

STANDARD FOR INPUTS SUITABLE IN ORGANIC PRODUCTION

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1. GENERAL PRINCIPLES

The present Standard should be applied to single commercial products that can be used in organic farming. Organic production and processing methods are based on the use of natural resources, organic and renewable resources. Organic farming preserves soil fertility, first of all through the organic 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 suffering 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

- IFOAM Norms and Accreditation Requirements.
- REGULATION (EC) N. 834/2007 on organic production and labelling.
- REGULATION (EC) N. 889/2008 of 5 September 2008 laying down detailed rules for the application of REGULATION (EC) N. 834/2007 on organic production and labelling of organic products, with regard to organic production, labelling and controls.
- National Organic Program, USDA (United States) and related Guidance and Instructions applicable.
- Japan Agricultural Standard, MAFF (Japan) and related Guidance and Instruction applicable.
- 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 (EC) N. 2003/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 October 2003 relating to fertilizers.
- 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. 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.
- REGULATIONS COMMISSION IMPLEMENTING REGULATION (EU) N. 540/2011 of 25 May 2011 implementing Regulation (EC) N. 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
- UNI CEI EN ISO/IEC 17065 – Assessment of conformity requirements for bodies that certify products, processes and services.

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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:** inputs used in organic production meet consumers expectations without opposition. Their production is socially right and economically sustainable and it respects cultural differences and protects animal health.

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:

- A description of the origin of each raw material should be supplied and also a GMO-free declaration and a description of the process used to cultivate, extract, produce, prepare the substance. Plants, animals, Bacterium, fungus, leavens that may be found in nature are allowed. Substances that require a physical transformation through a mechanical process or an organic method, like in the case of compost, fermentation, enzymatic digestion, are usually allowed. Limitations should be applied considering different criteria.
- Substances that have been chemically processed are considered synthetic and should follow what is indicated in the last point below.
- A description of the resource and its availability should be supplied in case of non-renewable resources (like minerals of extraction). The use of non-renewable resources is usually subject to limitations and restrictions.
- Only if these resources are obtained by using physical or mechanical processes can be used in addition to organic renewable resources. Inputs that contain nanomaterials, heavy metals, radioactive isotopes are forbidden or subject to strong limitations.
- Synthetic substances that come from non-renewable resources are usually prohibited. Synthetic products that are identical to natural products that are not available in needed quantity and quality, can be allowed but only if all requirements described in Chapter 5 are respected.

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- Extracted, recycled, recovered inputs or made through techniques or technologies that may damage the environment are restricted or prohibited.
- During processing, chemical adjuvants that are used to make complex substances simpler and that do not remain in the final composition of the final product, can be used.
- Equipment surface and utensils that might come into contact with organic products shall be free of contaminants such as nanomaterials, heavy metals, radioactive isotopes, unless there is verified absence of contamination risk.
- Application of prohibited substances, such as cleaning materials, to equipment or facilities shall not contaminate the input handled or processed therein.
- When non-organic products are prepared or stored in the preparation unit, the operator shall inform the control body.
- When facilities required necessarily pest control, the operation's pest control should not contaminate the certified input.
- Operators will not use packaging material that may contaminate the input.

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.

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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 the 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 norm and production standard taken as reference.

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This standard lists the fertilizing and phytosanitary substances allowed, for all other products (e.g., food and feed additives and carriers, processing aids, etc.) it is possible to refer to the positive lists contained in the organic norm and standard taken as reference, always respecting the Ifoam principles and basic standards.

For certification purposes, it is necessary to comply with all the regulations and guidance applicable in the countries of production and marketing of the products. It is necessary to consider both the legal requirements for organic products and those envisaged for the production sector and the category of certified products.

General conditions that can be applied to any kind of input:

- The use is allowed in organic farming only if the requirements indicated in the norm are respected.
- The use of the input in organic farming is allowed only in agreement with the National Norm of the State where the product is used that regulates the trading and use of such product.
- The mixing of the single products is possible except in case of different restriction for each single component.

As a pre-requisite for the certification of all products the Authorization for the use in Agriculture issued by the Authority of the Country where the product is produced and where the product should be sold (reported on the certificate) is necessary.

When the operator requests to indicate on the label or technical data sheet additional indications such as "*suitable in organic farming in accordance with the NOP*" or "*... in accordance with the JAS regulations*", the composition of the product must comply, in addition to the requirements indicated above, also to the technical specifications provided for by the NOP or JAS standard and related guidelines and instructions.

5.1 FERTILIZERS, SOIL CONDITIONERS AND NUTRIENTS

Name <i>Compound products or products containing only materials listed hereunder:</i>	Description, specific conditions and limits
Farmyard manure	Product comprising a mixture of animal excrements and vegetable matter (animal bedding and feed material). Factory farming origin forbidden.
Dried farmyard manure and dehydrated poultry manure	Factory farming origin forbidden.
Composted animal excrements, including poultry manure and composted farmyard manure included	Factory farming origin forbidden.
Liquid animal excrements	Use after controlled fermentation and/or appropriate dilution. Factory farming origin forbidden.
Composted or fermented mixture of household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production. Only vegetable and animal household waste. Only when produced in a closed and monitored collection system, accepted by the Member State. Maximum concentrations in mg/kg of dry matter:

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Name <i>Compound products or products containing only materials listed hereunder:</i>	Description, specific conditions and limits
	Cadmium: 0.7; Copper: 70; Nickel: 25; Lead: 45; Zinc: 200; Mercury: 0.4; Chromium (total): 70; Chromium (VI): not detectable.
Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery).
Mushroom culture wastes	The initial composition of the substrate shall be limited to products of this list.
Dejecta of worms (vermicompost) and insect frass-substrate mixture	Origin of raw materials not from factory farming.
Guano	
Composted or fermented mixture of vegetable matter	Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production.
Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	Factory farming origin forbidden. Not to be applied to edible parts of the crop. Animal by-products (including by-products of wild animals) of category 2 and 3 (categories as defined in Regulation (EC) N° 1069/2009).
Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or gelatinized bone meal Fish meal Meat meal Feather, hair and skin meal ('chiquette') Wool Fur (1) Hair Dairy products Hydrolysed proteins (2)	Animal by-products (including by-products of wild animals) of category 2 and 3 (categories as defined in Regulation (EC) N° 1069/2009). (1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable. (2) Not to be applied to edible parts of the crop.
Products and by-products of plant origin for fertilizers	Examples: oilseed cake meal, cocoa husks, malt culms.
Hydrolysed proteins of plant origin	
Seaweeds and seaweed products	As far as directly obtained by: (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or aqueous acid and/or alkaline solution; (iii) fermentation.

Name <i>Compound products or products containing only materials listed hereunder:</i>	Description, specific conditions and limits
	Only from organic or sustainable seaweed production or collection.
Sawdust and wood chips	Wood not chemically treated after felling.
Composted bark	Wood not chemically treated after felling.
Wood ash	From wood not chemically treated after felling.
Soft ground rock phosphate	
Aluminium-calcium phosphate	
Basic slag (Thomas phosphates or Thomas slag)	
Crude potassium salt	
Potassium sulphate, possibly containing magnesium salt	
Stillage and stillage extract	Ammonium stillage excluded.
Calcium carbonate, for instance: chalk, marl, ground limestone, Breton ameliorant, (maerl), phosphate chalk	Only of natural origin.
Mollusc waste	Only from organic aquaculture or from sustainable fisheries.
Egg shells	Factory farming origin forbidden.
Magnesium and calcium carbonate	Only of natural origin.
Magnesium sulphate (kieserite)	Only of natural origin.
Calcium chloride solution	Foliar treatment of apple trees, after identification of deficit of calcium.
Calcium sulphate (gypsum)	Only of natural origin.
Industrial lime from sugar production	By-product of sugar production from sugar beet and sugar cane.
Industrial lime from vacuum salt production	By-product of the vacuum salt production from brine found in mountains.
Elemental sulphur	Comparatively refined natural or industrial product (98%S).
Trace elements/micronutrients	
Sodium chloride	

Name Compound products or products containing only materials listed hereunder:	Description, specific conditions and limits
Stone meal, and clays	
Leonardite (Raw organic sediment rich in humic acids)	Only if obtained as a by-product of mining activities.
Humic and fulvic acids	Only if obtained by inorganic salts/solutions excluding ammonium salts; or obtained from drinking water purification.
Xylite	Only if obtained as a by-product of mining activities (e.g., by-product of brown coal mining).
Chitin (Polysaccharide obtained from the shell of crustaceans)	obtained from organic aquaculture or from sustainable fisheries, as defined in Article 4.1 (7) of Regulation (EU) N. 1380/2013. Animal by-products (including by-products of wild animals) of category 2 and 3 (categories as defined in Regulation (EC) N. 1069/2009).
Organic ⁽¹⁾ rich sediment from freshwater bodies formed under exclusion of oxygen (e.g., sapropel)	Only organic sediments that are by-products of freshwater body management or extracted from former freshwater areas. when applicable, extraction should be done in a way to cause minimal impact on the aquatic system. only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances. Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable .
Biochar - pyrolysis product made from a wide variety of organic materials of plant origin and applied as a soil conditioner	Only from plant materials, untreated or treated before harvest with products included in Annex I. Maximum value of 4 mg polycyclic aromatic hydro-carbons (PAHs) per kg dry matter (DM).

5.2 PESTICIDES (Basic Substance²)

CAS	Name	Specific conditions and limits
	<i>Equisetum arvense</i> L.	
9012-76-4	Chitosan hydrochloride	Obtained from organic aquaculture or from sustainable fisheries.
57-50-1	Sucrose	

⁽¹⁾ Organic here is used in the sense of organic chemistry, not organic farming

⁽²⁾ In Europe, only those basic substances as defined by Article 23 of Regulation (EC) N. 1107/2009 (2) which are food as defined in Article 2 of Regulation (EC) N. 178/ 2002 and have plant or animal origin. These substances not to be used as herbicides.

CAS	Name	Specific conditions and limits
1305-62-0	Calcium Hydroxide	When used as fungicide, only in fruit trees, including nurseries, to control <i>Nectria galligena</i> .
57-50-1	Sucrose*	
1305-62-0	Calcium Hydroxide	
90132-02-8	Vinegar	Not used as herbicide.
8002-43-5	Lecithins	
-	<i>Salix</i> spp. Cortex	
57-48-7	Fructose	
144-55-8	Sodium hydrogen carbonate	Not used as herbicide.
92129-90-3	Whey	
7783-28-0	Diammonium phosphate	Only in traps.
8001-21-6	Sunflower oil	
84012-40-8 90131-83-2	<i>Urtica</i> spp. (<i>Urtica dioica</i> extract) (<i>Urtica urens</i> extract)	
7722-84-1	Hydrogen peroxide	
7647-14-5	Sodium chloride	Not used as herbicide.
8029-31-0	Beer	
-	Mustard seeds powder*	
8002-72-0	Onion oil	

5.3 PESTICIDES (Low risk substance)

CAS	Name	Specific conditions and limits
	COS-OGA	
	Cerevisane and other products based on fragments of cells of micro-organisms	
10045-86-6	Ferric phosphate (iron (III) orthophosphate)	Preparations to be surface-spread between cultivated plants.
9008-22-4	Laminarin	Kelp shall be obtained from organic aquaculture or from sustainable fisheries.

5.4 PESTICIDES (Other substances)

CAS	Name	Specific conditions and limits
131929-60-7 131929-63-0	Spinosad	
124-38-9	Carbon dioxide	

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CAS	Name	Specific conditions and limits
74-85-1	Ethylene	
i.a. 67701-09-1	Fatty acids	Not used as herbicide.
8008-99-9	Garlic extract (<i>Allium sativum</i>)	
	Hydrolysed proteins excluding gelatine	
298-14-6	Potassium hydrogen carbonate	
98999-15-6	Repellents by smell of animal or plant origin/sheep fat	Only on non-edible parts of the crop and where crop material is not ingested by sheep or goats.
	Pheromones and other semiochemicals	Only in traps and dispensers.
1332-58-7	Aluminium silicate (aka Kaolin)	
61790-53-2	Kieselgur (diatomaceous earth)	
14808-60-7	Quartz sand	
7637-86-9		
11141-17-6	Azadirachtin (Margosa extract)	Extracted from Neem tree seeds (<i>Azadirachta indica</i>)
8000-29-1	Plant oils (e.g., citronella oil, clove oil, rape seed oil, spearmint oil, orange oil, tea tree extract)	
84961-50-2		
8002-13-9		
8008-79-5		
8028-48-6		
5989-27-5		
8003-34-7	Pyrethrins extracted from plants	
7704-34-9	Sulphur	
64742-46-7	Paraffin oils	
72623-86-0		
97862-82-3		
8042-47-5		
1344-81-6	Lime sulphur (calcium polysulphide)	
9050-36-6	Maltodextrin	
97-53-0	Terpenes: only eugenol, geraniol and thymol	
106-24-1		
89-83-8		
20427-59-2	Copper compounds in the form of: copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture, and tribasic copper sulphate	In Europe, only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.
1332-65-6		
1332-40-7		
1317-39-1		
8011-63-0		
12527-76-3		
1333-22-8		
	Quassia extracted from Quassia amara	Only as insecticide, repellent

CAS	Name	Specific conditions and limits
52918-63-5 91465-08-6	Pyrethroids (only deltamethrin or lambda-cyhalothrin)	Only in traps with specific attractants Only against <i>Bactrocera oleae</i> and <i>Ceratitis capitata</i> , until January 2025
8012-89-3	Beeswax	Only as pruning agent/wound protectant

5.4 MICRO-ORGANISMS (including viruses)

Micro-organisms including viruses are biological control agents that are considered as active substances (in Europe by Regulation (EC) N. 1107/2009).

Micro-organisms may be used in organic production provided that they are not from GMO origin.

In Europe they must be listed in part A, B and D of the Annex to Implementing Regulation (EU) N. 540/2011 may be used in accordance with the uses, conditions and restrictions in the relevant review reports available under Implementing Regulation (EU) N. 540/2011.

Other biological control agents, such as beneficial insects, mites and nematodes, are not covered by Regulation (EC) N. 1107/2009. They may be used in organic production as natural enemies of pests in accordance with national law.

6. TECHNICAL 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.

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

Will be evaluated the high level of recyclability, biodegradability, the disposal of pollutants or toxic substances, the absence of phytotoxic effects and eco-toxic, for wildlife and for the man if by chance.

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 coadjuvant 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.

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- 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

8.1 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.
- M 37 – Protocol agreement for the activity of control and Sub Licensee Contract – IFOAM Accredited seal (if requested), signed by the legal representative of the company.

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.

8.2 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;
- the risk assessment form (M_MT RA) to assign the risk level and relative frequency of audit, based on the following criteria:

Risk Factor	Value		
	1	2	Notes
RAW MATERIAL (GMO RISK)	Animal origin	Vegetable, algae, mychorriza and fungi origin	
NON CONFORMITY OCCURRED LAST YEAR	No important irregularity	Infractions	
SIZE	Protocol amount < 3000€	Protocol amount > 3000€	Defined case by case basis
N IN FERTILIZER	N < 3%	N > 3%	Mandatory testing
PESTICIDE	//	For all products	Mandatory testing

Control frequency	Value
Every 3 years	< 5
Every 2 years	6 - 8
Every year	9-10

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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.

8.3 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).

8.4 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).

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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.

8.5 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.

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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 should also indicate:

- Production unit.
- List of the single inputs used in the composition (it is possible not to indicate the quantities).
- Purpose of use.
- The indication “can be used in organic farming”.
- The reference to Bioagricert control to check the conformity with the present Standard.
- Bioagricert Inputs trademark (optional).

An example of label concerning a fertilizer is reported below.

Fertilizer based on organic and mineral products

Produced by company XXXXXXXXXXXXXXXXXXXX address xxxxxxxxxxxx (control code BAC YYYYYY)

Composition: XXXXXXXXXXXXXXXXXXXX and other mandatory information

Suitable for use in organic farming, according to “Standard Bioagricert-IFOAM Inputs”

Controlled by Bioagricert



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

The Logo Bioagricert - IFOAM Inputs can be used if the licensee subscribes the Sub Licensee Contract for use of the IFOAM Accredited seal.

All details regarding licensing and labelling are defined in the Sub Licensee Contract – IFOAM Accredited seal.

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11. MAINTENANCE OF CERTIFICATION

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

In order to maintain the conformity, the Operator should:

- always comply with Bioagricert Regulation, with Bioagricert Protocol of agreement for certification and Sub Licensee Contract – IFOAM 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. The operator should consider also complaints coming from sub licensees for whom he is responsible;
- 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.

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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. Sub licensees' non-conformities are also protested against the licensee of reference.

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,

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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 input conformity assessment to the NOP rules, Bioagricert adopts the applicable points of the **INSTRUCTION FOR MATERIAL EVALUATION IO_013**

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 available at <http://agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx>.

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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.

For the purposes of conformity assessment, the substances and restrictions indicated 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)).”

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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

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

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

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