspension or revocation when a certificate operator does not respond to the notice of proposed suspension or revocation, or combined notification, through a request for mediation (§ 205.663) or resource (§ 205.681) (Template I letter NOPS or NOPR suspension or revocation - letters NOPS or NOPR suspension or revocation).

Notice of suspension or revocation includes:

- A description of the not-conformity;
- The reasons for the proposed suspension or revocation;
- The effective date proposed for suspension or revocation of certification;
- The impact of the suspension or revocation on the future decision on certification.

(G) Imposition of civil penalties (§ 205.662 (g))

In addition to suspension or revocation, any certified operator who knowingly sells or label a product as organic, except that according to the law, will be subject to a maximum \$ 11, 000 civil penalty for each violation.

(A). the NOP will consider pursuing civil penalties when there is clear and convincing evidence that one not conformity is both intentional and more.

(B). the accredited CB shall communicate such non-conformities to the NOP Compliance and Enforcement Division (C & E) for review and action. This communication must be accompanied by supporting documentation and must be filed within 30 days after the verification of the intentional NC and more.

C. the NOP C & E will conduct the review of such communications, on the basis of the documentation submitted by the accredited CB and/or decisions and resource presentations. The NOP will recommend civil penalties against operators who have committed intentional violations or older toward the OFPA or NOP standard.

10.3.3 Authorities Who Issued The Sanctions And Their Recipients

The authorities that issue the penalties are specified in the following table:

	NC emission Report (M_034)	Non conformity (NONC) - Applicant notification	Notification of refusal of certification - Applicant	Combined denial of certification notification without initial NONC (Intentionality)	Notice of non compliance (NONC) - certified operators	Notice of proposal (NOPS) suspension or revocation (NOPR)	Combined reporting NONC, NOPS and NOPR	Notice of proposed suspension or revocation, without an initial NONC (intentional violation)	Notification of partial Suspension or partial revocation Violation intentionally or refutation or correction without success	Notice of suspension or revocation
Inspector	X									
Evaluator /NC manager	X	X			X					
Manager of Sector		X			X					
Certification Committee		X	X	X	X	X	X	X	X	X

The sanctions applied to the operators listed in the following table:

	Notice of non compliance (NONC)	Notification of refusal of certification	Notice of proposal (NOPS) suspension or revocation (NOPR)	Combined reporting	Notice of suspension or revocation
New operators	X	X		X	
Certified operators	X		X	X	X

10.3.4 Mediation And Appeal

The operator has the right to request mediation to Bioagricert in accordance with § 205.663 (Mediation) or presenting a resource before the Agricultural Marketing Service Administrator in accordance with § 205.681 (Appeals).

The operator may ask the mediation Bioagricert, sending a letter to the Committee for Appeal (CRI) with details, within 15 days after receiving the notification.

Bioagricert can accept or reject the request for mediation (BAC will send a notice in writing to the operator for the rejection of the request for mediation - Template L Letter of mediation - mediation Charter); the operator has the right to request an appeal, pursuant to § 205.681, within 30 days of the date of the notification in writing of the denial of the request for mediation.

It is possible to make a complaint to the Agricultural Marketing Service (AMS):

- A new operator applicant certification against the notification of refusal of certification issued by BAC
- a certified operator against the notice of proposed suspension or revocation of certification.

Appeal Rejected: when presented out of time or problems are not appealable.

Appeal Accepted: when Agricultural Marketing Service (AMS) in accordance with the appeal filed by the new operator or the operator certificate against the decision of BAC, will be issued the certificate to the new operator or the certified operator will continue its certification.

Appeal Denied: when Agricultural Marketing Service (AMS) is not in accordance with the appeal, the decision of BAC is effective.

Formal administrative procedures: immediately to a denial of an appeal, will take place a formal administrative proceedings to suspend or revoke certification.

Appeal closed without decision : sometimes appeal are closed without a decision, for example, a resource may be closed through an agreement instead of issuing a decision.

10.4 PROCEDURE FOR THE MANAGEMENT OF NOT-CONFORMITIES ACCORDING TO EU REGULATION

Within the scope of the three categories of not conformity, failure, irregularity and infringement, based on the level of severity and on the graduality criteria the following sanctions are applied: warning, suppression of the organic statements, certification suspension and exclusion of the operator .

Warning: It's a the invitation to the operator to solve the raised FAILURE identifying the causes and applying corrective actions just to avoid the repetition.

Suppression of organic statements: it implies the prohibition for the operator to indicate on the labels and advertising material which concern products subject to the NC, any reference to the method of organic farming in relation to the lot, or the entire production involved in the IRREGULARITY. If it is not possible to apply the suppression of the organic statements due to the lack of product, Bioagricert will act with proper measures related to the detected irregularity. On the basis of a notice of suppression, Bioagricert can modify the Certificate of Organic products.

Suspension of certification: may cover one or more activities (production, preparation, etc), one or more production units or the entire company. The suspension applies to the individual activity or production unit if the INFRINGEMENT does not have repercussions on other activities or production units. The suspension implies the prohibition to the operator, for a period defined by the applicable regulations, to market products with statements referring to the organic production methods and brings ti the suppression of organic statements also for products already on the market . During the period of suspension, the operator is

required to continue to apply the organic method in accordance to EC Reg. 834/07. Bioagricert, based on a notice of suspension, will make the relevant changes to the Certificate of Organic products.

Exclusion of the operator: it consists in the withdrawal of the certificate of organic products by Bioagricert, following the INFRINGEMENT and it implies the opening of the procedure of cancellation from the list of organic operators. The exclusion may imply the suppression of organic statements on the products already on the market. If an excluded operator wants to apply again for the certification, its inclusion will be subject to the removal of the not conformity that caused the exclusion, after proper verifications carried out by the CB.

10.4.1 Additional Activities Following Sanctions

The different types of measures described in the previous paragraphs, considering their characteristics and areas of control in which they fall, they may require additional activities by Bioagricert against operators to whom a NC has been raised. These activities may include:

- additional examination of documents,
- additional inspections,
- samples.

Bioagricert informs the operator of any additional activities foreseen following the sanctions applied, together with sending the notice of sanction.

10.5 NOTICES

The ways to communicate information about the NC and sanctions, are divided into:

- **internal** : from the moment in which risen a not-conformity to all communications related to the same and to the consequent.
- **external** : from the sending of the sanction to the operator involved until communication to the competent authorities and the other CBs to ensure efficient management of the control of the "production chain".

10.5.1 Internal Notice

Operational modalities used for the internal notice can vary based on the urgency of the NC:

- NC with urgent procedure (willful violations, major non-conformities / irregularities and infringements): send by fax or e-mail to BAC the NC report within 48 hours from the notification to the operator;
- NC without urgent procedure (minor not conformities / Failure): allows you to send a copy of the NC report within 15 days.

All communications concerning the NC and the sanctions are transmitted in copy to the inspector and to the evaluator for a following verification.

10.5.2 External Notice

- **Preventive Notice to the operator (or precautionary suppression of the organic statements)**

Signaling to the operator of the "ongoing investigation" with the confinement of the batch of product, in particular for non-compliances related to the results of the analysis and for the existing term between the first positive result and the result of the check. It is adopted the same methodology of the "preliminary" phase in the case of particularly complex situations. Review of the sanction has to be performed within 60 days from the first communication, with subsequent communication of its result (revocation and/or confirmation) to the operator.

- **External Notice of sanctions**

BAC informs the competent authorities about all sanctions imposed, including revocations or confirmations of precautionary suspensions. The suppression of organic statements, certification suspensions and exclusions of the operators are notified to the competent authorities together with the first information sent to the operator. Once they become final, the sanctions are communicated to the other CB involved. The data included in the external notice are: name of operator, identification number and sanctions.

In its database, BAC maintains such information always available.

10.5.3 Appeal

BAC policies and procedures aim to ensure constructive and timely resolution of appeals, the procedure provides the opportunity for the applicant to formally submit the case and the existence of an independent element to ensure the impartiality of the process of appeal.

Operators can appeal against the decisions of BAC within 15 days from the receipt, detailing the reasons of the disagreement and requesting a review of the decision.

Appeal must be submitted to the BAC Appeal Committee (CRI), at BAC headoffice. The composition of CRI is detailed in the *Doc. OB01 – Organisation: Seats, personnel and suppliers*.

Upon receipt of the appeal, the SCR convene the CRI which meets and examines the relevant documentation, comparing the motivations of the operator and those of the CC of BAC that issued the decision under appeal.

Once it has evaluated the appeal, the CRI issues a document which is sent to the appelliant operator and to BAC, containing results of the appeal with the reasons of the decisions within 30 days starting from date of notification of the decision to the operator. Any justified reasons (eg. waiting for response about AC or other operators /certification bodies) may delay the decision of the CRI for a period of up to 30 more days. The receipt of the appeal does not stop, however, the enforceability of the adopted sanctions, until further pronouncement of CRI. In case of non-acceptance the appeal, decision is definitive Expenses shall be beared by the losing party. BAC ensures that any staff, who have performed evaluation of certification, consulting activity, or employed by the appelliant during the two year previous to the opening of the complaint, doesn't take part to the decision about the result of the appeal.

10.6 Exchange Of Information Between Control Authorities, Control Bodies And Competent Authorities

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.

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.

The previous control authority or control body shall hand over the relevant elements of the control file of the operator concerned and the reports to the subsequent control authority or control body.

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.

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.

10.7 Exchange Of Information Between Member States And The Commission

The Notification could be sent by the involved State Member and/or by the competent CB of the notifying State on the European Commission web portal AWAI through the information system OFIS which assigns an identification code to the progressive notification itself reported on all subsequent communications regarding the case. The DG Agri EEC send by e-mail a request for information to Bioagricert if the case involves an operator who is subject to Bioagricert control in Third Countries, with direct link to the original Notification and its annexes on the OFIS system portal .

If Bioagricert found the involvement of operators controlled by other CBs, promptly informs the said CBs.

Bioagricert draws up the Reply to the OFIS Notification on the OFIS system portal of the EU within 30 calendar days from the date of the original notification.

The Member State Which sent the original notification may ask the replying Member State for additional information, if needed. In any case, after receiving a reply or additional information from a Notified Member State, the Member State Which sent the original notification Shall make the Necessary entries and updates in the OFIS system.

11. REGISTRATION OF BAC

Bioagricert maintains an updated controlled operators file. Each operator has a record, electronic and paper which contains the complete documentation for the certification, with indication of the name, the BAC code and the number of file position. The records contain the following documents:

Documents	Producer	SFG	Process	Imp/Exp	MT
M142 Application form	X	X	X	X	
M083/A notification of primary production activity	X	X			
M083/B notification of processing activity			X	X	
PAPI (Annual Production plan)	X	X			
Statement for the reduction of the conversion	X	X			
Maps or diagrams, lay out	X	X	X	X	X
Titles of possession and/or allotment certificates	X	X			
M052- management of raw materials	X	X			
M054 prophylaxis beekeeping	X	X			
M055 records of "Number of apiaries per year"	X	X			
M080- Organic System Plan for producers	X	X			
M079- Organic System Plan for processing			X	X	
M081-MT Organic System Plan for INPUTS					X
M082/A- request of certification for producers (PAP, PAPZ)	X	X			
M082/c application of certification for processing			X	X	
M183A request approval labels equivalence NOP-COR			X	X	
M081-m- request for certification of INPUTS					X
M24- recipe Form			X	X	
M081-MTR composition of INPUTS					X
M027- list of qualified suppliers			X	X	
M182 verification suppliers NOT certified BAC equiv. NOP-COR	X	X	X		
M184 verification suppliers certified BAC equiv. NOP-COR	X	X	X		
Labels			X	X	X
Technical data sheets	X	X	X	X	X
Statement OGM Free			X	X	X
M032- sampling and analysis result Forms	X	X	X	X	X
M034- not compliance report	X	X	X	X	X

M140 – Farm Inspection Report	X	X without ICS			
M_215 Checklist of producers	X	X without ICS			
M092 Audit Report for small producers/farmers groups with ICS		X			
M092/A brief Inspection		X			
M_084_A Checklist NOP for farms	X	X			
M57-inspection of the food processor and annexes			X	X	
Annex A: Control products in entrance/input			X	X	
Annex B: Control product in exit / output			X	X	
Annex C: Control input/output products (Mass Balance)			X	X	
Annex D: processing Checklist			X	X	
Annex E: traceability meats and eggs			X	X	
Annex H: IFOAM Checklist			X	X	
Annex I: NOP Checklist			X		
Annex L: Checklist COR/NOP equivalence			X	X	
Annex M: Control external complains			X	X	
M099 organic products registers			X	X	

M_084_C Checklist NOP for processors			X		
M_085 NOP Summary	X	X	X	X	
M214 IFOAM Inputs checklist					X
M201A rv. 01 assessment electronic record	X	X	X	X	X
M126 rv. 03 Organic Products Certificate	X	X	X	X	
M119 rv. 00 Product Certificate according to the NOP Organic Agriculture Rules	X	X	X	X	
M117 rv. 00 Certificate of Conformity to Organic Agriculture Method	X	X	X	X	
M180 rv. 01 NOP/COR equivalency certification and annex	X	X	X	X	
M162 rv.01 Certificate of Conformity according to the Bioagricert Inputs Production Standard					X
Certificate of inspection for import				X	
Transaction certificate				X	
Documents of transaction of organic products	X	X	X	X	

The internal documentation is kept within the BAG management system, with access to staff authorized by BAC according to different authorizations on the basis of functions and responsibilities

Registrations are maintained for at least five years, as foreseen by the regulations in force. Bioagricert keeps confidential records, which are transported, transmitted and transferred in order to ensure that confidentiality is maintained; Bioagricert maintains a list of staff who has access to the archives of recordings Bioagricert, listed in doc. ONFT_00

11.1 REGISTRATIONS MAINTAINED BY THE OPERATORS

Operators must maintain the registrations relating to the process, product, complains and not conformities. Registrations are used by BAC for evaluation.

11.1.1. Registrations On The Product And The Process

Operators who make production activities must maintain the following registrations:

- *Registers of the operators of plant production (Producers/Farmers)* , where there are registered all farming operations, the purchase and the use of INPUTS (fertilizers, products for defense against insects and deseases, etc.) and propagation material, the quantity of harvested products and the products sold. Accounting has to show the correspondence between the quantities entering (production) and coming out (sale and re-use); the data have to be justified with proper documents (invoices, certificates, technical data sheets, documents of transaction, etc.)
- *Register of livestock production farm*, where are recorded details of identification of animals, ear tag or batch number, the creation of breeding, entry/exit of the animals in the faerm (births, acquisitions, sales).
- *Annual beekeeping, production records* ,where are recorded the formation of hives, the number of beehives, the translation of the same, date and mode of transport, input/output products of the products obtained, for each of the colonies or hives.
- *Registration of health treatments for animal production and beekeeping*, where are registered all the treatments made to the animals on the basis of the following information: diagnosis, date of starting of prophylaxis, product used, dosage and period of delivery,and time of suspension.
- *Register of sales of plant, livestock, beekeeping productions*, where are registered the products sold by tracing the provenance of the same, n ° of the plot, n ° of registration, number of the lot of origin. Conservation of the sales/ transaction documents, is equivalent to the maintenance of the sales register. The registration of sales may be replaced by the BioAgriCert Software which described the following § 11.1.3 b

Operators which make the activities of processing must maintain a financial and accounting Registers where there are recorded the following:

- nature, quantity, vendor or exporter of the products in entrance (input);
- the stages of processing of such products (process);
- nature, quantity and destination of the products coming out/ sold by the company (output).

Accounting has to show the correspondence between the quantities entering (raw materials), the production going out (sale); the data have to be justified with proper documents (invoices, certificates, technical data sheets, documents of transaction, etc..)

BAC provides processing companies the "*register of entry and exit (Input-Output) for processors of organic products M99*", a Formpad of *organic* products transaction documents or, Alternatively, install the BioAgriCert Software.

Operators carrying out import and export activity must maintain a financial and accounting Register where are recorded:

- nature, quantity, vendor or exporter of the products in coming (input);
- nature, amount, recipients of the products sold by the company (output).

Accounting has to show the correspondence between the quantities entering (raw materials), production, and products sold/ coming out (sale); the data have to be justified with proper documents (invoices, certificates, technical data sheets, documents of transaction, etc.).

11.1.2. Registration And Management Of Complaints

The operators have to register all complaints that have been reported to them and the documentation of the corrective actions taken to manage them and to prevent their recurrence. The licensee must also take into consideration complaints communicated to any sub-licensees which assumed responsibility for the conformity of the product. Registrations can be kept in the Register provided by BAC or, alternatively, on their own Registers.

11.1.3 Registrations In The Bioagricert Software

The BioAgriCert Software, SB is a management program owned by BAC that manages the registrations of the movement of organic products, load/processing/sale, and allows more effective controls. The SB is given to the controlled Operators for free and is of voluntary use by the licensee which signs the license agreement.

In the SB are encoded:

- organic raw material and semi processed products;
- the recipes, with the kg of each ingredient required to obtain 100 kg of product;
- products, with denomination, recipe, weight and the trade mark;
- qualified suppliers, with the specification of their CB and certificate;
- clients.

The following storehouse movements are recorded in the SB:

- ✓ the entrance of the operator productions, selfproduction, or the receival of raw materials, semi-finished products and finished organic products with related certificates of conformity and fiscal documents;
- ✓ the processing with reference to the processinf records forms. For each process is recorded the entry in store of the corresponding quantity produced , the corresponding output from the warehouse of the raw materials with the quantities of ingredients used. It is recorded, in addition, the labels used in the process;
- ✓ the sale of raw materials, semi-finished products and finished products with indication of the fiscal document. The operator can print transaction documents, where it is declared the compliance with the Reg. CE 834/07 of organic products.

There is also a simplified SB version, for the management of sale and the issuance of documents of transaction.

11.2 ADVERTISEMENT AND TRANSPARENCY

The publicity and transparency of the certification system is guaranteed by BAC through the following instruments:

-the web site www.bioagricert.org, BAC publishes the requirements and all documents of the certification system for operators and rights and duties of BAC and operators as detailed in certification procedure of each specific certification scheme ;

-on the website www.trasparente-check.com are published all product certifications issued and still valid.

The BAC list of licensees is a public document, the LdL contains: the name of the licensee and the products, with an indication of the standards in accordance which they are certified. The LdL is available upon simple request at the BAC head office or at the Accreditation Bodies.

Through their own means of communication to the public (website www.bioagricert.org) or upon request, BAC makes available and updated the means by which BAC gets economic and financial support and general information on Fees applied in section 6.3.

12. THE UPDATING OF THE INFORMATION PROVIDED BY THE OPERATORS

The licensee must inform BAC on every modification that they willing to make to the product, the production process or management, that may affect the conformity of the product itself. Similarly, the operator has to promptly communicate all accidental events on their knowledge that may affect the conformity of the process/product.

It is the responsibility of BAC to assess whether announced changes need further inspection and/or other investigations. In this case, the licensee not use the license for products originating from such modified conditions, until it has not obtained the revision of the BAC Certificate of organic products .

13. THE LICENSE MANAGEMENT

13.1 EXTENSION OF THE LICENSE

The licensee to apply for the extension of the Licence has to send the related documents. Once received, the BAC head of sector, evaluated the need to carry out other checks and activates the evaluation procedure. **On the basis of the outcome of the verifications, the head of sector or the CC, decide on the extension of the certificate.**

13.2 SUSPENSION OF THE LICENSE

The Licence relating to a specific product may be suspended for a period due to violations, as described in paragraph. § 10.

Another case is the suspension of license upon request of the licensee for a period, by a momentary interruption of the activity of production of the company. When the license is suspended, the licensee may not commercialize the product (s) with the references to the organic production method or BAC certification and cannot longer put marks of conformity on the products, or use, in any form, the certificate of organic products.

During the period of suspension, the certificate of organic products will be cancelled from LoL.

If the certification is restored after the suspension, Bioagricert can make changes to official documents of certification (Certificate of Organic Products), the information to the public, the authorization of the use of trademarks, etc., in order to ensure that there are all the appropriate indications that the product continues to be certified. If, as a condition to restore the certification, it is taken a decision to reduce the scope of certification, Bioagricert makes changes to official certification documents, to the information to the public, to the authorization of the use of trademarks, etc., in order to ensure that the reduced scope of the certification is clearly communicated to the customer and should be clearly specified in the certification documentation and information to the public.

13.3 WITHDRAWAL AND CANCELLATION OF THE LICENSE

The license is **withdrawn**:

- in the cases and in the procedures described at § 10 involving the exclusion of the operator from the control system;
- in case of non-observance of the financial conditions set out in the contract with BAC.

BAC informs the operator of the revocation of the license and consequently communicates this event also to the competent authorities and the other CBs. The operator may not use any reference and advertising, related to the organic production method and/or BAC control and certifications. If requested by BAC, the operator must return any certification documents in their possession. BAC will find out that the above is executed and the CC decides the consequences related to the certified product, if ask the operator to remove the mark of conformity from all products in store and, where possible, also for products already sold, or grant special authorization to eliminate the certified products, or take other appropriate decisions.

The license is **cancelled** in the following cases:

- the licensee does not want to renew the license (only according to the NOP/USDA standard, when a company wants to surrend, must send an official letter of surrendering from the certification. Until this document did not arrive, BAC is forced to make the annual inspection to the company. If the company does not make it possible, BAC will have to issue a not conformity with the revocation of the certificate that will imply the impossibility for the company to be certified under the NOP/USDA scheme over a period of time of 5 years);
- the licensee does not want to conform to changes to the requirements for certification;
- the licensee leaves the activity or the product is not produced anymore

- the licensee wants to change CB ; in this case BAC provides to the new CB, which assume the control, the same information and documents provided to 8.6 (only in accordance with the NOP/USDA standard, the operator will have to respect the procedure NOP2604 from 25/09/2012).

14. CORRECT USE OF LICENSES AND CONFORMITY LOGO

- The logo of Bioagricert is deposited in The "Ufficio Italiano Brevetti e Marchi" in Rome and for use applied the following criteria and procedures:
- the logo is property of BAC, which exerts a protection legal for your composition, their control and their jobs.
- logo is unmistakable, coded or designed for facilitate detection of forms counterfeit or other kind of abuse;
- logo cannot be moved from one product to another;
- the logo is directly put in each product unit, except when physical size or the type of product make it not possible. In this case, logo is used in the smallest container in which the product is marketed;
- the use of the logo on the labelling, on the documents of advertising on the letterhead and fiscal documents it is permitted to the operators that have organic products certificate. The logo Bioagricert may be associated with the logo of the accreditation body in agreement with rules defined by this last.

The licensee has the right to make public the news have got the permission to use the logo or the certificate of organic products.

In advertising, brochures, posters, etc, related to the certification of organic products, the licensee must respect the following precautions:

- the Company must ensure that the consumer does not make confusion between the products certified and not, obtained by the company, therefore references should be clear and exclusive to certified products;
- the Company need to clarify that the certification granted by BAC refers to products/processes and not to the all company or organization.

The misuse of logos and misleading advertising are subject to penalty as stated to §10. The misuse of logos and certificates, for example errors in printing or advertising, not followed by appropriate corrective action, they are cause of sanctions that can go from suspension or revocation of the license, up to the claim by damages. The false claims and the falsification of certificates and logos, are processed.

15. COMPLAINS

Bioagricert quality policy considers very important confidence in certification by customers and consumers, and therefore proposes the objective of timely resolution of complaints on products certified.

BAC President is responsible for the management of complaints, with the assistance of the quality assurance office .

The management procedure of the complaint includes the registration of the complaint in the Register of Complaints M_50, a first confirmation response to the complainant about taking charge of the claim or the rejection, followed by the handling of the complaint through an investigation to identify the causes and possible corrective actions that resolve the complaint and may prevent a recurrence of the problem that led to the complaint.

Considering the nature of the complaint and of the development of the investigation, they may require the support of additional activities to the operator such as additional inspections, sampling and / or document review.

If relevant to the complaint received, Bioagricert applies the cautionary suppression of organic statements for the time of the investigation.

The outcome and the conclusion of the investigation and the reasons for its decisions are communicated within 30 days from the receipt of the complaint by BAC to the complainant and to the interested parties, except conditions of confidentiality, where appropriate, the CA in such exchanges of information, if applicable.

Any justified reasons (eg. waiting for response about AC or other operators /certification bodies) may delay resolution of the complaint for a period of up to 30 more days. BAC ensures that any staff, who have performed evaluation of certification, consulting activity, during the two year previous to the opening of the complaint, doesn't take part to the decision about the result of the complaint