**Organic Regulation Toolkit for Governments**

Produced by IFOAM – *Organics International*

*Document last updated on February 22, 2018*

**Country X National Organic Regulation**

Regulating the Production, Processing, Labelling and Marketing of Organically Produced Products

*Adopted by authority, date*

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# Foreword

This regulation was approved by \_\_\_\_\_ in accordance with \_\_\_\_.

This regulation was published on the \_\_\_date.

Put here other introduction needed based on the national legislation context (link with other laws and official documents).

The aims of this regulation are:

1. To protect consumers against deception and fraud in the market place and unsubstantiated product claims, while facilitating their access to trustworthy organic products;
2. To protect producers of organic produce against misrepresentation of other agricultural produce as being organic (unfair competition);
3. To provide a national definition of organic agriculture for the purpose of further policy support towards the sector.
4. To ensure that the national understanding of organic agriculture delivers the expected outcomes of organic agriculture within the territory of \_\_\_Country X and is compatible with international interpretations, expectations and developments regarding organic agriculture.
5. To facilitate the export and import of organic products.

This regulation was developed taking into account international recommendations expressed in:

* The norms and policy recommendations of the International Federation of Organic Agriculture Movements (IFOAM).
* The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999).
* The UNEP-UNCTAD publication “Best Practices for Organic Policy” (2008).
* The publications of the International Task Force on Harmonization and Equivalence (ITF), namely “*Harmonization and Equivalence in Organic Agriculture*” Volumes I to VI, “*Strategy on Solutions for Harmonizing International Regulation of Organic Agriculture*” Volumes I to III, and the “*Equitool - Guide for Assessing Equivalence of Organic Standards and Technical Regulations*” and its Annex the “*Common Objectives and Requirements of Organic Standards (COROS)*”.

The regulation was developed with a view to, whenever possible, harmonize the production requirements and control procedures with those of other countries (particularly trade partners) and international institutions.

# Article I: Definitions

For the purposes of this regulation the following definitions apply:

**Additive:** An enrichment, supplement or other substance which can be added to a foodstuff or other product to affect its keeping quality, consistency, color, taste, smell or other technical property (For full definition, see Codex Alimentarius).

**Amino acid isolate:** amino acid substance (e.g. methionine, lysine, threonine) that has been isolated or extracted to a more pure form than occurs in the parent material (e.g. soy, corn, etc).

**Aquaculture:** The managed production of aquatic plants and/or animals in fresh, brackish or salt water in a circumscribed (demarcated) environment.

**Ayurvedic:** Traditional Indian system of medicine.

**Biodiversity:** The variety of life forms and ecosystem types on Earth. Includes genetic diversity (i.e. diversity within species), species diversity (i.e. the number and variety of species) and ecosystem diversity (total number of ecosystem types), as well as the dynamic effects they engender.

**Breeding:** Selection of plants or animals to reproduce and/or to further develop desired characteristics in succeeding generations.

**Buffer Zone:** A clearly defined and identifiable boundary area bordering an organic production site that is established to limit application of, or contact with, prohibited substances from an adjacent area.

**Certificate:** Document, delivered by the conformity assessment body, attesting that the product or operator is in compliance with a specified organic standard.

**Compost:** Decayed organic material used as a fertility amendment in agricultural production, produced by a combination of actions over time by microbes, invertebrates, temperature, and other elemental factors (e.g., moisture content, aeration). Composted material shows practically no substantive indication as to the original substrate(s) from which it was made.

**Conformity Assessment:** Codified system of verification that an operator complies with the relevant organic standard.

**Conformity Assessment Body:** An organization that conducts the conformity assessment of organic operators. This may be a third party certification body or a participatory guarantee system.

**Contamination:** Contact of organic product or land with a substance prohibited for organic production or handling.

**Conventional:** Conventional means any material, production or processing practice that is not organic or organic “in conversion”.

**Conversion Period:** The time between the start of the organic management and the acceptance of crops and animal husbandry as organic.

**Crop Rotation:** The practice of alternating the species or families of annual and/or biennial crops grown on a specific field in a planned pattern or sequence to break weed, pest and disease cycles and to maintain or improve soil fertility and organic matter content.

**Culture:** Microorganisms, tissue, or organ, growing on or in a medium and substrate.

**Direct Source Organism:** The specific plant, animal, or microbe that produces a given input or ingredient.

**Disinfect:** To reduce, by physical or chemical means, the number of potentially harmful microorganisms in the environment, to a level that does not compromise product safety or suitability.

**Farm Unit:** The total area of land under control of one farmer or a collective of farmers, including all the farming activities or enterprises.

**Genetic Diversity:** The variability among living organisms from agricultural, forest and aquatic ecosystems; this includes diversity within species and between species.

**Genetic Engineering:** A set of techniques from molecular biology (such as recombinant DNA) by which the genetic material of plants, animals, microorganisms, cells and other biological units are altered in ways or with results that could not be obtained by methods of natural mating and reproduction or natural recombination. Techniques of genetic engineering include, but are not limited to: recombinant DNA, cell fusion, micro- and macro-injection, and encapsulation. Genetically engineered organisms do not include organisms resulting from techniques such as conjugation, transduction and natural hybridization.

**Genetically Modified Organism (GMO):** A plant, animal, or microbe that is transformed by genetic engineering.

**Genetic Resources:** Genetic material of actual or potential value.

**Green Manure:** A crop that is incorporated into the soil for the purpose of soil improvement. This may include spontaneous crops, plants or weeds.

**Habitat:** The area over which a plant or animal species naturally exists; the area where a species occurs. Also used to indicate types of habitat, e.g. seashore, riverbank, woodland, grassland.

**High Conservation Value Area:** An area that has been identified as having outstanding and critical importance due to its environmental, socioeconomic, biodiversity or landscape values.

**Homeopathic Treatment:** Treatment of disease based on administration of remedies prepared through successive dilutions of a substance that in larger amounts produces symptoms in healthy subjects similar to those of the disease itself.

**Hydroponic Systems:** Crop production systems in inert media and/or water solutions using dissociated nutrients (in suspension or solution) as prime source of nutrient supply. Growing crops in water only is not considered a hydroponic system.

**IFOAM**: International Federation of Organic Agriculture Movements

**Ingredient:** Any substance, including additives, used in the manufacture or preparation of a product or present in the final product although possibly in a modified form.

**Irradiation (ionizing radiation):** High energy emissions from radio-nucleotides, capable of altering a product’s molecular structure for the purpose of controlling microbial contaminants, pathogens, parasites and pests in food, preserving food or inhibiting physiological processes such as sprouting or ripening, or for the purpose of inducing mutations for selection and breeding.

**Label:** Any written, printed or graphic representation that is present on a product, accompanies the product, or is displayed near the product.

**Landless animal husbandry systems**: systems by which the operator of the livestock does not manage agricultural land and/or has not established a long-term cooperation agreement with another operator organically managing agricultural land, whether it be for pasture, supply of feed or disposal of manure & effluent.

**Manure:** All livestock excrement that may be mixed with litter material.

**Media (plural) or Medium (singular):** The substance in which an organism, tissue, or organ exists, which includes the substrate.

**Multiplication:** The growing on of seed stock or plant material to increase supply for future planting.

**Nanomaterials:** substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition.

**Operator:** An individual or business enterprise responsible for ensuring that products meet the requirements of an organic standard.

**Organic Product:** A product that has been produced, processed, and/or handled in compliance with organic standards.

**Organic Seed and Plant Material:** Seed and planting material that is produced under certified organic management.

**Parallel Production:** Any production where the same unit is growing, breeding, handling or processing the same products in an organic system and in a non-organic system. A situation with “organic” and “in conversion” production of the same product is also parallel production. Parallel production is a special instance of split production.

**Participatory guarantee system (PGS):** Quality assurance systems, usually locally focused, which certify producers based on verification of compliance with the standard through active participation of stakeholders. Technical characteristics of functioning PGS are described in Article 6.3.

**Processing Aid:** Any substance or material, not including apparatus or utensils, and not consumed as a product ingredient by itself, intentionally used in the processing of raw materials, the product or its ingredients, to fulfill a certain technical purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product. This includes filtration auxiliaries and solvents used for extraction.

**Propagation:** The reproduction of plants by sexual (i.e. seed) or asexual (i.e. cuttings, root division) means.

**Protected cropping:** The growing of crops under forms of constructed or man-made protection such as greenhouses, polytunnels, plastic roofs, nets, fleece, or cloches.

**Ruderal:** (of a plant) growing in waste places, along roadsides or in rubbish.

**Sanitize:** To adequately treat produce or product-contact surfaces by a process that is effective in destroying or substantially reducing the numbers of vegetative cells of microorganisms of public health concern, and other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

**Soil:** Soil is the natural living ecosystem that develops on the surface of the earth as a result of the influence of climate, topography, biological activity, time, and sometimes cultivation, on the mineral parent material. Soil is composed of air, water, minerals, organisms and organic matter and is connected to the outermost layer of the earth.

**Soil fertility:** The potential capacity of the soil to supply nutrients required for plant growth.

**Soil health:** Soil health is the continued capacity of the soil to function as a vital living system, within ecosystem and land use boundaries, to sustain biological productivity, maintain the quality of air and water environments, and promote plant, animal and human health. Soil health is the ability of soil to perform according to its potential and changes over time due to human use and management or to natural events.

**Soil quality:** Soil quality is the functional capacity of the soil, within ecosystem and land-use boundaries, to sustain biological productivity, maintain environmental quality and promote plant, animal, microbial and human health. Soil quality is a function of its biological, physical and chemical properties, many of which are a function of soil organic matter content, which influence the capacity of soil to perform crop production and environmental functions, including the absence of contaminants.

**Source separated**: Human excrement collected separately from waste streams that contain prohibited substances.

**Split Production:** Where only part of the farm or processing unit is organic. The remainder of the property can be (a) non-organic, and/or (b) in conversion. Also see parallel production.

**Substrate:** The substance that an organism grows in and lives upon.

**Synthetic:** A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral source, except that such a term shall not apply to substances created by naturally occurring biological processes.

# Article II: Principles and Objectives of Organic Agriculture

2.1. Organic Agriculture is a production system that sustains the health of soils, ecosystems and people. It relies on ecological processes, biodiversity and cycles adapted to local conditions, rather than the use of inputs with adverse effects. Organic Agriculture combines tradition, innovation and science to benefit the shared environment and promote fair relationships and a good quality of life for all involved. Organic Agriculture is based on 4 Principles: Health, Ecology, Fairness and Care (see Appendix 6).

2.2. The organic production system, as described in this regulation, is designed to:

1. Manage resources, including soil fertility, in a long-term, ecological and system-based approach.
2. Avoid synthetic inputs at all stages of the organic product chain, and avoid exposure of people and the environment to persistent, potentially harmful chemicals.
3. Minimize pollution and degradation of the production unit and surrounding environment.
4. Exclude unproven, unnatural and harmful technologies, such as genetic engineering, irradiation and nanotechnologies.
5. Treat animals in a responsible manner, and promote their natural health.
6. Maintain organic integrity and identity throughout the supply chain.
7. Provide employees and workers with social justice and equal opportunities.

# Article III: Scope of this Regulation

3.1. This regulation applies to the following products which carry, or are intended to carry, descriptive labelling referring to organic production methods:

(a) Unprocessed plants and plant products, livestock and livestock products

(b) Processed agricultural crop and livestock products derived from (a) above, intended for animal feed or for human food consumption.

3.2. A product will be regarded as bearing indications referring to organic production methods where, in the labelling or claims, including advertising material or commercial documents, the product, or its ingredients, is described by the term “organic [replace by the corresponding word in local language]” or its derivatives suggesting to the purchaser that the product or its ingredients were obtained according to organic production methods.

3.3. Compliance with this regulation is mandatory only for products marketed to the final consumer within the territory of \_\_Country name. Products which are not sold, or raw farm products that are sold on-farm to the final consumer, are exempted from complying with Article VI (Conformity Assessment Rules) and related requirements in Article 4.2 of this regulation.

This regulation remains voluntary for products that are intended only for export, as those may choose to comply with the organic regulation of the importing country only.

3.4. However, compliance with this regulation is mandatory for any product bearing the national organic logo, both for domestic sales and international sales. Products bearing the national organic logo may only do so in accordance with rules and guidelines developed in relation to the logo use.

3.5. This regulation does not cover products of hunting and fishing, aquaculture and processed cosmetics and textile products.

# Article IV: Labelling and Claims

4.1. Organically produced products from plant and animal origin may be labelled as "product of organic agriculture", "organic", “organically produced", "certified organic" or with a similar wording referring to "organic”.

4.2. Both for domestically produced products and for imported products, the labeling and claims of a product may refer to organic production methods only where:

a) The product was produced in compliance with the national organic standard (requirements in Article 5) or in compliance with an equivalent organic standard. Recognized as equivalent are all standards and technical regulations officially recognized as equivalent to the Common Objectives and Requirements of Organic Standards (COROS). This includes all standards and regulations approved in the IFOAM Family of Standards[[1]](#footnote-1), for the scope of their approval.

b) The operator has been certified in accordance with the conformity assessment rules laid down in this regulation (Article 6) or with conformity assessment rules of equivalent effectiveness. Recognized as equivalent conformity assessment systems are all organic certification conducted in the scope of an established national or international organic accreditation program. This requirement shall apply to all operators that produce, process, handle, or sell organic products, except when a handler does not re-pack the product or alter its packaging or labelling in any way.

c)  the product labelling refers to the name and/or code number of the conformity assessment body to which the operator who has carried out the production or the most recent processing operation is subject.

d) The producer or handler shall provide copies of valid organic certificates demonstrating, compliance with points a) and b) above, to buyers or to the authorities when requested.

e) for imported products, the importer has informed the \_competent authority of its organic imports activity.

# Article V: Rules for production, processing, handling and labeling

Note: We have here included the rules of production (National Organic Standard) into the text of the regulation template. However, we recommend governments to consider whether the regulation text could here simply refer to a separate document, using a language such as “The Rules for production, processing, handling and labeling shall be laid down in the National Organic Standard maintained by the Ministry of Agriculture”. The idea is that the National Organic Standard may require relatively frequent updates, and it may be too cumbersome to handle every such update through a parliamentarian process (as for the general regulation). It may be more workable that the maintenance and update of the National Organic Standard be managed by Ministerial decree, by the National Bureau of Standard, by the National Organic Sector Umbrella Organization, or by any other authorized body, depending on the national context.

### 5.1. ORGANIC ECOSYSTEMS

#### 5.1.1 Ecosystem Management

**General Principle**

Organic farming benefits the quality of ecosystems.

**Requirements**

**5.1.1.1** Operators shall design and implement measures to maintain and improve landscape and enhance biodiversity quality, by maintaining on-farm wildlife refuge habitats or establishing them where none exist. Such habitats may include, but are not limited to:

1. extensive grassland such as moorlands, reed land or dry land;
2. in general all areas which are not under rotation and are not heavily manured: extensive pastures, meadows, extensive grassland, extensive orchards, hedges, hedgerows, edges between agriculture and forest land, groups of trees and/or bushes, and forest and woodland;
3. ecologically rich fallow land or arable land;
4. ecologically diversified (extensive) field margins;
5. waterways, pools, springs, ditches, floodplains, wetlands, swamps and other water-rich areas which are not used for intensive agriculture or aquaculture production;
6. areas with ruderal flora;
7. wildlife corridors that provide linkages and connectivity to native habitat.

**5.1.1.2** Clearing or destruction of High Conservation Value Areas is prohibited. Farming areas installed on land that has been obtained by clearing of High Conservation Value Areas in the preceding 5 years shall not be considered compliant with this standard.

#### 5.1.2 Soil and Water Conservation

**General Principle**

Organic farming methods conserve and improve the soil, maintain water quality and use water efficiently and responsibly.

**Requirements**

**5.1.2.1** Operators shall take defined and appropriate measures to prevent erosion and minimize loss of topsoil. Such measures may include, but are not limited to: minimal tillage, contour plowing, crop selection, maintenance of soil plant cover and other management practices that conserve soil.

**5.1.2.2** Land preparation by burning vegetation or crop residues is prohibited, except in cases where burning is used to suppress the spread of disease, to stimulate seed germination, or to remove intractable residues.

**5.1.2.3** Operators shall return nutrients, organic matter and other resources removed from the soil through harvesting by the recycling, regeneration and addition of organic materials and nutrients.

**5.1.2.4** Stocking densities and grazing shall not degrade land or pollute water resources. This applies also to all manure management and applications.

**5.1.2.5** Operators shall prevent or remedy soil and water salinization where these pose a problem.

**5.1.2.6** Operators shall not deplete nor excessively exploit water resources, and shall seek to preserve water quality. They shall where possible recycle rainwater and monitor water extraction.

#### 5.1.3 Inappropriate technologies

**General Principle**

Organic agriculture and aquaculture are based on the precautionary principle and should prevent significant risks by adopting appropriate technologies and rejecting unpredictable ones.

**Requirements**

**5.1.3.1**  The deliberate use or negligent introduction of genetically engineered organisms or their derivatives is prohibited. This shall include animals, seed, propagation material, feed, and farm inputs such as fertilizers, soil conditioners, or crop protection materials, but shall exclude vaccines.

**5.1.3.2** Organic operators shall not use ingredients, additives or processing aids derived from GMOs.

**5.1.3.3** Inputs, processing aids and ingredients shall be traced back one step in the biological chain to the direct source organism from which they are produced to verify that they are not derived from GMOs**.**

**5.1.3.4** On farms with split (including parallel) production, the use of genetically engineered organisms is not permitted in any production activity on the farm.

**5.1.3.5** The use of nanomaterials is prohibited in organic production and processing, including in packaging and product contact surfaces. No substance allowed under this standard shall be allowed in nano form.

#### 5.1.4 Wild Harvested Products and Common/Public Land Management

**General Principle**

Organic management sustains and prevents degradation of common biotic and abiotic resources, including areas used for rangeland, fisheries, forests, and forage for bees, as well as neighboring land, air and water.

**Requirements:**

**5.1.4.1**  Wild harvested products shall only be derived from a sustainable growing environment. Products shall not be harvested at a rate that exceeds the sustainable yield of the ecosystem, or threatens the existence of plant, fungal or animal species, including those not directly exploited.

**5.1.4.2** Operators shall harvest products only from a clearly defined area where prohibited substances have not been applied.

**5.1.4.3** The collection or harvest area shall be at an appropriate distance from conventional farming or other pollution sources in order to avoid contamination.

**5.1.4.4** The operator who manages the harvesting or gathering of common resource products shall be familiar with the defined collecting or harvesting area, including the impacts of collectors not involved in the organic scheme.

**5.1.4.5.** Operators shall take measures to ensure that wild, sedentary aquatic species are collected only from areas where the water is not contaminated by substances prohibited in these standards.

### 5.2. GENERAL REQUIREMENTS FOR CROP PRODUCTION AND ANIMAL HUSBANDRY

#### 5.2.1 Split Production and Parallel Production

**General Principle**

The whole farm, including livestock, is converted to organic management practices according to the standards over a period of time.

**Requirements:**

**5.2.1.1** If the whole farm is not converted (split production) the organic and conventional parts of the farm shall be clearly and continuously separated.

**5.2.1.2** Simultaneous production of the same products (parallel production) is only permitted where such production is undertaken in a way that allows clear and continuous and verifiable separation of all operations and products claimed as organic. Organic and non-organic units in parallel production must be physically, financially and operationally separated.

**5.2.1.3** Prohibited materials shall not be stored where organic products are grown and handled.

#### 5.2.2 Maintenance of Organic Management

**General Principle**

Organic production systems require an ongoing commitment to organic production practices.

**Requirements:**

**5.2.2.1** The production system shall not rely upon continuous switching between organic and conventional management.

### 5.3 . CROP PRODUCTION

#### 5.3.1 Choice of Crops and Varieties and propagation of planting materials

**General Principle**

Species and varieties cultivated in organic agriculture systems are selected for adaptability to the local soil and climatic conditions and tolerance to pests and diseases. All seeds and plant material are organic.

**Requirements:**

**5.3.1.1** Operators shall use organically produced seed and planting material whenever available in appropriate varieties and quality. When organic seed and planting materials are not available in sufficient quantity or quality for the required variety or equivalent varieties, in-conversion materials may be used. When none of these are available, conventional materials may be used provided that they have not been treated with post-harvest pesticides not otherwise permitted by this standard, unless the post-harvest treatment is prescribed by law for phytosanitary purposes.

**5.3.1.2** Seeds and plant materials shall be propagated under organic management for one generation, in the case of annuals, and for perennials, two growing periods, or 18 months, whichever is the longer, before being certified as organic seed and plant material.

**5.3.1.3** Propagation may be based on generative propagation (seeds) as well as

vegetative propagation derived from various plant organs e.g.

* 1. partitioned tubers, scales, husks;
	2. partitioned bulbs, brood, bulbs, bulbils, offset bulbs etc.;
	3. layer, cut and graft shoots;
	4. rhizomes;
	5. meristem culture.

**5.3.1.4** All multiplication practices on the farm, except meristem culture, shall be under organic management.

**5.3.1.5** Vegetal propagation materials, bedding materials and substrates shall only consist of substances listed in appendices 2 and 3.

#### 5.3.2 Conversion Period (Plant Production)

**General Principle**

A conversion period enables the establishment of an organic management system and builds soil health and fertility.

**Requirements:**

**5.3.2.1** All the requirements of this standard shall be met for the duration of the conversion period.

**5.3.2.2** The start of the conversion period shall be calculated from the date that an application has been received and agreed to by the conformity assessment body. The conversion period may however be calculated retroactively, subject to approval by the conformity assessment body, and based on sound and incontrovertible evidence[[2]](#footnote-2) of full application of the standard for a period at least as long as described in 5.3.2.3.

**5.3.2.3** The length of the conversion period shall be at least:

- 12 months before sowing or planting in the case of annual production

- 12 months before grazing or harvest for pastures and meadows

- 18 months before harvest for other perennials.

#### 5.3.3 Diversity in Crop Production

**General Principle**

The development of living soils is the foundation of organic production. Soil health and quality are the basis of soil management practices and are critical to successful pest, disease and weed management. Organic growing systems are soil based, care for the soil and surrounding ecosystems, provide support for a diversity of species, are based on nutrient recycling and mitigate soil and nutrient losses.

**Requirements:**

**5.3.3.1** Crop rotations for annual crops shall be established to manage pressure from pests, weeds and diseases and to maintain soil fertility, unless the operator ensures diversity in plant production by other means. Crop rotations shall be diverse and include soil-improving plants such as green manure, legumes or deep rooting plants.

**5.3.3.2** For orchards and plantations, there shall be managed floor cover and diversity or refuge plantings.

#### 5.3.4 Soil Fertility and Fertilization

**General Principle**

Organic farming returns microbial, plant or animal material to the soil to increase or at least maintain its fertility and biological activity.

**Requirements:**

**5.3.4.1** Soil organic matter, microbial activity and general soil health and fertility shall be improved if low and maintained or improved if satisfactory. The operator shall prevent over-accumulation of heavy metals and other pollutants in the soils.

**5.3.4.2** Material of microbial, plant or animal origin shall form the basis of the fertility program. Maintenance of fertility may not rely solely on off-farm inputs.

**5.3.4.3** Nutrients and fertility products shall be applied in a way that does not harm soil, water, and biodiversity.

**5.3.4.4** Material applied to the land or crop shall be in accordance with Appendix 2.

**5.3.4.5** Fertility amendments in Appendix 2 that are rapidly available to the plants are exceptionally allowed only as a necessary complement when other fertility building techniques have been applied and are insufficient.

**5.3.4.6** Human excrement shall be handled in a way that reduces risk of pathogens and parasites and shall not be applied within six months of the harvest of annual crops for human consumption with edible portions in contact with the soil.

**5.3.4.7** Mineral fertilizers shall only be used in a program addressing long-term fertility needs together with other techniques such as organic matter additions, green manures, crop rotations and nitrogen fixation by plants. Their use shall be justified by appropriate soil and leaf analysis or diagnosed by an independent expert.

**5.3.4.8** Mineral fertilizers shall be applied in the form in which they are naturally composed and extracted and shall not be rendered more soluble by chemical treatment.

**5.3.4.9** Chilean nitrate and all synthetic fertilizers, including urea, are prohibited.

**5.3.4.10** The production of terrestrial plants shall be soil-based. The production of such crops in hydroponic systems is prohibited. “Soil-based” means that apart from the propagation or seedling stages, a plant must spend its life in the soil. For herbs, flowers and ornamentals in pots that are sold directly to the final consumer, the CB can allow production on permitted growing media.

**5.3.4.11** The removal of soil from the farm is prohibited. Incidental removal of soil when harvesting crops is permitted.

**5.3.4.12** For mushroom production, substrates shall be made of products of organic agriculture, or other non-chemically treated natural products such as peat, wood, mineral products or soil.

#### 5.3.5 Pest, Disease and Weed Management

**General Principles**

Organic farming systems apply biological and cultural means to prevent unacceptable losses from pests, diseases and weeds. They use crops and varieties that are well-adapted to the environment and a balanced fertility program to maintain fertile soils with high biological activity, locally adapted rotations, companion planting, green manures, functional biodiversity, habitat management, beneficial organisms and other recognized organic practices as described in this standard.

**Recommendation:**

In case operators need to use commercial formulated inputs, preference should be given to formulations approved for use in organic agriculture by a specialized organic material review organization/program.

**Requirements:**

**5.3.5.1** The organic production system shall include biological, cultural and mechanical mechanisms to manage pests, weeds and diseases. These include:

**a.** choice of appropriate species and varieties;

**b.** appropriate rotation programs, intercropping and companion planting;

**c.** mechanical cultivation;

**d.** protection of natural enemies of pests through provision of favorable habitat, such as hedges, nesting sites and ecological buffer zones that maintain the original vegetation to house pest predators;

**e.** natural enemies including release of predators and parasites;

**f.** mulching and mowing;

**g.** grazing by animals;

**h.** mechanical controls such as traps, barriers, light and sound.

**i.** on-farm preparations from local plants, animals and micro-organisms.

**5.3.5.2** When the measures in 5.3.5.1 are not sufficient, pest, disease and weed management substances permitted under Appendix 3 may be used.

**5.3.5.3** Substances that do not appear on Appendix 3 are prohibited for use in organic production.

**5.3.5.4** Physical methods for pest, disease and weed management are permitted, including the application of heat.

**5.3.5.5** Thermal sterilization of soils is prohibited, except in instances of severe disease or pest infestation that cannot be otherwise remedied through measures in 5.3.5.1, 5.3.5.2 and 5.3.5.4 and after prior approval of the conformity assessment body.

**5.4.5.6** Any formulated input shall have only active ingredients listed in Appendix 3. All other ingredients shall not be carcinogens, teratogens, mutagens, or neurotoxins.

#### 5.3.6 Avoiding Contamination

**General Principle**

All relevant measures are taken to ensure that organic soil and organic products are protected from contamination.

**Requirements:**

**5.3.6.1** The operator shall monitor crops, soil, water, and inputs for risks of contamination by prohibited substances and environmental contaminants.

**5.3.6.2** The operator shall employ measures including barriers and buffer zones to avoid potential contamination and limit contaminants in organic products.

**5.3.6.3** All equipment from conventional farming systems shall be thoroughly cleaned of potentially contaminating materials before being used on organically managed areas.

**5.3.6.4** For synthetic structure coverings, mulches, fleeces, insect netting and silage wrapping, only products based on polyethylene and polypropylene or other polycarbonates, and biodegradable materials (e.g. starch based), are permitted. These shall be removed from the soil after use and shall not be burned on the farmland.

**5.3.7 *Protected cropping***

**General principle**

All the rules on crop production apply to protected cropping, including those concerning conversion period (5.3.2), diversity of crop production (5.3.3), and soil fertility and fertilization (5.3.4). Natural light, air and water are essential components of organic plant production.

**Requirements:**

**5.3.7.1** Artificial light is only allowed for plant propagation and as a complement to sunlight to extend the day length to a maximum of 16 hours.

**5.3.7.2** Operators shall monitor, record and optimize any energy used for artificial light, heating, cooling, ventilation, humidity and other climate control.

### 5.4 . ANIMAL HUSBANDRY

#### 5.4.1 Animal Management

**General Principle**

Organic livestock husbandry is based on the harmonious relationship between land, plants and livestock, respect for the physiological and behavioral needs of livestock and the feeding of good-quality organically grown feedstuffs. Stocking rates for livestock should be appropriate for the region in question taking into consideration the body size/weight of the breeds maintained, feed production capacity, stock health, nutrient balance, and environmental impact.

**Requirements:**

**5.4.1.1** Landless animal husbandry systems are prohibited.

**5.4.1.2** The operator shall ensure that the environment, the facilities, stocking density and flock/herd size provides for the behavioral needs of the animals.

**5.4.1.3** In particular, the operator shall ensure the following animal welfare conditions:

**a.** sufficient free movement and opportunity to express normal patterns of behavior, such as space to stand naturally, lie down easily, move around freely, groom themselves, sleep and nest comfortably, as well as assume all natural postures and movements such as stretching etc.;

**b.** sufficient fresh air, water, feed, thermal comfort and natural daylight, to satisfy the needs of the animals;

**c.** access to resting areas, shelter and protection from sunlight, temperature, rain, mud and wind adequate to reduce animal stress;

**d.** provision of suitable materials and areas for exploratory and foraging behaviors;

**e.** in addition to these general welfare conditions for all animal categories, provisions for specific animal groups also have to be taken into account, e.g. for cattle: social grooming and grazing; for pigs: rooting, separate lying-, activity/dunging- and feeding-areas, free farrowing, group housing; for poultry: nesting, wing stretching/flapping, foraging, dust-bathing, perching and preening.

*Note: animals whose management system requires outdoor tethering to make use of grazing can still be managed in compliance with these requirements.*

**5.4.1.4** Herd animals shall not be kept in isolation from other animals of the same species. This provision does not apply to small herds for mostly self-sufficient production. Operators may isolate male animals, sick animals and those about to give birth.

**5.4.1.5** Construction materials and methods and production equipment that might significantly harm human or animal health shall not be used.

**5.4.1.6** Operators shall manage pests and diseases in livestock housing and shall use the following methods according to these priorities:

**a.** preventative methods such as disruption, elimination of habitat and access to facilities;

**b.** mechanical, physical and biological methods.

**c.** substances (other than pesticides) used in traps.

**d**. substances listed in Appendix 5 of this standard;

**e.** other substances only when required by law for the control of notifiable diseases.

**5.4.1.7** When animals are housed, the operator shall ensure that:

**a.** where animals require bedding, adequate natural materials are provided. Bedding materials that are normally consumed by the animals shall be organic.

**b.** building construction provides for insulation, heating, cooling and ventilation of the building, ensuring that air circulation, dust levels, temperature, relative air humidity, and gas concentrations are within levels that are not harmful to the livestock.

**c.** no animals shall be kept in closed cages.

**d.** animals are protected from predation by wild and feral animals.

**e.** the above animal welfare requirements are fulfilled.

**f.** animals are regularly visited and monitored.

**g.** when welfare and health problems occur, appropriate management adjustments are implemented (e.g. reducing stocking density).

**5.4.1.8** All animals shall have unrestricted and daily access to pasture or a soil-based open-air exercise area or run, with vegetation, whenever the physiological condition of the animal, the weather and the state of the ground permit. Such areas may be partially covered. Animals may temporarily be kept indoors because of inclement weather, health condition, reproduction, specific handling requirements or at night. Lactation shall not be considered a valid condition for keeping animals indoors.

**5.4.1.9** The maximum hours of artificial light used to prolong natural day length shall not exceed a maximum that respects the natural behavior, geographical conditions and general health of the animals. For laying hens, a minimum daily rest period of 8 continuous hours without artificial light shall be respected.

#### 5.4.2 Animal Origin and Conversion Period

**General Principle**

Organic animals are born and raised on organic holdings. Animal husbandry systems that change from conventional to organic production require a conversion period.

**Requirements:**

**5.4.2.1** All the requirements of this standard for land and animals must be met for the duration of the conversion period before the resulting product may be considered as organic. Land and animals may be converted simultaneously.

**5.4.2.2.** Offspring may be considered organic only if their mother has been organically managed throughout the pregnancy.

Milk may be considered organic only if the dairy animal has been organically managed throughout the pregnancy preceding lactation.

Eggs may be considered organic only if the poultry has been organically managed from 2 days old.

**5.4.2.3** Animals for meat shall be raised organically from birth, except for poultry where 2 day old conventional poultry may be brought in when organic poultry is not available.

**5.4.2.4** Breeding stock may be brought in from conventional farms to a yearly maximum of 10% of the adult animals of the same species on the farm. Non-organic female breeding replacements must be nulliparous.

*Exceptions of more than 10% may be made, limited to the following circumstances:*

*a. unforeseen severe natural or man-made events;*

*b. considerable enlargement of the farm;*

*c. establishment of a new type of animal production on the farm;*

*d. holdings with less than 10 animals.*

#### 5.4.3 Breeds and Breeding

**General Principle**

Breeds are adapted to local conditions.

**Requirements:**

**5.4.3.1** Breeding systems shall be based on breeds that can reproduce successfully under natural conditions without human involvement.

**5.4.3.2** Artificial insemination is permitted.

**5.4.3.3** Embryo transfer techniques and cloning are prohibited.

**5.4.3.4** Hormones are prohibited to induce ovulation and birth unless applied to individual animals for medical reasons and under veterinary supervision.

#### 5.4.4 Mutilations

**General Principle**

Organic farming respects the animal’s distinctive characteristics.

**Requirements:**

**5.4.4.1** Mutilations are prohibited, with the following exceptions and only if animal suffering is minimized and anesthetics are used where appropriate:

*a. castrations;*

*b. tail docking of lambs;*

*c. dehorning;*

*d. ringing, except for pigs;*

#### 5.4.5 Animal Nutrition

**General Principle**

Organic animals receive their nutritional needs from organic forage and feed of good quality.

**Requirements:**

**5.4.5.1** Animals shall be fed organic feed.

Operators may feed a limited percentage of non-organic feed under specific conditions in the following cases:

a. organic feed is of inadequate quantity or quality;

b. areas where organic agriculture is in early stages of development;

c. grazing of non-organic grass or vegetation during seasonal migration.

In no such case may the percentage of non-organic feed exceed 30% dry matter per animal calculated on an annual basis.

Operators may feed a higher percentage of non-organic feed for a limited time under specific conditions, following extreme and exceptional weather conditions or manmade or natural disasters beyond the control of the operator.

**5.4.5.2** Animals shall be offered a balanced diet that provides all of the nutritional needs of the animals in a form allowing them to exhibit their natural feeding and digestive behavior.

**5.4.5.3** More than 50% of the feed shall come from the farm unit itself, surrounding natural grazing areas, or be produced in co-operation with other organic farms in the region. However, the conformity assessment body may grant an exception to this in regions where organic feed production is in an early stage of development or temporarily deficient, or in cases of unpredictably low crop production on the farm or in the region.

**5.4.5.4** For the calculation of feeding allowances only, feed produced on the farm unit during the first year of organic management may be classed as organic. This refers only to feed for animals that are being produced within the farm unit. Such feed may not be sold or otherwise marketed as organic.

**5.4.5.5** The following substances are prohibited in the diet:

**a.** farm animal byproducts (e.g. abattoir waste) to ruminants;

**b.** slaughter products of the same species;

**c.** all types of excrements including droppings, dung or other manure;

**d.** feed subjected to solvent extraction (e.g. hexane) or the addition of other chemical agents;

**e.** synthetic amino-acids andamino-acid isolates;

**f.** urea and other synthetic nitrogen compounds;

**g.** synthetic growth promoters or stimulants;

**h.** synthetic appetizers;

**i.** preservatives, except when used as a processing aid;

**j.** artificial coloring agents.

**5.4.5.6** Animals may be fed vitamins, trace elements and supplements from natural sources whenever available. Synthetic vitamins, minerals and supplements may only be used when natural sources are not available in sufficient quantity and quality, after prior approval from the conformity assessment body.

**5.4.5.7** All ruminants shall have daily access to roughage. Ruminants must be grazed throughout the entire grazing season(s).

**5.4.5.8** Fodder preservatives such as the following may be used:

**a.** bacteria, fungi and enzymes;

**b.** natural products of food industry;

**c.** plant based products.

**d.** vitamins and minerals subject to the order of preference in 5.4.5.6.

**e.** synthetic chemical fodder preservatives such as acetic, formic and propionic acid, only in severe weather conditions and after prior approval of the conformity assessment body.

**5.4.5.9** Young stock from mammals shall be provided maternal milk or organic milk from their own species and shall be weaned only after a minimum period as specified below:

1. Calves and foals: 3 months
2. Piglets: 6 weeks
3. Lambs and kids: 7 weeks

#### 5.4.6 Veterinary Medicine

**General Principle**

Organic management practices promote and maintain the health and well-being of animals through balanced organic nutrition, stress-free living conditions and breed selection for resistance to diseases, parasites and infections.

**Requirements:**

**5.4.6.1** The operator shall take all practical measures to ensure the health and well being of the animals through preventative animal husbandry practices such as:

**a.** selection of appropriate breeds or strains of animals;

**b.** adoption of animal husbandry practices appropriate to the requirements of each species, such as regular exercise and access to pasture and/or open-air runs, to encourage the natural immunological defense of animal to stimulate natural immunity and tolerance to diseases;

**c.** provision of good quality organic feed;

**d.** appropriate stocking densities;

**e.** grazing rotation and management.

**5.4.6.2** If an animal becomes sick or injured despite preventative measures, that animal shall be treated promptly and adequately, if necessary in isolation and in suitable housing. Operators shall give preference to natural medicines and treatments, including homeopathy, Ayurvedic medicine and acupuncture.

**5.4.6.3** Use of synthetic allopathic veterinary drugs or antibiotics will normally cause the animal to lose its organic status. Producers shall not withhold such medication where doing so will result in unnecessary suffering of the livestock.

The animal may retain its organic status only if:

a. the operator can demonstrate compliance with 5.4.6.1, and

b natural and alternative medicines and treatments are unlikely to be effective to cure sickness or injury, or are not available to the operator, and

c. the chemically synthetized allopathic veterinary medical products or antibiotics are used under the supervision of a veterinarian, and

d. withdrawal periods shall be not less than double of that required by legislation, or a minimum of 14 days, whichever is longer.

e. this is granted for a maximum of three courses of remedial treatments with chemically synthesized allopathic veterinary medicinal products or antibiotics within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

**5.4.6.4** Prophylactic use of any synthetic allopathic veterinary drug is prohibited.

**5.4.6.5** Substances of synthetic origin used to stimulate production or suppress natural growth are prohibited.

**5.4.6.6** Vaccinations are allowed only in the following cases:

**a.** when an endemic disease is known or expected to be a problem in the region of the farm and where this disease cannot be controlled by other management techniques, or

**b.** when a vaccination is legally required.

#### 5.4.7 Transport and Slaughter

**General Principle**

Organic animals are subjected to minimum stress during transport and slaughter.

**Requirements:**

**5.4.7.1** Animals shall be handled calmly and gently during transport and slaughter.

**5.4.7.2** The use of electric prods and other such instruments is prohibited.

**5.4.7.3** Organic animals shall be provided with conditions during transportation and slaughter that reduce and minimize the adverse effects of: stress, loading and unloading, mixing different groups of animals, extreme temperatures and relative humidity. The type of transport shall meet the specific needs of the species being transported.

**5.4.7.4** The operator shall ensure an adequate food and water supply during transport and at the slaughterhouse.

**5.4.7.5** Animals shall not be treated with synthetic tranquilizers or stimulants prior to or during transport.

**5.4.7.6** Each animal or group of animals shall be identifiable at each step in the transport and slaughter process.

**5.4.7.7** Slaughterhouse journey times shall not exceed eight hours.

**5.4.7.8** Those responsible for transportation and slaughtering shall avoid contact (sight, sound or smell) of each live animal with dead animals or animals in the killing process.

**5.4.7.9** Each animal shall be effectively stunned before being bled to death. The equipment used for stunning shall be in good working order. Exceptions can be made according to religious practice. Where animals are bled without prior stunning this should take place in a calm environment. Slaughter techniques must prioritize animal welfare and aim to eliminate any stress, pain, or suffering endured by the animal.

#### 5.4.8 Bee Keeping

**General Principle**

Bee keeping is an important activity that contributes to enhancement of the agriculture andforestry production through the pollinating action of bees.

**Requirements:**

**5.4.8.1** The areas within a 3 km radius of the hives shall consist of organically managed fields, uncultivated land and/or wild natural areas in a way that ensures access to sources of honeydew, nectar and pollen that meets organic crop production requirements sufficient to supply all of the bees’ nutritional needs.

**5.4.8.2** The operator shall not place hives within a foraging distance (5 kms) of fields or other areas with a high contamination risk (e.g. conventional fields, industrial zones and highways).

**5.4.8.3** The hives shall consist primarily of natural materials and present no risk of contamination to the environment or the bee products. Use of construction materials with potentially toxic effects is prohibited.

**5.4.8.4** At the end of the production season, hives shall be left with reserves of honey and pollen sufficient for the colony to survive the dormancy period. Any supplementary feeding in response to unexpected need shall be carried out only between the last honey harvest and the start of the next nectar or honeydew flow period. In such cases, organic honey or organic sugar shall be used.

**5.4.8.5** Bee colonies may be converted to organic production. Introduced bees shall come from organic production units when available. Bee products may be sold as organically produced when the requirements of this standard have been complied with for at least one year.

**5.4.8.6** During the conversion period, the wax shall be replaced by organically produced wax, except where no prohibited products have been previously used in the hive and where is no risk of contamination of wax. In cases where all the wax cannot be replaced during a one-year period, the conversion period shall be extended to cover the full replacement of the wax.

**5.4.8.7** For pest and disease control the following are permitted:

**a.** lactic acid, formic acid;

**b.** oxalic acid, acetic acid;

**c.** sulfur;

**d.** natural essential oils (e.g. menthol, eucalyptol, camphor);

**e.** *Bacillus thuringiensis*;

**f.** steam, direct flame and caustic soda for hive disinfection.

**5.4.8.8** Where preventative measures fail, veterinary medicinal products may be used provided the following are adhered to:

**a.** preference is given to phyto-therapeutic and homeopathic treatment;

**b.** if allopathic chemically synthesized medicinal products are used, the bee products shall not be sold as organic;

**c.** treated hives shall be placed in isolation and undergo a conversion period of one year.

**5.4.8.9** The practice of destroying the male brood is permitted only to contain infestation with *Varroa* (mites).

**5.4.8.10** The health and welfare of the hive shall be primarily achieved by hygiene and hive management.

**5.4.8.11** The destruction of bees in the combs as a method of harvesting of bee products is prohibited.

**5.4.8.12** Mutilations, such as clipping of the wings of queen bees, are prohibited.

**5.4.8.13** Artificial insemination of queen bees is permitted.

**5.4.8.14** The use of chemical synthetic bee repellents is prohibited. The use of smoke should be kept to a minimum. Acceptable smoking materials should be natural or from materials that meet the requirements of these standards.

**5.4.8.15** Honey temperatures shall be maintained as low as possible, and not exceed 45°C, during the extraction and processing of products derived from bee keeping.

### 5.5. PROCESSING AND HANDLING

#### 5.5.1 General

**General Principle**

Organic processing and handling provides consumers with nutritious, high quality supplies of organic products, and organic farmers with a market without compromise to the organic integrity of their products.

**Requirements:**

**5.5.1.1** Handlers and processors shall not co-mingle organic products with non-organic products.

**5.5.1.2** Handlers and processers shall ensure traceability in the organic processing and handling chain.

**5.5.1.3** All organic products shall be clearly identified as such and processed, stored and transported in a way that prevents substitution by or contact with conventional products through the entire process.

**5.5.1.4** When non-organic products are prepared or stored in the preparation unit, the operator shall inform the conformity assessment body.

**5.5.1.5** The handler or processor shall take all necessary measures to prevent organic products from being contaminated by pollutants and contaminants, including the cleaning, decontamination, or if necessary disinfection of facilities and equipment.

**5.5.1.6** The handler or processor shall identify and minimize risks of environmental pollution resulting from their activity.

**5.5.1.7** Processors shall respect the principles of good manufacturing practices. This shall include maintaining appropriate procedures based on identification of critical processing steps.

#### 5.5.2 Ingredients

**General Principle**

Organic processed products are made from organic ingredients.

**Requirements:**

**5.5.2.1** All ingredients used in an organic processed product shall be organically produced whenever available, except for those additives and processing aids that appear in Appendix 4.

In cases where an ingredient of organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic raw materials, provided that:

a. they are not genetically engineered or contain nanomaterials , and

b. prior permission from the conformity assessment body is obtained.

c. the requirements in section 5.6.1.3 shall be met.

**5.5.2.2** Using organic and non-organic forms of the same ingredient in a single product is prohibited.

**5.5.2.3** Water and salt may be used as ingredients in the production of organic products and are not included in the percentage calculations of organic ingredients.

**5.5.2.4** Minerals (including trace elements), vitamins and similar isolated ingredients shall not be used unless their use is legally required.

**5.5.2.5** Preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products. Cultures that are prepared or multiplied in-house shall comply with the requirements for the organic production of microorganisms.

**5.5.2.6** For the production of organic micro-organisms for processed food and feed, only organically produced substrate shall be used.

#### 5.5.3 Processing Methods

**General Principle**

Organic processing and handling provides the consumer with high quality supplies of organic products without compromise to the integrity of the products and protects the environment.

**Requirements:**

**5.5.3.1** Techniques used to process organic products shall be biological, physical, and mechanical in nature. Any additives, processing aids, or other material that reacts chemically with organic products or modifies it must be organically produced or appear in Appendix 4 Table 1 and shall be used in accordance with noted restrictions.

**5.5.3.2** Substances and techniques shall not be used that:

**a.** reconstitute properties lost by the processing and storage of organic products;

1. conceal negligent processing;

**c.** or may otherwise be misleading as to the true nature of these products.

 Water may be used for re-hydration or reconstitution.

**5.5.3.3** Solvents used to extract organic products shall be either organically produced or food grade substances that appear on Appendix 4, Table 1 consistent with the annotation.

**5.5.3.4** Irradiation is not permitted for any ingredient or the final product.

**5.5.3.5** Filtration equipment shall not contain asbestos, or utilize techniques or substances that may contaminate the product. Filtration agents and adjuvants are considered processing aids and therefore must appear in Appendix 4.

**5.5.3.6** The following conditions of storage are permitted (for allowed substances in these conditions, see Appendix 4):

**a.** controlled atmosphere;

**b.** temperature control;

**c.** drying;

**d.** humidity regulation.

**5.5.3.7** Intentional manufacture or use of nanomaterials in organic products is prohibited.

**5.5.3.8** Equipment surfaces and utensils that might come into contact with organic products shall be free of nanomaterials, unless there is verified absence of contamination risk.

#### 5.5.4 Pest and Disease Control

**General Principle**

Organic products are protected from pests and diseases by the use of good manufacturing practices that include proper cleaning, sanitation and hygiene, without the use of chemical pest control treatments or irradiation.

**Requirements:**

**5.5.4.1** Handlers and processors shall manage pests and shall use the following methods according to these priorities:

**a.** preventative methods such as disruption, elimination of habitat and access to facilities;

**b.** mechanical, physical and biological methods, including visual detection, sound, ultra-sound, light and UV-light, temperature control, controlled atmosphere and diatomaceous earth.

**c.** substances according to the Appendices of this standard;

**d.** substances (other than pesticides) used in traps.

**5.5.4.2** Prohibited pest control practices include, but are not limited to, the following substances and methods:

**a.** pesticides not contained in Appendix 3;

**b.** fumigation with ethylene oxide, methyl bromide, aluminum phosphide or other substance not contained in Appendix 4;

**c.**  ionizing radiation.

**5.5.4.3** The direct use or application of a prohibited method or material renders that product no longer organic. The operator shall take necessary precautions to prevent contamination, including the removal of organic products and related packaging materials from the storage or processing facility, and measures to decontaminate the equipment or facilities. Application of prohibited substances to equipment or facilities shall not contaminate organic product handled or processed therein. Application of prohibited substances to equipment or facilities shall not compromise the organic integrity of product handled or processed therein and shall be documented to attest this.

#### 5.5.5 Packaging

**General Principle**

Organic product packaging has minimal adverse impacts on the product and on the

environment.

**Requirements:**

**5.5.5.1** Operators shall not use packaging material that may contaminate organic products. This includes reused bags or containers that have been in contact with any substance likely to compromise the organic integrity. Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, fumigant, or nanomaterials are prohibited.

**5.5.5.2** Operators shall demonstrate efforts to minimize packaging and/or choose packaging materials with minimum environmental impact. The total environmental impact of production, use and disposal of packaging must be considered.

#### 5.5.6 Cleaning, Disinfecting, and Sanitizing of Processing Facilities

**General Principle**

Organic products are safe, of high quality, and free of substances used to clean, disinfect, and sanitize the processing facilities.

**Requirements:**

**5.5.6.1** Operators shall take all necessary precautions to protect organic products against contamination by substances prohibited in organic farming and handling, pests, disease-causing organisms, and foreign substances.

**5.5.6.2** Water and substances that appear in Appendix 4, Table 2, may be used as equipment cleansers and equipment disinfectants that may come into direct contact with the product.[[3]](#footnote-3)

**5.5.6.3** Operations that use other cleaners, sanitizers, and disinfectants on product contact surfaces shall use them in a way that does not contaminate the product. The operator shall perform an intervening event between the use of any cleaner, sanitizer, or disinfectant and the contact of organic product with that surface sufficient to prevent residual contamination of that organic product.

### 5.6. LABELING

#### 5.6.1 General

**General Principle**

Organic products are clearly and accurately labeled as organic.

**Requirements**

**5.6.1.1.** Products produced in accordance with this standard may be labeled as organic.

**5.6.1.2** Labels must identify the following:

a. the person or company legally responsible for the product

b. the body that assures conformity to the applicable organic standard.

**5.6.1.3** Processed products shall be labeled according to the following minimum requirements:

a. Where 95 to 100% of the ingredients (by weight) are organic, the product may be labeled as “organic”.

b. Where less than 95% but not less than 70% of the ingredients (by weight) are organic, these product cannot be labeled as “organic”, but phrases such as “made with organic ingredients” can be used, provided the proportion of organic ingredients is clearly stated.

c. Where less than 70% of the ingredients (by weight) are organic, the product cannot be labeled as “organic”, nor bear phrases such as “made with organic ingredients” on the package front, nor bear any certification body seal, national logo, or other identifying mark which represents organic certification of a product or product ingredients, but individual ingredients may be called “organic” in the ingredients list.

Notes on calculating percentages:

Water and salt are not included in the percentage calculations of organic ingredients.

**5.6.1.4** All ingredients of a multi-ingredient product shall be listed on the product label in order of their weight percentage. It shall be apparent which ingredients are of organic certified origin and which are not. All additives shall be listed with their full name. If herbs and/or spices constitute less than 2% of the total weight of the product, they may be listed as “spices” or “herbs” without stating the percentage.

**5.6.1.5** “In-conversion” ingredients may be used in multi-ingredient feed. However the ingredient list must identify their status and the total percentages of “in-conversion”, organic and non-organic ingredients on a dry matter basis.

**5.6.1.6** Multi-component products, live or unprocessed (such as vegetable boxes) may be sold or marketed as organic only if all the components are organic.

**5.6.1.7** The label for in-conversion products shall be clearly distinguishable from the label for organic products. Only single ingredient plant products may be labeled as “in-conversion”.

### 5.7. SOCIAL JUSTICE

**General Principle**

Social justice and social rights are an integral part of organic agriculture and processing. The fairness principle of organic agriculture emphasizes that those involved in organic agriculture should conduct human relationships in a manner that ensures fairness at all levels and to all parties involved.

**Requirements:**

**5.7.1.** Production that violates human rights and social justice requirements in this chapter cannot be declared organic.

**5.7.2** Operators shall not violate indigenous land rights.

**5.7.3** Operators shall not use forced or involuntary labor or apply any pressure such as retaining part of the workers’ wages, property or documents.

**5.7.4** 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.

**5.7.5** Operators shall provide their employees and contractors equal opportunity and treatment, and shall not act in a discriminatory way.

**5.7.6** 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.

**5.7.7** 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.

**5.7.8** 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.

**5.7.9** Operators shall not use child labor[[4]](#footnote-4), except that children are allowed to experience work on their family’s farm or business or a neighboring farm provided that:

a. such work is not dangerous or hazardous to their health and safety;

b. it does not jeopardize the child’s educational, moral, social, mental, spiritual and physical development;

c. children are supervised by adults or have authorization from a legal guardian*.*

**5.7.10** Operators shall provide written terms and conditions of employment to both permanent and temporary employees, in a language and presentation understandable to the worker. The terms and conditions must specify at least:

**-** wages;

- frequency and method of payment;

- location, type and hours of work;

- recognition of workers’ freedom of association;

- disciplinary procedure;

- health and safety procedure;

- eligibility and terms of overtime, holiday pay, sickness benefit and other benefits such as maternity and paternity leave; and

- worker’s right to terminate employment.

Operators shall ensure that the workers understand the terms of their employment contract. Operators shall respect the terms of the contract in good faith, including timely payment of wages.

*Exception: in cases where:*

*- the operator has less than 10 employees over the course of the year, or*

*- the operator is unable to write, or*

*- workers are hired for periods of less than 6 days, or*

*- emergency labor is needed to address unpredictable problems*

*oral mutual agreements on the terms and conditions of employment are sufficient.*

**5.7.11** Operators shall ensure adequate access to potable water.

**5.7.12** 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.

**5.7.13** 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.

**5.7.14** 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.

**5.7.15** Requirements in this section apply equally to all workers on the operation regardless of how they are employed[[5]](#footnote-5), except for subcontractors performing non-production core business functions such as plumbing, machine repair, or electrical work.

# Article VI: National Conformity assessment rules

6.1 Operators in \_\_\_Country X shall be certified to the National Organic Standard or an equivalent organic standard (as defined under 4.2.b) by either:

 a. A third party certification body registered with the \_\_competent authority and holding, for the scope of the relevant organic standard, a valid organic recognition or accreditation as elaborated in Article 6.2, or

 b. An approved Participatory Guarantee System, as elaborated in article 6.3.

6.2 Valid organic recognitions or accreditations include:

* 1. Approval by the \_\_\_\_competent authority of Country X, based on compliance of the certification body with the IFOAM Accreditation Requirements for Bodies Certifying Organic Production and Processing or a norm based on these requirements
	2. Official approval of the certification body or control authority under the EU organic regulation,
	3. USDA National Organic Program accreditation
	4. IFOAM Accreditation
	5. \_\_\_\_\_*Fill in here any other accreditations that you think should be recognized as a starting point. (Guidance: look at what accreditations CBs are already having for export markets and approve those as equivalent. Alternatively, you may use the phrase* “*e. Other accreditation programs and systems of approval / registration of organic certification bodies recognized by IFOAM-Organics International as equivalent to the IROCB– list available on https://www.ifoam.bio/sites/default/files/conformity\_systs\_list\_web.pdf”).*
	6. Other accreditations or recognitions as added to a public list maintained by the \_\_\_competent authority.

6.3 Participatory Guarantee Systems (PGS) may be approved if they comply with the PGS requirements as laid out in Appendix 7. Approved PGS are those that have received approval at the national level by the \_\_\_competent authority, following the procedure defined in Appendix 8.

* 1. Conformity assessment bodies certifying operators within \_\_\_country referred to in 6.1.a and 6.1.b shall implement the following actions:
1. Withdraw certification to any operator for which major non-compliances have been detected.
2. Inform the \_\_\_competent authority of all de-certification cases (and the reasons associated to it).
3. Act upon cases or suspected cases of fraud amongst their operators, and inform the competent authority accordingly.
4. Manage the use the national organic logo by their operators, in accordance to the national rules and guidelines related to the logo.
5. Provide data on certified operators, as requested by the \_\_\_competent authority.

# Article VII: National Committee on Organic Agriculture

* 1. The \_\_\_competent authority shall establish a National Committee on Organic Agriculture composed of representatives of at least the following stakeholders:
1. The\_\_\_competent authority
2. Organic producers
3. Organic traders or retailers
4. Organic sector support organizations (NGO, science and research, consultancies, etc.)
	1. The National Committee on Organic Agriculture shall take an active role in the following processes:
5. Consultation of national and international stakeholders in the preparation of amendments to this regulation and related documents.
6. Amendments to the present organic regulation, including development of the organic standard and modifications to the lists of substances in Appendix, in accordance with the criteria in Appendix 1.
7. Development of complementary regulations and guidelines.
8. Development and continuous adjustment of the Strategic National Organic Action Plan.
9. Liaising with international partners for external recognition of the national organic guarantee system (including the approval of the national standard into the IFOAM Family of Standards).

# Article VIII: Penalties for violation of this regulation

(Note: a section on penalties for violation of this regulation (fraud) has not been developed, but it is recommended that this aspect be developed in line with existing national regulations).

# APPENDIX 1: CRITERIA FOR THE EVALUATION OF INPUTS, ADDITIVES AND PROCESSING AIDS FOR ORGANIC PRODUCTION AND PROCESSING

**General Principles**

Organic production and processing systems are based on the use of natural, biological, renewable, and regenerative resources. Organic agriculture maintains soil fertility primarily through the recycling of organic matter. Nutrient availability is primarily dependent on the activity of soil organisms. Pests, diseases, and weeds are managed primarily through cultural practices. Organic livestock are nourished primarily through organically produced feed and forage, and are kept in living conditions that allow for natural behavior and avoidance of stress. Organic foods and other products are made from organically produced ingredients that are processed primarily by biological, mechanical, and physical means.

**Input Lists**

The following Appendices contain lists of the inputs, additives, processing aids, and other substances that are allowed for use in organic production, handling, and processing under this standard. These lists may be amended based on a review by the responsible Technical Committee, taking into account the below criteria for evaluation of inputs.

**Production Input Criteria**

Inputs used in organic production are consistent with the principles of organic farming outlined in the relevant chapters of this standard and are evaluated against criteria based upon the Precautionary Principle:

‘*When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.’*

*‘The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.’*

**The criteria used to evaluate organic production inputs are based on the following principles:**

**Necessity and alternatives:** Any input used is necessary for sustainable production, is essential to maintain the quantity and quality of the product, and is the best available technology.

**Source and manufacturing process:** Organic production is based on the use of natural, biological, and renewable resources.

**Environment:** Organic production and processing is sustainable for the environment. **Human health:** Organic techniques promote human health and food safety. Quality: Organic methods improve or maintain product quality.

**Social, Economic, and Ethical:** Inputs used in organic production meet consumer perceptions and expectations without resistance or opposition. Organic production is socially just and economically sustainable, and organic methods respect cultural diversity and protect animal welfare.

Dossiers for a given substance must address these criteria based on the data requirements and decision rules stated in the criteria below, and meet the criteria to be added to the Appendices.

**A) Crop and Livestock Criteria**

The following criteria are applied to inputs that are used to evaluate dossiers submitted for crop production.

***1. Necessity and Alternatives***

All dossiers shall document the necessity of the substance, its essential nature in organic production systems, and the availability of alternative methods, practices, and inputs.

1.1 The input is necessary to produce crops or livestock in sufficient quantity and of suitable quality; to cycle nutrients; to enhance biological activity; to provide a balanced animal diet; to protect crops and livestock from pests, parasites, and diseases; to regulate growth; and to maintain and improve soil quality.

1.2 A given substance shall be evaluated with reference to other available inputs or practices that may be used as alternatives to the substance.

1.3 Every input shall be evaluated in the context in which the product will be used (e.g. crop, volume, frequency of application, specific purpose).

***2. Source and Manufacturing Process***

All dossiers shall document sources and manufacturing processes.

2.1 Biological substances require a description of the source organism(s), a verifiable statement that they are not genetically engineered, and the processes required to breed, culture, produce, multiply, extract, or otherwise prepare the substance for use. Naturally occurring plants, animals, fungi, bacteria and other organisms are generally allowed. Substances that undergo physical transformations, such as by mechanical processing, or biological methods, like composting, fermentation, and enzymatic digestion are also generally allowed. Limitations and prohibitions may be set based on consideration of the other criteria. Substances that are modified by chemical reaction are considered synthetic and therefore subject to protocol 2.3 below.

2.2 Natural non-renewable resources—such as mined minerals—require a description of the deposit or occurrence in nature. Non-renewable resources are generally restricted or limited in their use. They may be used as a supplement to renewable biological resources, provided they are extracted by physical and mechanical means, and are not rendered synthetic by chemical reaction. Inputs with high levels of natural environmental contaminants, such as heavy metals, radioactive isotopes, and salinity, may be prohibited or further restricted.

2.3 Synthetic substances from non-renewable resources are generally prohibited. Synthetic, nature-identical products that are not available in sufficient quantities and qualities in their natural form may be allowed, provided that all other criteria are satisfied.

2.4 Inputs that are extracted, recovered, or manufactured by means that are environmentally destructive may be restricted or prohibited.

***3. Environment***

All dossiers shall document the substance’s environmental impact.

3.1 The environmental impact of a substance includes, but is not limited to, the following parameters: Acute toxicity, persistence, degradability, areas of concentration; biological, chemical, and physical interactions with the environment, including known synergistic effects with other inputs used in organic production.

3.2 Effect of substance on the agro-ecosystem, including soil health; the effects of the substance on soil organisms; soil fertility and structure; crops and livestock.

3.3 Substances with high salt indexes, measured toxicity to non-target organisms, and persistent adverse effects may be prohibited or restricted in their use.

3.4 Inputs used for crop production shall be considered for their impact on livestock and wildlife.

***4. Human Health***

All dossiers shall document the impacts of the substance on human health.

4.1 Documentation about human health includes, but is not limited to: acute and chronic toxicity, half-lives, degradants, and metabolites. Substances reported to have adverse effects may be prohibited or restricted in their use to reduce potential risks to human health.

4.2 Dossiers shall document any human who might be exposed by all possible pathways, at every stage: workers and farmers who extract, manufacture, apply, or otherwise use the substance; neighbors who may be exposed through its release into the environment; and consumers exposed by ingestion of food-borne residues.

***5. Quality***

All dossiers shall document the substance’s effect on product quality. Quality includes, but is not limited to, nutrition, flavor, taste, storage, and appearance of the raw product.

***6. Social, Economic, and Ethical Considerations***

All dossiers shall document the substance’s social, economic, and cultural implications.

6.1 Social and economic implications include, but are not limited to, the impact of the substance on the communities where they are made and used, whether the use of the substance favors any economic structure and scale, and the historical use of the substance in traditional foods.

6.2 Consumer perceptions of the compatibility of inputs shall be taken into account. Inputs should not meet resistance or opposition of consumers of organic products. An input might be reasonably considered by consumers to be incompatible with organic production in situations where there is scientific uncertainty about the impact of the substance on the environment or human health. Inputs should respect the general opinion of consumers about what is natural and organic.

6.3 Inputs used for animal feed and livestock production shall be evaluated for their impact on animal health, welfare, and behavior. Medications must either alleviate or prevent animal suffering. Animal inputs that cause suffering or have a negative influence on the natural behavior or physical functioning of animals kept at the farm may be prohibited or restricted.

**B) Processing and Handling Criteria**

***Introduction***

These criteria apply to the evaluation of additives and processing aids. Substances used for technical, sensory, and dietary purposes are subject to these criteria. The criteria may also apply to substances in contact with the product. For processing, an input, non-organic ingredient, additive, or processing aid shall be essential to maintain or improve human health, environmental safety, animal welfare, product quality, production efficiency, consumer acceptance, ecological protection, biodiversity, or landscape. Carriers and preservatives used in the preparation of additives and processing aids must also be taken into consideration. The following aspects and criteria should be used to evaluate additives and processing aids in organic products. All of the criteria below shall be fully and positively documented in a dossier and review for an input to be allowed in organic processing.

***1. Necessity and Alternatives***

All dossiers shall document the necessity of the additive, processing aid, or carrier, its essential nature in organic processing and for the proposed application, and the availability of alternative methods, practices, and inputs. Each substance shall be evaluated with respect to its specific uses and applications, and shall be added when it is demonstrated to be absolutely essential and necessary for the production of a specific product that is consistent with organic principles stated in this standard.

1.1. All dossiers shall take into consideration the technical feasibility of the following alternatives:

a) Whole products that are organically produced according to the standard.

b) Products that are organically produced and processed according to the standard.

c) Purified products of raw materials of non-agricultural origin, e.g. salt.

d) Purified products of raw materials of an agricultural origin that have not been organically produced and processed according to the standard but appear on Appendix 4.

1.2 If an ingredient is required to manufacture a processed product to independently established minimum technical specifications recognized by consumers, and no organic substitute is available, then a non-organic ingredient may be deemed essential.

1.3 A given additive, processing aid, or carrier shall be evaluated with reference to other available ingredients or techniques that may be used as alternatives to the substance.

1.4 A substance is considered essential if a processed product requires that substance in order to meet established standards of identity, governmental regulations, or widely accepted consumer expectations.

***2. Source and Manufacturing Process***

All dossiers shall document the substance’s sources and manufacturing processes.

2.1 Additives and processing aids from biological sources, such as fermentation cultures, enzymes, flavors, and gums must be derived from naturally occurring organisms by the use of biological, mechanical, and physical methods. Non-organic forms are allowed in organic products only if there are no organic sources.

2.2 Natural non-renewable resources — such as salt and mined minerals — must be obtained by physical and mechanical means, and are not rendered synthetic by chemical reaction. Dossiers must document and meet Food Chemical Codex specifications for natural contaminants, such as heavy metals, radioactive isotopes, and salinity, and may be prohibited or restricted based on unacceptable levels of contamination.

2.3 Synthetic nature-identical products that are not available in sufficient quantities and qualities in their natural form may be allowed provided all other criteria are satisfied.

2.4 Synthetic substances from non-renewable resources are generally prohibited as additives and processing aids.

***3. Environment***

All dossiers shall document the substance’s environmental impact.

Documentation for environmental impact: the release of any harmful waste stream or by-products from both manufacturing and use in processing. Additives and processing aids that result in toxic by-products or polluting waste may be restricted or prohibited. This includes persistence, degradation, and areas of concentration.

***4. Human Health***

All dossiers shall document the impacts of the substance on human health.

4.1 Documentation about human health includes, but is not limited to: acute and chronic toxicity, allergenicity, half-lives, degradants, and metabolites. Substances reported to have adverse effects may be prohibited or restricted in their use to reduce potential risks to human health.

4.2 Dossiers shall document any human who might be exposed by all possible pathways: workers and farmers who manufacture, apply, or otherwise use the substance; neighbors who may be exposed through release into the environment; and consumers exposed by ingestion of food-borne residues.

4.3 Dossiers can be submitted only for processing aids and additives evaluated by the Joint FAO/ WHO Expert Committee on Food Additives (JECFA) of the Codex Alimentarius.

a) A food additive shall have an Acceptable Daily Intake (ADI) level that is either ‘not specified’ or ‘not limited’ to qualify for use without limitation.

b) A food additive with any other status shall either be prohibited or have specific use restrictions to limit dietary exposure.

c) Evaluation of food additives shall also take into account known allergenicity and immunological responses.

4.4 Information about the practical daily intake of the substance by several groups of humans should be taken into account. It should be demonstrated that no group has a normal intake that is higher than the accepted ADI.

***5. Quality (in processed products)***

5.1 All dossiers shall document the substance’s effect on overall product quality, including, but not limited to, nutrition, flavor, taste, storage, and appearance.

5.2 Additives and processing aids shall not detract from the nutritional quality of the product.

5.3 A substance shall not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law.

5.4 Non-organic ingredients, additives, or processing aids used to process organic products shall not compromise the authenticity or overall quality of the product or deceive the consumer of the product’s value.

5.5 Each additive shall be evaluated with respect to its specific uses and applications without preference for any specific techniques or equipment, and shall be added to the list only when it is demonstrated to be absolutely essential and necessary for the formulation and production of a specific product that is consistent with organic principles stated in this standard.

***6. Social, Economic, and Ethical Considerations***

6.1 All dossiers shall document the substance’s social, economic, and cultural, implications.

6.2 Social, economic, implications include, but are not limited to, adverse impacts on communities caused by the manufacture and use of the substance, whether certain economic structures or scales are favored by the use of the processing aid; and the historical use of the additive or processing aid in traditional products.

6.3 Consumer perceptions of the compatibility of additives and processing aids shall be taken into account. An input might be reasonably considered to be incompatible with organic production in situations where there is scientific uncertainty about the impact of the substance on the environment or human health. Inputs should respect the general opinion of consumers about what is natural and organic.

# APPENDIX 2: FERTILIZERS AND SOIL CONDITIONERS

|  |  |
| --- | --- |
| **SUBSTANCES DESCRIPTION, COMPOSITIONAL REQUIREMENTS** | **CONDITIONS FOR USE** |
|  |  |
| **I. PLANT AND ANIMAL ORIGIN** |  |
| Farmyard manure, slurry and urine | Shall not constitute the main source of nitrogen in the absence of complimentary and additional nitrogen generating practices on farm and shall not be from conventional intensive livestock production systems without prior permission from the conformity assessment body |
| Guano |  |
| Source separated human excrement  | Only in compliance with requirement 5.4.4.5. |
| Vermicastings |  |
| Blood meal, meat meal, bone, bone meal |  |
| Hoof and horn meal, feather meal, fish and shell products, wool, hide, fur, hair, dairy products |  |
| Biodegradable processing by-products, plant or animal origin, e.g. by-products of food, feed, oilseed, brewery, distillery or textile processing | Free of significant contaminants; or composted before bringing onto organic land and confirmed free of significant contaminants |
| Crop residues and plant materials, mulch, green manure, straw |   |
| Wood, bark, sawdust, wood shavings, wood ash, wood charcoal |  Only if not chemically treated  |
| Seaweed and seaweed products | As far as obtained by: (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or potassium hydroxide solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation.  |
| Peat (prohibited for soil conditioning) | Excluding synthetic additives; permitted only in horticulture (floriculture, nursery plants, potting mixes). |
| Plant preparations and extracts |  |
| Compost made from ingredients listed in this appendix, |  |
| spent mushroom waste, humus from worms and insects, |  |
| urban composts and household wastes from separated sources which are monitored for contamination |  |
|  |  |
| **II. MINERAL ORIGIN** |  |
|  |  |
| **Calcareous and magnesium amendments:** |  |
| Limestone, gypsum, marl, maerl, chalk, sugar beet lime, |  |
| calcium chloride, |  |
| Magnesium rock, kieserite and Epsom salt (magnesium |  |
| sulfate) |  |
| Other non-synthetic calcareous and magnesium amendments  |  |
|  |  |
| Clay (e.g. bentonite, perlite, vermiculite, zeolite) |  |
| Mineral potassium (e.g. sulfate of potash, muriate of potash, kainite, sylvanite, patenkali) | Shall be obtained by physical procedures but not enriched by chemical processes |
| Phosphates in non-synthetic form (e.g. rock phosphate, colloidal phosphate, apatite) | Cadmium content less than or equal to 90 mg/kg of P2O5 |
| Pulverized rock, stone meal, crushed stone. |  |
| Sodium chloride |  |
| Sulfur |  |
| Trace elements, e.g.:boric acid, sodiumborate, calciumborate, borethanolamin,cobalt-acetate, cobalt-sulphate,copper oxide, copper sulfate, copper hydroxide, copper silicate, copper carbonate, copper citrateferric oxide, ferric sulfate, ferrous sulfate, iron citrate, iron sulfate, or iron tartratemanganous oxide, manganese sulfate and manganese carbonateselenic acid, selenous acid,sodiummolybdate, molybdic oxidezinc carbonate, zinc oxide, zinc silicate, and zinc sulfate | Use restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert.Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant. |
|  |  |
| **III. MICROBIOLOGICAL** |  |
| Biodegradable processing by-products of microbial origin, |  |
| e.g. by-products of brewery or distillery processing |  |
| Microbiological preparations based on naturally occurring organisms |  |
|  |  |
| **IV. OTHERS** |  |
| Biodynamic preparations |  |
| Calcium lignosulfonate |  |

# APPENDIX 3: CROP PROTECTANTS AND GROWTH REGULATORS

|  |  |
| --- | --- |
| **SUBSTANCES DESCRIPTION, COMPOSITIONAL REQUIREMENTS** | **CONDITIONS FOR USE** |
|  |  |
| **I. PLANT AND ANIMAL ORIGIN** |  |
| Algal preparations | As far as obtained by: (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or potassium hydroxide solutions, provided that the minimum amount of solvent necessary is used for extraction; (iii) fermentation. |
| Animal preparations and oils |  |
| Beeswax |  |
| Chitin nematicides (natural origin) | Not processed by acid hydrolysis |
| Coffee grounds |  |
| Corn gluten meal  |  |
| Dairy products (e.g. milk, casein) |  |
| Gelatin |  |
| Lecithin |  |
| Natural acids (e.g. vinegar) |  |
| Neem (Azadirachta indica) |  |
| Plant oils |  |
| Plant preparations |  |
| Plant based repellents |  |
| Propolis |  |
| Pyrethrum (Chrysanthemum cinerariaefolium) | The synergist Piperonyl butoxide is prohibited.  |
| Quassia (Quassia amara) |  |
| Rotenone (Derris elliptica, Lonchocarpus spp. Tephrosia spp.) | Not near waterways. Subject to approval by the CB |
| Ryania (Ryania speciosa) |  |
| Sabadilla |  |
|  |  |
| **II. MINERAL ORIGIN** |  |
| Chloride of lime (calcium chloride) |  |
| Clay (e.g. bentonite, perlite, vermiculite, zeolite) |  |
| Copper salts (e.g. sulfate, hydroxide, oxychloride, octanoate | Max 6 kg Cu/ha per year (on a rolling average basis) |
| Diatomaceous earth |  |
| Light mineral oils (paraffin) |  |
| Lime sulfur (Calcium polysulfide) |  |
| Potassium bicarbonate |  |
| Calcium hydroxide (hydrated lime) |  For application on aerial plant parts only |
| Silicates (e.g. sodium silicates, quartz) |  |
| Sodium bicarbonate |  |
| Sulfur |  |
|  |  |
| **III. MICROORGANISMS** |  |
| Fungal preparations (e.g. spinosad) |  |
| Bacterial preparations (e.g. Bacillus thuringiensis) |  |
| Release of parasites, predators and sterilized insects |  |
| Viral preparations (e.g. granulosis virus) |  |
|  |  |
| **IV. OTHERS** |  |
| Biodynamic preparations |  |
| Carbon dioxide | Shall not be the result of burning fuel solely to produce carbon dioxide; allowed only as a by-product of other processes. |
| Ethyl alcohol |  |
| Homeopathic and Ayurvedic preparations |  |
| Iron phosphates (for use as molluscicide) |  |
| Seasalt and salty water |  |
| Soft soap |  |
|  |  |
| **V. TRAPS, BARRIERS, REPELLENTS** |  |
| Physical methods (e.g. chromatic traps, mechanical traps) |  |
| Mulches, nets |  |
| Pheromones – in traps and dispensers only |  |

# APPENDIX 4 – TABLE 1: LIST OF APPROVED ADDITIVES[[6]](#footnote-6) AND PROCESSING / POST-HARVEST HANDLING AIDS

Substances of certified organic origin must be used if commercially available. If organic sources are not available, natural sources must be used if commercially available. Only if organic and natural sources are not available, synthetic forms of the substances below may be used.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **INT’L****NUMBERING SYSTEM** | **PRODUCT** | **ADDITIVE** | **PROC. & Post Har. Han.****AID** | **LIMITATION/ NOTE** |
| INS 170 | Calcium carbonate | X | X | Not for coloring |
| INS 184 | Tannic acid |  | X | Filtration aid for wine |
| INS 220 | Sulfur dioxide | X |  | Only for wine |
| INS 224 | Potassium metabisulphite | X |  | Only for wine |
| INS 270 | Lactic acid | X | X |  |
| INS 290 | Carbon dioxide | X | X |  |
| INS 296 | L-malic acid | X | X |  |
| INS 300 | Ascorbic acid | X |  |  |
| INS 306 | Tocopherols, mixed natural concentrates | X |  |  |
| INS 322 | Lecithin | X | X | Obtained without bleaches |
| INS 330 | Citric acid | X | X |  |
| INS 331 | Sodium citrates | X |  |  |
| INS 332 | Potassium citrates | X |  |  |
| INS 333 | Calcium citrates | X |  |  |
| INS 334 | Tartaric acid | X | X | Only for wine |
| INS 335 | Sodium tartrate | X | X |  |
| INS 336 | Potassium tartrate | X | X |  |
| INS 341 | Mono calcium phosphate | X |  | Only for “raising flour” |
| INS 342 | Ammonium phosphate | X |  | Restricted to 0.3 gm/l in wine |
| INS 400 | Alginic acid | X |  |  |
| INS 401 | Sodium alginate | X |  |  |
| INS 402 | Potassium alginate | X |  |  |
| INS 406 | Agar | X |  |  |
| INS 407 | Carrageenan | X |  |  |
| INS 410 | Locust bean gum | X |  |  |
| INS 412 | Guar gum | X |  |  |
| INS 413 | Tragacanth gum | X |  |  |
| INS 414 | Arabic gum | X |  |  |
| INS 415 | Xanthan gum | X |  |  |
| INS 428 | Gelatin |  | X |  |
| INS 440 | Pectin | X |  | Unmodified |
| INS 500 | Sodium carbonates | X | X |  |
| INS 501 | Potassium carbonates | X | X |  |
| INS 503 | Ammonium carbonates | X |  | Only for cereal products, confectionery, cakes and biscuits |
| INS 504 | Magnesium carbonates | X |  |  |
| INS 508 | Potassium chloride | X |  |  |
| INS 509 | Calcium chloride | X | X |  |
| INS 511 | Magnesium chloride | X | X | Only for soybean products |
| INS 513 | Sulfuric acid | X | X | As processing aid for pH adjustment of water during sugar processing.As additive for wine and apple cider production |
| INS 516 | Calcium sulfate | X |  | For soybean products, confectionery and in bakers’ yeast |
| INS 517 | Ammonium sulfate | X |  | Only for wine, restricted to 0.3 mg/l |
| INS 524 | Sodium hydroxide | X | X | For sugar processing and for the surface treatment of traditional bakery products |
| INS 526 | Calcium hydroxide | X | X | Food additive for maize tortilla flourProcessing aid for sugar |
| INS 551 | Silicon dioxide (amorphous) |  | X |  |
| INS 553 | Talc |  | X |  |
| INS 558 | Bentonite |  | X | Only for fruit and vegetable products |
| INS 901 | Beeswax |  | X |  |
| INS 903 | Carnauba wax |  | X |  |
| INS 938 | Argon | X |  |  |
| INS 941 | Nitrogen | X | X |  |
| INS 948 | Oxygen | X | X |  |
|  | Ethylene |  | X | De-greening of citrus and ripening |
|  | Activated carbon |  | X |  |
|  | Casein |  | X | Only for wine |
|  | Cellulose |  | X |  |
|  | Diatomaceous earth |  | X |  |
|  | Ethanol |  | X |  |
|  | Isinglass |  | X | Only for wine |
|  | Kaolin |  | X |  |
|  | Perlite |  | X |  |
|  | Plant and animal oils |  | X | For extraction only |
|  | Preparations of bark |  | X | Only for sugar |

**Flavoring Agents**

**Operators may use:**

• organic flavoring extracts (including volatile oils), and, if not available,

• natural flavoring preparations approved by the conformity assessment body. Such approval shall include assessment that natural flavors shall meet the following criteria:

* the sources are plant, animal or mineral;
* the process of production is in accordance with a recognized organic standard;
* they are produced by means of solvents such as vegetal oils, water, ethanol, carbon dioxide and mechanical and physical processes.

**Preparations of Micro-organisms and Enzymes for use in food processing (see 5.6.2.5)**

These may be used as ingredient or processing aids with approval from the conformity assessment body:

• Organic certified micro-organisms

• Preparations of micro-organisms

• Enzymes and enzyme preparations

# APPENDIX 4 – TABLE 2: INDICATIVE LIST OF EQUIPMENT CLEANSERS AND EQUIPMENT DISINFECTANTS

|  |  |
| --- | --- |
| **PRODUCT** | **LIMITATION/NOTE** |
|  |  |
| Acetic acid |  |
| Alcohol, ethyl (ethanol) |  |
| Alcohol, isopropyl (isopropanol) |  |
| Calcium hydroxide (slaked lime) |  |
| Calcium hypochlorite | An intervening event or action must occur to eliminate risks of contamination |
| Calcium oxide (quicklime) |  |
| Chloride of lime (calcium oxychloride, calcium chloride, and calcium hydroxide) |  |
| Chlorine dioxide | An intervening event or action must occur to eliminate risks of contamination |
| Citric acid |  |
| Formic acid |  |
| Hydrogen peroxide |  |
| Lactic acid |  |
| Natural essences of plants |  |
| Oxalic acid |  |
| Ozone |  |
| Peracetic acid |  |
| Phosphoric acid | Only for dairy equipment |
| Plant extracts |  |
| Potassium soap | An intervening event or action must occur to eliminate risks of contamination |
| Sodium carbonate |  |
| Sodium hydroxide (caustic soda) | An intervening event or action must occur to eliminate risks of contamination |
| Sodium hypochlorite | An intervening event or action must occur to eliminate risks of contamination |
| Sodium soap | An intervening event or action must occur to eliminate risks of contamination |

# APPENDIX 5: SUBSTANCES FOR PEST AND DISEASE CONTROL AND DISINFECTION IN LIVESTOCK HOUSING AND EQUIPMENT

|  |
| --- |
| **PRODUCT** |
| Alkali carbonates |
| Calcium oxide (lime, quicklime) |
| Caustic potash (potassium hydroxide) |
| Caustic soda (sodium hydroxide) |
| Citric, peracetic acid, formic, lactic, oxalic and acetic acid |
| Cleaning and disinfection products for teats and milking facilities |
| Ethanol and isopropanol |
| Hydrogen peroxide |
| Iodine |
| Milk of lime (=slack lime, cal, pickinglime, hydrated lime, slaked lime) = calcium hydroxide |
| Natural essences of plants |
| Nitric acid (dairy equipment) |
| Phosphoric acid (dairy equipment) |
| Potassium and sodium soap |
| Sodium carbonate |
| Sodium hypochlorite (e.g. as liquid bleach) |
| Water and steam |

# APPENDIX 6: PRINCIPLES OF ORGANIC AGRICULTURE

**1. Principle of Health**

Organic Agriculture should sustain and enhance the health of soil, plant, animal, human and planet as one and indivisible.

This principle points out that the health of individuals and communities cannot be separated from the health of ecosystems - healthy soils produce healthy crops that foster the health of animals and people.

Health is the wholeness and integrity of living systems. It is not simply the absence of illness, but the maintenance of physical, mental, social and ecological well-being. Immunity, resilience and regeneration are key characteristics of health.

The role of Organic Agriculture, whether in farming, processing, distribution, or consumption, is to sustain and enhance the health of ecosystems and organisms from the smallest in the soil to human beings. In particular, organic agriculture is intended to produce high quality, nutritious food that contributes to preventive health care and well-being. In view of this it should avoid the use of fertilizers, pesticides, animal drugs and food additives that may have adverse health effects.

**2. Principle of Ecology**

Organic Agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them.

This principle roots Organic Agriculture within living ecological systems. It states that production is to be based on ecological processes, and recycling. Nourishment and well-being are achieved through the ecology of the specific production environment. For example, in the case of crops this is the living soil; for animals it is the farm ecosystem; for fish and marine organisms, the aquatic environment.

Organic farming, pastoral and wild harvest systems should fit the cycles and ecological balances in nature. These cycles are universal but their operation is site-specific. Organic management must be adapted to local conditions, ecology, culture and scale. Inputs should be reduced by reuse, recycling and efficient management of materials and energy in order to maintain and improve environmental quality and conserve resources.

Organic Agriculture should attain ecological balance through the design of farming systems, establishment of habitats and maintenance of genetic and agricultural diversity. Those who produce, process, trade, or consume organic products should protect and benefit the common environment including landscapes, climate, habitats, biodiversity, air and water.

**3. Principle of Fairness**

Organic Agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities

Fairness is characterized by equity, respect, justice and stewardship of the shared world, both among people and in their relations to other living beings.

This principle emphasizes that those involved in Organic Agriculture should conduct human relationships in a manner that ensures fairness at all levels and to all parties - farmers, workers, processors, distributors, traders and consumers. Organic Agriculture should provide everyone involved with a good quality of life, and contribute to food sovereignty and reduction of poverty. It aims to produce a sufficient supply of good quality food and other products.

This principle insists that animals should be provided with the conditions and opportunities of life that accord with their physiology, natural behavior and well-being.

Natural and environmental resources that are used for production and consumption should be managed in a way that is socially and ecologically just and should be held in trust for future generations. Fairness requires systems of production, distribution and trade that are open and equitable and account for real environmental and social costs.

**4. Principle of Care**

Organic Agriculture should be managed in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment.

Organic Agriculture is a living and dynamic system that responds to internal and external demands and conditions. Practitioners of Organic Agriculture can enhance efficiency and increase productivity, but this should not be at the risk of jeopardizing health and well-being. Consequently, new technologies need to be assessed and existing methods reviewed. Given the incomplete understanding of ecosystems and agriculture, care must be taken.

This principle states that precaution and responsibility are the key concerns in management, development and technology choices in Organic Agriculture. Science is necessary to ensure that Organic Agriculture is healthy, safe and ecologically sound. However, scientific knowledge alone is not sufficient. Practical experience, accumulated wisdom and traditional and indigenous knowledge offer valid solutions, tested by time. Organic Agriculture should prevent significant risks by adopting appropriate technologies and rejecting unpredictable ones, such as genetic engineering. Decisions should reflect the values and needs of all who might be affected, through transparent and participatory processes.

# APPENDIX 7: Requirements for the approval of Participatory Guarantee Systems

1. The PGS certifies its producers to the national or regional organic standard or a compliant standard.
2. The PGS is a participatory organization or structure, whereby producers (at minimum) and other stakeholders (desirable) participate, voluntarily and transparently, in the choice of the standard (which may be the national/regional standard or a standard compliant with it), the procedures for verification and sanctions, and the choice of people with particular responsibility in the PGS.
3. PGS implementation mechanisms are locally and culturally adapted and relevant, and efforts are made to minimize paperwork needed for certification.
4. Participating producers take a public pledge to follow the standard and are subsequently receiving on-site reviews/inspections at minimum once a year to demonstrate and verify their continued compliance with the standard.
5. The PGS ensures compliance of its certified producers with the standard and implements a system for managing non-compliances, with specific consequences that are implemented, including suspending producers in the case of serious non-compliances.
6. The PGS allows for site visits by consumers and other interested persons and it provides a list of approved producers and other group members, as well as other PGS documentation on request (some PGS may carry this information on their website). The PGS grants consumers and other stakeholders the possibility to become active members of the PGS.
7. Farm/site review/inspection involves a team, including experienced persons and peer producers. Experience in facilitating peer reviews and in on-site “inspection” may have been acquired through training or learning-by-doing. Reciprocal[[7]](#footnote-7) inspection is not considered a valid procedure except if it is additional to a non-reciprocal inspection by a team fulfilling the above minimum criteria.
8. The PGS has a mechanism to accept, objectively assess and feed into the verification process any information identifying potential non-compliances acquired outside of the farm/site visits (e.g. continued “social control”, external observations, consumer complaints, etc.).
9. Decisions to endorse each producer’s certification status are taken by a group (sub-committee) with the appropriate technical experience and includes at least 1 producer representative. The PGS does not delegate the decision of certification to an external body or organization, but may request advice from external bodies. The PGS has mechanisms to minimize conflicts of interest, and to ensure consistency on the level of the certification decision.
10. Information about compliance is generated, maintained and updated (minimum annually) for each producer. This information includes data on production, details of compliance and non-compliance with the standard, etc.
11. The PGS provides specific recognition or market access to its endorsed producers only. This may be in the form of a certificate and/or a product logo and/or, access to a specific marketing place, etc.
12. The PGS promotes on-going capacity building of producers as well as knowledge and advice sharing among group members.

# APPENDIX 8: Procedure for approval of Participatory Guarantee Systems by the competent authority

This document outlines the procedure to be used for approval of PGS initiatives by the competent authority[[8]](#footnote-8) for use of the (National Organic Logo) and generally to make organic claims. It should be read and used together with the Requirements for Approval of Participatory Guarantee Systems (Appendix 7).

1 General Policy

 a. Approved PGS are those that have received approval at the national level by the \_\_\_competent authority.

 b. The approval process shall include persons or organizations other than those engaged in supporting the PGS[[9]](#footnote-9).

 c. Approval shall be based on the submission of a complete file prepared by the applicant PGS (see 2.2 Application, below) and the documented verification through file review and on-site visit by the \_\_\_competent authority (or a person or a committee appointed by the \_\_\_competent authority for this purpose) of the compliance of the applicant PGS with the Requirements for the Approval of PGS and the National Organic Standard or an equivalent organic standard (as defined under 4.2.b).

 d. Approvals may be conditional, i.e. that the PGS shall implement specific improvements before or after the decision has become effective.

 e. The initial approval of PGS initiatives is valid for a period of 12 months unless otherwise decided by the competent authority.

 f. Subsequent approvals are valid for a period of 36 months unless otherwise decided by the competent authority.

 g. The approval may be suspended or cancelled, with the latter as the last resort option, by the \_\_\_competent authority if serious non-compliances with the criteria are observed, following a fair and transparent process.

 h. Before the expiry of the approval, the approved PGS initiative shall re-submit a new and updated file and be subject to a new file review and on-site visit by the \_\_\_competent authority (or a person or a committee appointed by the \_\_\_competent authority for this purpose) in order to renew its approval.

2 Procedures

2.1 Inquiry

Any PGS interested in applying for approval will receive from the \_\_\_competent authority:

a. This procedure (or a simplified version of it)

b. The Requirements for the Approval of PGS

c. The National Organic Standard

d. Rules for the use of the national organic logo

e. Agreement on the use of the national organic logo

2.2 Application

The PGS initiative applying for approval will submit to the \_\_\_competent authority their file containing the following up-to-date information:

a. Its PGS Manual explaining the PGS structure and the certification procedure in such a way that allows verification of the existence of procedures or processes that ensure compliance with the Requirements for the Approval of PGS.

b. A completed application form (according to template[[10]](#footnote-10))

c. The current list of its endorsed producers and their registered categories of production.

2.3 Application review

A person or committee appointed by the \_\_\_competent authority will review the application file and

a. seek clarification on any unresolved matters directly with the authorized person from the applicant PGS initiative;

b. determine, based on the criteria set out in Appendix 7 (see above) if the PGS has reached a sufficient stage of development to proceed with the application process;

c. assign one or more persons to make an on-site assessment visit.

2.4 On site assessment visit(s)

An individual or group, with working knowledge of PGS, appointed by the \_\_\_competent authority[[11]](#footnote-11), will carry out on-site assessment visit(s) or visits will be made by an individual or group appointed by the \_\_\_competent authority. The visit(s) can include[[12]](#footnote-12):

a. a review of the relevant documentation;

b. a review of the files of a sample number of members of the PGS initiative;

c. on-site visits of a sample of members for which the files have been reviewed, interviews with PGS members and other stakeholders having knowledge of the PGS, to determine their depth of knowledge of the PGS standards and operating procedures, as well as confidence in the system.

d. interview with other local stakeholders having knowledge of the PGS, if appropriate (e.g. the buyers, some local technicians or NGOs, etc.)

e. an exit discussion with the PGS members where the findings are presented

The visit(s) shall be recorded in a PGS Assessment Form[[13]](#footnote-13).

2.5 Decision

A committee appointed by the \_\_\_competent authority will review the file and the result of the on-site assessment visit and shall

a. seek clarification on any unresolved matters

b. determine if the PGS can be approved

c. determine any conditions that have to be fulfilled before or after approving the PGS and granting access to the National Organic Logo. Any such condition shall have a clearly spelled out time line.

The decision and any applicable conditions shall be recorded on the PGS Assessment Form.

2.6 Registration and licensing

Once a PGS has been approved,

a. the decision will be communicated to the PGS by means of a standard letter

b. an agreement on the use of the national organic logo will be signed,

c. a certificate will be issued

d. the relevant data will be included in the \_\_\_national registry of organic producers maintained by the competent authority.

2.7 Monitoring and complaints

There may be on-site visits by the \_\_\_competent authority within the approval period to verify continued compliance if judged necessary.

The \_\_\_competent authority shall provide information to the public about where formal complaints related to the functioning of PGS initiatives may be submitted.

The \_\_\_competent authority shall investigate in a timely manner any formal complaints received against an approved PGS initiative. Such an investigation shall include at least:

a. Evaluation of the nature of the complaint and if an investigation should take place,

b. Investigation of the actual situation,

c. Asking the PGS initiative for any comments or corrections,

d. Informing the complainant about the outcome.

In a complaints process, the identity of the complainant shall not be disclosed to the PGS initiative.

The \_\_\_competent authority shall keep a record of complaints received and their resolutions.

2.8 Transparency

The process of each approval and the basic data about the PGS initiatives shall be accessible for any interested parties, including members of the public.

2.9 Training

The persons involved in file reviews, on site visits and decision-making regarding the approval of the PGS shall be trained to perform their functions including, but not limited to:

1. working knowledge of PGS (i.e. familiarity with PGS key elements and features, practical experience with PGS implementation, etc.)
2. knowledge about the National Organic Standard or an equivalent organic standard
3. the system for the use of the National Organic Logo.
4. the Requirements for the Approval of PGS (see Appendix 7).
5. This procedure
6. The relevant forms and templates provided by the competent authority in the context of the PGS approval procedure.

2.10 Managing the process

The \_\_\_competent authority (or a person or a committee appointed by the \_\_\_competent authority for this purpose) shall be responsible for the management of the whole process and each step. A file shall be kept for each PGS with all the relevant documents.

1. The list of standards approved into the IFOAM Family of Standards is available at: <http://www.ifoam.org/en/ifoam-family-standards> [↑](#footnote-ref-1)
2. For example, verification of full compliance to the standard through a PGS, is considered such sound and incontrovertible evidence, for products entering the third party certification system, and the other way round. [↑](#footnote-ref-2)
3. Note: this clause does not preclude other terminal sanitizers to be used, as the list is simply indicative. [↑](#footnote-ref-3)
4. For the purpose of this standard, all people under 13 are considered children. [↑](#footnote-ref-4)
5. For example, direct employment, employment agencies, labor contractors and employment brokers. [↑](#footnote-ref-5)
6. Additives may contain carriers, which shall be evaluated. [↑](#footnote-ref-6)
7. Reciprocal means that producer A inspects producer B, and B inspects A, which can create conflicts of interest. [↑](#footnote-ref-7)
8. *Template note: “Competent authority” is used in this appendix as the default entity approving the PGS initiatives. However, the competent authority may decide to delegate this role to a separate body or organization: in this case, adjust the template accordingly.* [↑](#footnote-ref-8)
9. This means that if the competent authority is engaged in assistance to PGS initiatives (group formation, training, etc.), at least one other person who is not engaged in assistance to the PGS shall also be included in the decision-making for the approval. This is to reduce the risk of conflict of interest. [↑](#footnote-ref-9)
10. A template is currently being developed. [↑](#footnote-ref-10)
11. The competent authority, based on its available resources and skills, appoints an individual or group from its own staff members or an external expert. However, the competent authority may decide to delegate this role to a separate body or organization: in this case, adjust the template accordingly. [↑](#footnote-ref-11)
12. The competent authority decides on which of the items in the list are mandatory for the on site assessment visit(s): in this case, adjust the template accordingly. [↑](#footnote-ref-12)
13. Same as above. [↑](#footnote-ref-13)