CERTIFICATION STANDARD
INPUT SUITABLE IN ORGANIC PRODUCTION
MEZZI TECNICI PER LE PRODUZIONI BIOLOGICHE

INDEX

INPUTS bioagricert

1. GENERAL PRINCIPLES

This Standard applies to technical means (inputs) in order to assess their suitability for use in organic production.

Technical means include: fertilizers, pesticides, corroborants, materials used for mulching or other agricultural practices, additives and adjuvants (food and feed), substances used for cleaning production premises and plants and any other substance or material functional to organic production processes.

Organic production and processing methods are based on the use of natural, biological and renewable resources. Organic farming maintains soil fertility, first and foremost through the reuse of biological material.

The nutritional value of the soil depends on the presence of organisms. Pests, weeds and diseases are treated, first of all, using cultivation methods. Organic animals are fed with organic feeds and are kept in conditions that avoid any sufferance and stress. Organic animals and products obtained using products that are processed only using physical, mechanical and organic procedures.

According to this principle, inputs production may avoid the use of substances that may damage human or animal health and the environment and the impoverishment of natural resources.

Inputs production should take into account at least: soil and water contamination, nutritional imbalance of cultivations where inputs are not used, risks for human and animal health, impoverishment of natural resources.

2. REGULATORY REFERENCES

- REGULATION (EU) N. 848/2018 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) N. 834/2007.
- REGULATION (EU) N. 1009/2019 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 laying down rules on the making available on the market of EU fertilizing products and amending.
- REGULATION (EC) N. 2003/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 October 2003 relating to fertilizers.
- REGULATION (EC) N. 1069/2009 and (EC) N. 1107/2009 and repealing Regulation (EC) N. 2003/2003.
- REGULATION (EC) N. 1829/2003 of 22 September 2003 relating to genetically modified food and feed.
- REGULATION (EC) N. 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed produced from genetically modified organisms and amending Directive 2001/18/EC.
- REGULATION (EC) N. 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
- IMPLEMENTING REGULATION (EU) N. 540/2011 of 25 May 2011 and IMPLEMENTING REGULATION (EC) N. 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

1. REGULATION (EC) NO 1829/2003 of 22 September 2003 on genetically modified food and feed.
2. National Organic Program NOP/USDA (United States), Guidance and Instructions for Accredited Certifying Agents and Certified Operations.
3. Japan Agricultural Standard, JAS/MAFF (Japan) and applicable guidelines.

- UNI CEI EN ISO/IEC 17065 – Assessment of conformity requirements for bodies that certify products, processes and services.

3. INPUTS PRODUCTION METHOD

In general, the production of inputs bases on the use of ingredients or raw materials included in those allowed by Bioagricert Standard and other official regulations (e.g., EC Regulation 889/2008, NOP/USDA, JAS, etc.), preferably made with transformation / physical preparation (please see the list reported par. 5).

The evaluation methods of the production processes should be based on the "prevention and caution" principle.

When the activity of inputs production may damage human or animal health or the environment, the operator should take preventive measures to limit the risks even if the risks cannot be scientifically determined. The operator who applies for inputs certification should demonstrate to have identified the possible risks and the corrective actions to limit them.

The preventive measures protocol should include all the areas that may be damaged.

The preventive measures protocol should include all possible alternative solutions and also the case where no alternatives are available.

4. EVALUATION OF INPUTS FOR ORGANIC FARMING

The evaluation of inputs to use in organic farming should be based on the following principles:

- **Need of alternatives:** each input used is necessary for sustainable production, it is essential to keep product quantity and quality and it is the best available technology.
- **Origin of raw materials:** use natural resources, organic resources or renewable resources.
- **Human Health:** production methods protect human health and food safety.
- **Quality:** organic methods improve or keep product quality.
- **Social, Economic, Ethical:** production must be socially just, economically sustainable, respect cultural diversity and protect animal welfare.

The certification application should be sent together with a technical report on the production process.

4.1 Origin of raw materials and production process.

All dossiers should document the origin of raw materials and the production process:

- For each individual feedstock, a description of the source organism, a verifiable declaration that these substances are not genetically modified, and the process used to breed, cultivate, produce, multiply, extract or, in other words, prepare the substances for use, are required. Plants, animals, bacteria, fungi that occur naturally in nature are generally allowed.
- Substances that require physical transformation, for example through a mechanical process or a biological method such as composting, fermentation, enzymatic digestion, are generally allowed.
- Limitations and prohibitions can be established based on the consideration of other criteria. Substances that are modified by chemical reaction are considered synthetic and must meet the requirements set out in Chapter 5 of these Specifications.
- Non-renewable natural resources (such as mining minerals) require a description of sediment and availability in nature.
- The use of non-renewable resources is usually subject to restrictions or limitations. They can be used as a supplement to renewable biological resources, as long as they are extracted through physical and mechanical processes and are not subjected to chemical reactions. Inputs with a high level of natural environmental contaminants, such as heavy metals, radioactive isotopes, and salinity, are prohibited or otherwise restricted.

- Synthetic substances from non-renewable resources are generally prohibited. Synthetic products that are identical to natural products that are not available in sufficient quantity and quality in their natural form may be admitted provided that all the criteria set out in Chapter 5 are met.
- Inputs that are extracted, recovered, or manufactured through means that are destructive to the environment must be restricted or prohibited.
- The use of chemical manufacturing auxiliaries is allowed provided that they are functional to the process and useful for transforming complex substances into simpler ones, but which do not enter into the final composition of the product.
- All measures must be put in place to prevent and avoid contamination of the certified product with substances that are not permitted (e.g. deriving from previous processing).
- The materials used for packaging must not contaminate the inputs contained.

4.2 Environment

Processing should be sustainable for the environment. The environmental impact of each substance should be demonstrated and documented:

- The environmental impact of one substance should include (but it is not limited to) to following parameters: water toxicity, persistence, degradability, concentration area, chemical, physical and biological interaction with environment, including known synergic effects with other inputs used in organic agriculture.
- Effect of the substance on the agro-ecosystem, on soil organisms, on fertility and soil structure, on crops.
- The use of substances with a high level of salinity and medium toxicity to microorganism and collateral and persistent damages should be restricted and prohibited.

The inputs used on cultivations should be considered also for their impact on breeding and natural life.

4.3 Human health

The impact of each substance on human health should be demonstrated and documented:

- Documentation regarding impact on human health includes (but it is not limited to) to high and chronic toxicity, radioactivity period of present substances on inputs (if applicable), products of degradation and metabolites. The use of substance with collateral effects on human health is prohibited.
- Documents should specify who can be exposed to possible risks during all processing steps: processing managers, farmers, people that work with by-product of input processing. Environment waste from processing inputs, consumers exposed to ingestion of contaminated products.
- Products should be authorized and registered according to rules of the Country where the products will be sold.

4.4 Quality

The effect of a substance on the quality of the finished agricultural product should be documented; for example: nutritional values, taste, appearance. In case the final product needs to be stored and the used input does not affect the storage, this should be described.

4.5 Social, economic, ethical observations

Social, economic and cultural implications of the substance should be documented.

- Social and economic implications include impact of the substance on the community where it is produced and used; consider if the use may improve the economic structure and if the use of the substance is part of a tradition.
- Consumers feelings on the compatibility of inputs should be considered. Inputs do not have to meet consumers opposition. Consumers, in fact, may consider an input not compatible with organic production in case there is scientific uncertainty on the impact of such input on the environment or on human health. Inputs should respect consumers' general opinion on "what is natural and organic".
- Operators shall not violate indigenous land rights.
- Production that violates human rights and social justice requirements in this chapter cannot be declared organic.
- Operators shall not use forced or involuntary labor or apply any pressure such as retaining part of the workers' wages, property or documents.
- Operators shall not interfere with the right of their employees, suppliers, farmers and contractors to organize and to bargain collectively, free from interference, intimidation and retaliation.
- Operators shall provide their employees and contractors equal opportunity and treatment and shall not act in a discriminatory way.
- Operators shall have a disciplinary procedure with a system of warning before any suspension or dismissal. Workers dismissed shall be given full details of reasons for dismissal.
- Employees shall be granted the right to take at least one day off after six consecutive days of work. Operators shall not require workers to work more than the contracted hours and the national or regional sectorial legislation. Overtime shall be remunerated in the form of supplementary payments or time off in lieu.
- Operators shall never require an employee to work who is ill or requiring medical attention and shall not sanction an employee for the sole fact of missing work due to illness.
- Operators shall pay employees wages and benefits that meet legal minimum requirements of the operation's jurisdiction or, in the absence of this minimum, the sectorial benchmark
- Operators shall not hire child labor.
- Operators shall provide written terms and conditions of employment to both permanent and temporary employees.
- Operators shall ensure adequate access to potable water.
- Operators shall provide appropriate safety training and equipment to protect workers from noise, dust, sunlight and exposure to chemicals or other hazards in all production and processing operations.
- Operators shall provide residential employees with habitable housing and access to potable water; to sanitary and cooking facilities and to basic medical care. If families reside on the operation, the operator shall also enable access to basic medical care for family members and to school for children.
- Operators shall comply with minimum national social requirements in the countries of operation.
- Operators with more than 10 employees must have a written employment policy and maintain records to demonstrate full compliance with the requirements of this section. Workers will have access to their own files.

In this regard, the company must submit a dossier describing the process and, as a minimum, the documentation.

5. PRODUCTS THAT CAN BE USED FOR THE ORGANIC PRODUCTION

The certification applies to all inputs allowed for organic production, starting from plant production, breeding and processing including all other sectors that fall or will fall within the scope of the Production Legislation and Standard taken as a reference.

Each Standard lists the fertilizers, plant protection products and all other substances (e.g. additives and excipients for food and feed, processing aids, etc.) whose use is allowed for organic production. In some cases, in addition to the positive lists of permitted substances (normally natural or of natural origin), there are also lists of prohibited natural substances (or physical processes).

For certification purposes, you must comply with all applicable regulations and guidelines in the countries where your products are manufactured and marketed. It is necessary to consider both the legal requirements for organic products and those for the production sector and the category of certified products.

General conditions applicable to any type of input:

1. The use of the input is allowed in organic farming only if the requirements indicated in the organic legislation in force in the country where the input is used are respected.
2. The use of the input in organic farming is allowed only in accordance with the general rule that regulates the trade and use of this product in the country where it is used.
3. Mixing of individual products is possible unless otherwise restricted for each individual component.
4. As a prerequisite for the certification of all products, the Authorization for use in agriculture issued by the Authority of the country of production and sale of the product is required.
5. When the Operator requests to indicate in the certificate, label or technical sheet additional indications such as "suitable for organic farming according to the NOP/USDA Regulation" or "... according to the JAS standard", the composition of the product must comply, in addition to the requirements indicated above, also with the technical specifications provided for by the NOP or JAS standard and related guidelines and application instructions.

Below you can consult the three main organic production regulations and the lists of permitted and/or prohibited substances for the different types of inputs (*).

	Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (Link) COMMISSION IMPLEMENTING REGULATION (EU) 2021/1165 of 15 July 2021 authorising the use of certain products and substances in organic production and establishing the lists thereof (Link)
USDA ORGANIC	NATIONAL ORGANIC PROGRAM (Link) The National List of Allowed and Prohibited Substances (Link)
JAS	The JAS Standards for organic plants and organic processed foods of plant origin were established in 2000 on the basis with the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods which were adopted by the Codex Alimentarius Commission (Link)

(*) Norms and standards undergo frequent revisions. The links indicated, at certain times, can be perfectly updated, in case of doubt consult Bioagricert or the official government websites.

6. OTHER INPUTS AND MATERIALS

Necessary for carrying out cultivation practices suitable for organic farming which remain for prolonged periods in contact with the ground and / or plants or animals. Among these are:

- Mulching materials.
- Packaging materials.
- Hedging cloth.
- Protective covers.
- Traps insects.
- Regulators pheromones.
- Product for cleaning and disinfection of building and installation for livestock production.
- Products and substances functional to the cleaning of production premises and plants
- Feed additives and adjuvants (feed)
- Food additives and adjuvants
- Any other substance or material functional to biological production processes.

Such materials must have the composition and / or structure such as not to give polluting substances and contaminants to plants, animals and soil.

In addition to compliance with current regulations on organic production (EU Reg. no. 848/2018 and no. 1165/2021), for the purposes of certification, traceability requirements, biodegradability performance, the possible use of recycled substances, the release of polluting or toxic substances, the absence of phytotoxic and eco-toxic effects, for wildlife and, possibly, for humans, will be asessed.

7. PREPARATION OF THE DOSSIER FOR THE REQUEST OF INPUTS CONFORMITY (MINIMUM REQUIREMENTS TO APPLY FOR CERTIFICATION)

a) Flow chart and description of the processing unit.
b) Flow chart from raw materials to finished product.
c) Description of the handling process, indicating:
   - Physical treatments done both on raw materials and on finished products.
   - Possible reactions or chemical treatments done.
   - Any additives or coadjutant used.
   - When non-organic products are prepared or stored in the preparation unit, the operator will inform the control body.
d) Description of each raw material used.
e) Indication of the origin of each raw material and its supplier.
f) Description and analysis of the finished product to check the quantity and quality of nutrients.
g) Analysis of the finished product to check pollutants, especially heavy metals, micro-organic pollutants and hydrocarbons.
h) Authorization for the use in organic farming issued by the Competent Authority of the Country where the product is produced and, if different, also of the Country where the product will be sold.

8. CERTIFICATION PROCESS - PROCEDURES FOR THE EVALUATION OF INPUTS CONFORMITY

9.1 Application

To start the certification procedure, the Operator should supply the following documents:

- Certification application documents: M 81 MTS; M 81 MT; M 81 MTR.
- Descriptive dossier (documents referred to in paragraph 6 of this Standard).

- Product information sheet and any kind of advertising project and label.

Documents submitted must be signed by a duly authorized representative of the operator.

With the signing of the documents listed above the operator accepts all the rules laid down in the Bioagricert certification documents.

9.2 Review of the Application document

At this stage the Bioagricert evaluator (TV/RDP) makes a technical assessment of the documentation submitted by the applicant in order to determine that it is complete and properly filled in, and to ensure that products and processes comply with all requirements for certification.

In particular RDP evaluates:

- the conformity of the application documents: M 81 MTS; M 81 MT; M 81 MTR;
- the conformity of products and processes, as determined by the Standard;
- the conformity of advertising projects and labels, as determined by the Standard;

Following a risk analysis, it defines the frequency of audits of the various production units involved, following the following criteria:

Tipo attività	**Frequenza minima audit**	**Modalità**
Processing (and other related activities)	Every year	On-site
Trading (only)	Every two years	On-site / On-line
Storage (only)	Every three years	On-site / On-line
Packaging (only)	Every three years	On-site

In case of detection of deviations / significant deficiencies (e.g., inconsistency or fail for lack of documentation), the evaluator notifies a Non-compliance to the Operator (according to the par. 13 - Non-Conformity and sanction system and Bioagricert Regulation - current version) with the description of the NC and the timing to be respected.

If the Operator sends in a timely manner the documentation integrative in response to the deficiencies and integrative documentation is satisfactory, RDP schedules the Initial Inspection. The TV/RDP tells the inspector about the deviations found and the adjustment requests.

9.3 Initial inspection

For inspection, Bioagricert selects an inspector with specific skills (qualifications, no conflicts of interest, knowledge of the language); the selection of the inspector is also based on geographic location of the company.

The inspection protocol includes the following key elements:

- Opening meeting (to confirm the scope of verification and proceed with the planning of specific activities, identifying staff member).
- Evaluation of operator's documents submitted in order to check the correspondence between the production site and what declared in the documentation.

- Verification of the effectiveness of the concrete measures taken by the Operator and the application of the: good working practices; formulation, processing, storage and transport system; separation and identification of raw materials and products; labelling.
- Review of book-keeping (records and accounts) in order to verify flow of goods (input/output reconciliation, mass balance calculation, batch traceability and shipments).
- Verification that non-conformities issued previously (e.g., NC arose from the evaluation of documents or from the inspection) have been resolved and associated corrective action have been implemented.
- Closing meeting to present the results of the inspection and the eventual Non-conformities: during the closing meeting the inspector presents the results of inspection, discusses the non- conformities identified and provides explanations on the iter, process and timing for management of non-conformity (the inspector notifies the Non compliances to the Operator, according to the par. 13 - Non-Conformity and sanction system and Bioagricert Regulation - current version, with the description of the NC and the timing to be respected).

9.4 Reporting

The inspector during the visit will use the following specific forms provided by Bioagricert:

- M 214_Checklist MT ;
- M 214 Annex A;
- M 214 Annex B;
- M 214 Annex C;
- Master 32 – Sampling;
- M34 - Non-conformity.

The inspector can also collect a sample of product or raw materials for the execution of laboratory tests or analysis (if required by Bioagricert sampling plan).

The results of inspection are formalized in the following form: Inspection report (214_Checklist MT ; M 214 Annex A; M 214 Annex B; M 214 Annex C); Master 32 – Sampling (if required by the sampling plan) and M34 - non-conformity (if presents), countersigned by the operator (or delegate) who receives a copy.

All inspection documents are sent to the Bioagricert office, by the inspector.

9.5 Final evaluation and proposal of certification

At this step the Evaluator reviews the completeness of documents, in particular:

- inspection report;
- non-conformity reports (eventual);
- test reports (eventual);
- eventual additional inspection visit - for verification closure of NC;
- labels and advertising projects.

If the evaluation result is positive, TV/RDP proposes the certification to the Sector Manager for the operator's enrolment in the List of Licensees (LdL) and the granting of the Certificate of Conformity.

In case of non-conformities which compromise the proposal of certification, RDP sets out the reasons and submits the dossier to the attention of the Sector Manager who puts on the agenda the following Certification Committee meeting.

In case of non-conformities which compromise the granting of the certification, the Bioagricert Sector Manager submits the dossier to the Certification Committee (CC), who asks the operator to apply corrective actions and the integration of the documentation, deciding the time for the adjustment.

The Operator must submit to Bioagricert, on time, a comprehensive documentation which shows that preventive and corrective actions have been implemented.

If within the deadline the operator demonstrates he has carried out the corrective actions, eliminating the lacks found, Bioagricert will repeat only the necessary parts of the initial inspection and of the tests and the CC deliberates for the certification. In the contrary case, the CC rejects the application specifying the reasons for denial.

All Non-compliances that may arise during the certification process will be managed according to the par.13 Non-Conformity and sanction system and Bioagricert Regulation (current version).

When requested by the operator, the conformity assessment can also be extended to the requirements envisaged by the main national regulations for organic farming (e.g., NOP, Organic JAS or Organic EU). In this case, all the requirements and restrictions envisaged by these standards will also be taken into consideration. When the evaluation is compliant in the certificate a note is reported “suitable for organic farming in accordance with ....”

9. CERTIFICATION DECISION - CERTIFICATE OF CONFORMITY

Decision of certification: the proposal of certification made by TV/RDP is submitted to the Sector Manager who, if approves it, deliberates the operator’s enrolment in the List of Licensees (LdL) and the granting of the Certificate of Conformity, in accordance with the criteria set out in the Standard.

With the deliberation of the Sector Manager or the Certification Committee, there is the:

- granting of the Certificate of Conformity and authorization to use the indications of conformity;
- operator’s enrolment in the List of Licensees (LdL) for the certified products;
- approval of the labels and granting the Logo application.

The Certification decisions may include the request for correction of minor non-conformities within a specified time period.

The Operator must submit to Bioagricert, on time, a comprehensive documentation which shows that preventive and corrective actions have been implemented.

The Certificate of Conformity does not replace any authorization provided for by the law and not cover the specific requirements established by each Country where the product may be produced or sold. It is the operator itself that should check that the product complies with the requirements provided for by the law of the country where the product is produced and/or used.

The certificates of conformity are valid for a maximum of three years from the date of issue.

10. LABELLING

All products that are sold for use in organic farming should be labeled in conformity with the official regulation of the Country where the products are produced and/or sold and they can also indicate:

- the wording "suitable for use in organic farming (pursuant to the... reference standard*"" or "suitable for use in organic farming (pursuant to the... Reference Rule*)" or "Allowed in organic farming (pursuant to the... reference rule*)"" ;
- the reference to the Bioagricert certification in compliance with this Standard;
- the Bioagricert Input certificatin logo (optional)

(*) EU Reg. 848/2018 (Europe) or NOP/USDA (United States) or JAS (Japan)

An example of label concerning a fertilizer is reported below.

Fertilizer based on organic and mineral components

Composition: XXXXXXXXXXXXXXX and other mandatory information

Suitable for use in organic farming

Certified by Bioagricert

(control code YYYYYYY) - optional

The products can be sold only after all advertising projects and labels have been approved.

11. MANTEINANCE OF CERTIFICATION

Once the certificate is issued, the Operator should always mantain compliance with this standard and with the law.

In order to maintain the conformity, the Operator should:

- always comply with Bioagricert Regulation, with Bioagricert agreement for certification and Sub Licensee Contract – Accredited seal;
- provide to Bioagricert and Accreditation Personnel the right of access to all appropriate facilities and all relevant documentation and records, including financial records;
- cooperate with Bioagricert inspectors and supply documents, information and records concerning the activities related certified products;
- communicate to Bioagricert (within 30 days) any changes in the product, process or management system which may modify the conformity (Descriptive documents should be updated, completely or in part, any time there is a change in the product or the process);
- inform Bioagricert on any accidental events that may modify the conformity and if he is involved in legal proceedings concerning the product conformity;
- records complaints and keep all documents concerning corrective actions taken.
- send advertising projects concerning certified products to Bioagricert for approval before publishing them; deceptive advertisements are considered a non-conformity and lead to a sanction. The incorrect use of trademarks and certificates, for example due to printing mistakes, may lead to the suspension and withdrawal of the certification and also to damage claim if no corrective actions are immediately taken (e.g., prove it was only a mistake). False assertions and the counterfeiting of trademarks and certificates are legally prosecuted.

All operator's seats must be opened to the Bioagricert inspector who carries out the inspection activity (and Accreditation Personnel, if present), at any time during the working hours and there must always be someone who should cooperate with the inspector.

12. SURVEILLANCE ACTIVITY

The surveillance activity has the aim to guarantee always the conformity with the requirements required by the Standard, and in particular to:

- Ensure that products marketed with references to the certificate comply with the characteristics referred to the Standard.
- Ensure the maintenance of the adequacy of structures, organization and process.
- Ensure the full implementation of all the provisions of the Standard.
- Ensure that changes to the product, the manufacturing process or quality system not compromise the conformity of the product and they comply with the provisions of the Standard.
- Ensure that Non-conformities issued previously (e.g., NC arose from the evaluation of documents or from the inspection) have been resolved and associated corrective action have been implemented.
- Ensure that changes to the standards and to related requirements have been effectively implemented.
- Verify that the trademarks on the product and advertising are used in accordance with the provisions of the Bioagricert Regulations and the Standard.
- Take samples of products and / or raw materials for the execution of tests or laboratory tests, in accordance with the sampling plan.

The Surveillance inspection is performed every 3 years, with a minimum of 1 inspection during the 3 years period. During the 3 years period all activities concerning the certified products should be checked. For the surveillance inspection the same rules described in this Standard apply.

In case where any change in the process or product occurs, Bioagricert may evaluate the necessity to schedule an additional inspection.

All Non-compliances that may arise during the surveillance activity will be managed according to Non-Conformity and sanction system and Bioagricert Regulation - current version.

13. RENEWAL OF CERTIFICATION AND EXTENSION OF CERTIFICATION

Renewal of certification
In general, re-evaluation follows the procedures for initial evaluation.
Operator shall send to Bioagricert the application for Renewal of certification (M 81 MTS) 1 month before the expiration date of the certificate in order to maintain the validity of certificate.

Extension of certification
The following possibilities for the license extension are provided:

- extension of the Certificate of conformity to new products;
- extension to new kind of activities and/or new structures: fields, breeding, processing lines, productive seats.

Operator shall send to Bioagricert the following documents: M 81 MTS and, if applicable, M 81 MT and M 81 MTR. The Scheme Manager evaluates the necessity of new inspections and evaluation procedures. On the basis of the evaluation and inspections result, the Sector Manager or the CC, decides on the license extension and grants the new certificate.

14. NON-CONFORMITY AND SANCTION SYSTEM

Non-conformity - definition
Missed satisfaction of a requirement (EN ISO 9000).
NCs can be caused by the operator or by events that are not due to the operator's direct responsibility. The community regulation provides for two different kinds of non-conformities according to the capability of influence or not the production process: irregularity and infraction. A different sanction corresponds to each one of them.

Irregularity - definition
It is the missing fulfilment of formal aspects of the production process, auto control system, documentation management and application of the norms; irregularities should not be prolonged and should not be due to devices, deceptions, concealments and/or fraudulent means. Irregularities usually do not affect the reliability of the production process and/or auto control system on the production process.
Furthermore, irregularities are divided into major (important) and minor (light).
This division considers the importance that the lack has on the process conformity and/or on the respect of the laws.

Infringement - definition
It is the missing fulfilment of an important aspect that may compromise fundamental aspects of the production process, auto control system, documentation management and application of the norms, contract obligation; infractions are prolonged and/or due to devices, deceptions, concealments and/or fraudulent means. Infractions really compromise one or some aspects of the production process.
They are divided into major (important) and minor (light).

Repetition-definition
A repetition (or reiteration) happens when an operator falls two or more times in the same non-conformity. This event, that is repeated more times in a certain period of time, is considered more serious. The non-conformities of the same kind are summed for a maximum of 24 months for irregularities and 36 months for infractions. So, if an operator commits the same irregularity after 24 months or the same infraction after 36 months, it is not calculated in the sum. The repetition is not applied to non-conformities which do not depend on the operator's responsibility.

Warning
It is an action that does not compromise the certification. Bioagricert warns the operator to close the non-conformity by identifying its causes and planning suitable actions in order not to repeat it.
The corrective action is controlled at the following inspection. If the operators do not respect the warning, the NC becomes more serious. An inspector or an evaluator (documents responsible/RDP) usually issues a warning.
In cases of infringements and irregularities classified as "important", the implementation and effectiveness of corrective actions must be verified with an extraordinary supplementary audit.

15. CONFORMITY ASSESSMENT FOR OTHER NORMS AND STANDARDS

When requested by the operator, the conformity assessment can also be extended to the requirements envisaged by the main national regulations for organic farming (e.g., NOP, Organic JAS or Organic EU, ecc.). In this case, all the requirements and restrictions envisaged by these standards will also be taken into consideration.

In the assessment activity, if necessary, Bioagricert can request further information, documents and data, also regarding the production processes of raw materials and the activities carried out by their suppliers.

If necessary (or required by law), Bioagricert may request an audit at the manufacturer's plant.

When the evaluation is compliant in the certificate a note is reported *"suitable for organic farming in accordance with ...."*

15.1 Assessment for National Organic Program (NOP)

For the inputconformity asessement s to the NOP rules, Bioagricert adopts the applicable points of the **INSTRUCTION FOR MATERIAL EVALUATION IO_013** which, in turn, refer to the USDA document "Interim Instruction Material Review" in the current version.

Materials are the substances to be used as an input in organic production and handling.

Materials include, but are not limited to:

A. fertilizers, soil amendments, potting soil, crop production aids, and pest control materials used in crop production;
B. feed supplements, feed additives, medications, and livestock production aids used in livestock production; and
C. ingredients, processing aids, post-harvest handling substances, sanitizers, and facility pest control materials used in processing and handling.

Certifiers have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:

1. Certifiers can verify that the material complies with the regulations by evaluating the product, all of the ingredients within the product, and, if applicable, the manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).
2. Certifiers may consult with another certifier who has already evaluated the product and accept that certifier's determination of the product's compliance with the regulations. The Washington State Department of Agriculture, as an accredited certifying agent, has a publicly available list of approved products (Link).
3. Certifiers may accept pesticides that have been determined by the U.S. Environmental Protection Agency (EPA) to comply with the USDA organic regulations.
4. Certifying agents may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials.

   The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for crop and livestock materials, as well as for materials used in organic handling.

BAC personnel dedicated to assessing the conformity of technical means with the NOP must pass a specific qualification path and demonstrate adequate levels of education, training and experience.

The performance of the assessor will be subject to monitoring and review by the scheme manager.

For the purposes of conformity assessment, all ingredients, sub-ingredients, processing aids and production methods must be examined at all stages associated with the production of the product being assessed.

The evaluation must include an examination of all synthetic and non-synthetic or agricultural and non-agricultural products in accordance with USDA biological regulations and NOP guidelines regarding material classification.

The conformity assessment takes place during audits in the production plant (when required) or through Technical Data Sheets (TDS), Safety Data Sheets (SDS), process flow charts, relevant analytical tests or product declarations regarding the requirements for the specific substance of the regulation and NOP guidelines.

The above documentation must be updated at least every three years, therefore, the date of issue of the document cannot be earlier than three years from the date of execution of the verification.

In the event that the assessor concludes that a product may not comply with the regulations and this product is authorized by another Certification Body, BAC notifies the NOP by writing to the email address: NOP.Guidance@ams.usda.gov.

In the event that the NOP determines that the regulations have not been correctly applied (possibly also by Bioagricert) and, therefore, the product does not comply with the regulations, the NOP will instruct the certification agent to revoke the approval of the product.

The NOP will communicate the decision to all certifying agents, indicating, if appropriate, a timeline for the discontinuation of the use of the product by biological activities.

For the purpose of conformity assessment, the assessor shall consult the list of substances and restrictions set out in the NOP National List and Guidance and Instructions for Accredited Certifying Agents and Certified Operations.

NOP National List - substances that may or may not be used in organic crop production

The National List of Allowed and Prohibited Substances identifies substances that may or may not be used in organic crop production. In general, synthetic substances are prohibited unless specifically allowed and non-synthetic substances are allowed unless specifically prohibited.

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling

There are two main criteria that determine whether a given substance, such as a fertilizer or pesticide, is allowed in organic crop production:

1. Synthetic substances are prohibited unless specifically allowed on the National List.
2. Nonsynthetic (natural) substances are allowed unless specifically prohibited on the National List.

In addition to these guidelines, genetically modified organisms are prohibited because they are produced by a prohibited method. Sewage sludge is prohibited because it usually contains prohibited substances.

§ 205.601 Synthetic substances allowed for use in organic crop production

The National List of synthetic substances includes materials that are specifically allowed in organic crop production.

The list includes algaecides, disinfectants, sanitizers, irrigation system cleaners, herbicides, animal repellents, insecticides, miticides, pheromones, rodenticides, slug baits, plant disease controls, soil amendments, and plant growth regulators; in short, many of the materials needed for crop production.

Any synthetic substance that is not on the National List is not allowed. For example, herbicides containing the synthetic material glyphosate are prohibited. Herbicides containing only natural substances, such as vinegar and clove oils, are allowed.

§ 205.602 Non-synthetic substances prohibited for use in organic crop production

This is the National List of natural, or nonsynthetic, materials that are specifically prohibited in organic crop production. This list includes natural—but highly toxic—materials, such as arsenic.

§205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the synthetic substances may be used in organic livestock production.

§205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The nonsynthetic substances may not be used in organic livestock production.

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

National Organic Program Handbook:
Guidance and Instructions for Accredited Certifying Agents and Certified Operations

Section A. Standards	Document	Date
Processed Animal Manure in Organic Crop Production	NOP 5006	7/22/2011
Reassessed Inert Ingredients | Notice to Petitioners	NOP 5008	7/22/2011
Approval of Liquid Fertilizers for Use in Organic Production	NOP 5012	7/22/2011
Certification of Organic Yeast	NOP 5014	7/22/2011
Compost and Vermicompost in Organic Crop Production | Response to Comments	NOP 5021	7/22/2011
Guidance: Substances Used in Post-Harvest Handling of Organic Products | Response to Comments	NOP 5023	1/15/2016
The Use of Chlorine Materials in Organic Production & Handling | Response to Comments	NOP 5026	7/22/2011
The Use of Kelp in Organic Livestock Feed | Response to Comments	NOP 5027, NOP 5027-1	2/28/2013
Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed | Response to Comments	NOP 5030, NOP 5030-1	2/28/2013
Classification of Materials | Decision Tree for Classification of Materials as Synthetic or Non-Synthetic | Decision Tree for Classification of Agricultural and Non-Agricultural Materials for Organic Livestock Production or Handling | Response to Comments	NOP 5033, NOP 5033-1, NOP 5033-2 NOP 5033-3	12/2/2016
Materials for Organic Crop Production | Materials for Organic Crop Production | Appendix of Prohibited Materials for Organic Crop Production | Response to Comments	NOP 5034, NOP 5034-1, NOP 5034-2 NOP 5034-3	12/2/2016

Section C. Accreditation	Document	Date
Material Review – Interim Instruction	NOP 3012	8/30/2016

Section G. Policy Memos	Document	Date
Humic Acid Extraction	PM 13-2	12/16/2013
Synthetic Algicides, Disinfectants, and Sanitizers Allowed in Organic Crop Production	PM 13-3	6/6/2014
Aquatic Plant Extracts	PM 14-1	3/12/2014
Chlorine Use in Egg Breaking Facilities	PM 14-2	8/5/2014
Nanotechnology	PM 15-2	3/24/2015
Electrolyzed Water	PM 15-4	9/11/2015

Section H. Notices to Certifying Agents	Document	Date
Sodium Nitrate Use in Organic Crop Production	Notice 12-1	9/11/2012