

APPROVAL OF THE TECHNICAL REGULATIONS OF ACT NO. 20.089, WHICH CREATES THE NATIONAL CERTIFICATION SYSTEM FOR ORGANIC AGRICULTURAL PRODUCTS

No. 2.- Santiago, January 22, 2016.

Having regard to:

The provisions of Article 32 (6) of the Political Constitution of the Republic of Chile; Decree With Force of Law No. 294 of 1960 of the Ministry of Finance, Organic Law of the Ministry of Agriculture; Act No. 18755 that establishes the organization and powers of the Agriculture and Livestock Service; Act No. 20089 which creates the National Certification System for Organic Agricultural Products; Decree With Force of Law No.1/19653 of 2000 of the Office of the Secretary General of the Presidency which drafted the consolidated, coordinated and systematized text of Act No. 18575, the Organic Constitutional Law of General Basis of State Administration; Decree No. 17 of 2007 of the Ministry of Agriculture and Resolution No. 1600 of 2008 of the Comptroller General of the Republic.

Considering:

That Act No. 20089, which creates the National Certification System for Organic Agricultural Products, stipulates in Article 5 that: "The requirements and protocols to register the different parties involved in the System and to implement the different phases of the operation itself, shall be established in a regulation that shall be issued for this purpose and, in this case, by means of technical rules. The aforementioned regulation and technical rules shall be respectively approved and made official by decrees from the Ministry of Agriculture and consequently these will be of a mandatory nature."

That on August 27, 2007 the Official Journal published Decree No. 17 of the Ministry of Agriculture, which formalizes the technical regulations of Act No. 20089, created the National Certification System for Organic Agricultural Products and was amended by Decree No.86 of 2011 of the Ministry of Agriculture in order to comply with international requirements on the subject.

That organic agriculture is a dynamic activity for which the requirements and procedures change with time which creates the need to constantly update the regulation that governs said activity.

That it has been decided to issue new technical regulations for Act No. 20089, which created the National Certification System for Organic Agricultural Products, in order to comply with the following objectives among others:

- a) Adapt certain definitions to criteria more consistent with the 'International Standards for Phytosanitary Measures - ISPM - No. 5', with regards to the 'Glossary for Phytosanitary Terms';
- b) Introduce the definitions that can be found in the standards of the International Federation of Organic Agriculture Movements (henceforth IFOAM), for the production and processing of organic products; and
- c) Take into account the directives for producing, processing, labeling and marketing organically produced food products which aim to harmonize the international requirements for organic products that have been adopted by the Codex Alimentarius Commission (combined program of the FAO/WHO).

We Decree:

1.- Approve the technical regulations of Act No. 20089, which created the National Certification System for Organic Agricultural Products and reads as follows:

CHILEAN TECHNICAL REGULATION FOR ORGANIC PRODUCTION

HEADING 1

Introduction

Article 1. The increasing deterioration of ecosystems shows the need to look for more environment-friendly production alternatives. The agricultural, livestock and forestry sectors are well aware of these global issues and have generated sustainable and ecological production alternatives, especially in the area of organic agriculture has been steadily developing on a national and global scale.

The most important aspects that make up the basis for organic agriculture are:

- a) Apply forestry, livestock or agricultural practices that do not deteriorate the productive resources and restore the natural balance;
- b) Improve the soil fertility on a chemical, physical and biological level;
- c) Preserve or increase the organic matter in the soil, recycling the leftovers of harvest, pruning, manure and guano of animals, among other methods, by applying different systems to introduce these into the soil;
- d) Boost the spatial and temporal biodiversity of the properties by using methods such as associated crops, crop rotation and silvopastoral systems;
- e) Eliminate the use of products of synthetic chemical origin that harm the environment or affect human health;
- f) Lean towards a balanced harmony between the production of crops and livestock; and
- g) Provide the adequate circumstances to allow the animals to maintain a good physical condition and express the basic aspects of their natural behavior.

All of the above has a preventive effect on the spread of pests and diseases and, at the same time, it increases the soil's natural fertility. This reduces the need to use external inputs, allowing the agricultural ecosystems to recover their natural balance.

HEADING 2

Scope and area of application

Article 2. This Regulation aims to determine the requirements for the production, processing, labeling and selling of organic, ecological or biological products.

This regulation applies to:

- a) unprocessed vegetables
- b) animals and unprocessed animal products
- c) unprocessed bee products
- d) unprocessed fungal products and
- e) processed vegetable, animal, bee, wine and fungal products.

HEADING 3

Terms and definitions

Article 3. For the purpose of this Regulation, the following terms and definitions shall apply:

1. Green fertilizer: Vegetable materials (cultivated or wild) introduced into the soil to improve structure and fertility.
2. Organic soil conditioner: Organic material or a mixture of organic materials used to favorably modify the soil's physical, chemical and/or biological properties and is not considered to be a fertilizer.
3. Official accreditation: Procedure by which an official body with the necessary authority formally recognizes the competence of a certification body to perform certification services.
4. Biological control agent: Natural enemy, antagonist, competitor or other organism that is used to keep pests under control.
5. Traditional agriculture: A different production system than the one defined in this Regulation.
6. Organic, ecological or biological agriculture: A holistic system of forestry, livestock and agricultural production based on the methods of ecological management with the main objective of achieving sustainable productivity based on the preservation and/or recovery of the natural resources in accordance with the stipulations of this Regulation.
7. Animal food or feed: Edible substance(s) consumed by animals which contribute energy and/or nutrients to their diet and that are not meant for human consumption. These may be protein or energy concentrates (e.g. grains of one or several species, whole, crushed and/or milled, and their by-products); preserved forages (e.g. grass, hay, silage and feed) and green forage.
8. Cultivation area: The soil surface that has been identified as a unit within the organic production operation.
9. Foraging area: Surface of a clearly delineated area in which the organic beekeeping production unit collects or extracts nectar, honeydew, pollen, propolis and water.
10. Competent Authority: The Agriculture and Livestock Service.
11. Animal welfare: A management system in which the animals enjoy minimum standards of protection, proper healthcare, access to food in accordance with the species' characteristics while avoiding movements that cause unnecessary pain and respecting the natural behavior of each species. Furthermore, the owner is expected to keep a record of the applied management.

12. Biodegradable: Substance that is subject to biological decomposition into biochemical components or simple chemicals.

13. Certification: A procedure by which the certification body verifies and certifies that the forestry, livestock or agricultural production process has been developed in compliance with the applicable technical regulations for obtaining products which are organic or organic in transition.

14. Certificate of transition: A document issued by a certifying body stating that a specific batch or consignment of goods comes from a production that has been certified.

15. Processing aid: This corresponds to substances added while processing a product in one of the following circumstances:

- a) if it is removed from the product in some way before it is packaged in its final form
- b) if it turns into one of the constituents that are a normal part of the product and if it does not significantly increase the quantity of the natural constituents that are normally found in the concerned product and
- c) if it has a technical or functional effect on the process but is only present in the finalized product in non-significant levels and it does not have a technical or functional effect on the concerned product.

16. Co-formulant: Any substance other than the active substance which was intentionally inserted into the formula of an agricultural input.

17. Compost: The product created by the aerobic fermentation of a mixture of organic matter under specific humidity and temperature conditions and the product of which is innocuous, free of phytotoxic effects and has an origin that is not traceable.

18. Biological compounds: Viruses, serums, toxins and analogue products of natural or synthetic origin, be they dead or alive organisms or material used for diagnosis, antitoxins or vaccines and the antigens or immunologic compounds of microorganisms for diagnostic use, treatment or prevention of animal diseases.

19. Contamination: The physical contact between prohibited substances and an organic operation, a part thereof or with organic products or their ingredients which may be caused by physical movement.

20. Contaminant: Any element, compound, substance, chemical or biological derivative, radiation, or a combination of any of these, of which the presence in the organic production unit, product or processed organic product could constitute a risk for organic certification.

21. Control: The use of any method that reduces or limits harm to agricultural products that was caused by pests, weeds or diseases, reducing these to levels that do not lower the productivity significantly.

22. Official or Mandatory Control: Any action carried out by the Competent Authority to control, remove or eradicate a quarantine pest which is present in a certain area of the country and to protect the unharmed areas.

23. Harvest: The activities of collecting the products generated by an agricultural operation.

24. Annual cultivation: The life cycle of a plant species within one season which does not exceed one year and comprises everything from the germination of the seed until the harvest.

25. Detergents: Surfactant compounds with surface tension reducing properties for the liquids they are dissolved into.

26. Drugs for animal use: Products used for animal healthcare purposes. These include, furthermore, compounds that are part of the diet

for specific purposes (e.g. growth promoters, among others). This does not include the food itself.

27. Meadow or pasture: Soil covered by herbaceous vegetation, used for cattle grazing, and managed to feed animals and maintain or improve the quality of the soil, the water and the vegetation resources.

28. Certifying body or certification body: The responsible authority for verifying whether the forestry, agricultural or livestock production is performed in compliance with the applicable technical regulation for producing products that are organic or organic in transition. This includes the certification bodies and ecological farmer organizations.

29. External packaging: Any packaging, wrapping, vessel or container for an agricultural product that is used for purposes other than exhibiting and/or selling the product.

30. Manure: Fecal matter, urine and bedding materials from animals that have not been composted.

31. Fertilizers: The simple substances or mixtures thereof that contain one or more recognized nutrients which are mainly used for their nutritive content for plants and have been designed, used or recognized for helping to stimulate plant growth.

32. Forage: Plant material, fresh, dried or silaged (grass, hay or silage) used to feed cattle.

33. Livestock: Any bovine, ovine, caprine, porcine, equine or camelid animal used for food or in the production of food, fibers or other consumption products of farm origin, including domestic and wild animals.

34. Guano: Bird excrement.

35. Coastal guano: Sea bird guano that is found accumulated in large quantities on the coasts of various islands of Peru and the north of Chile. This is used as a fertilizer in agriculture.

36. Hydroponics: A method of cultivating plants with their roots in a mineral nutrient solution alone or in an inert medium instead of farming soil.

37. Ingredient: Any substance used in the preparation of a farming product that is still present in the final commercial product that will be consumed including additives.

38. Inspection: An assessment of compliance to this regulation for organic production by means of observation and judgment and combined, where necessary, with measurements, tests/samples or comparison of patterns.

39. Sludge: Solid, half solid or liquid residue generated by production processes different from the ones produced by treating domestic wastewater.

40. Domestic sludge: Solid, half solid or liquid residue generated by treating domestic wastewater.

41. Batch: A group of vessels that contain a farm product of the same type, located in the same transport, warehouse or packaging site.

42. Organic matter: Remnants, residue or waste of any living organism.

43. Propagation material: Any vegetable organism and its parts (rhizome, tubercle, grafts, roots, leaf or stem cuttings, buds, among others) that are used in the production and propagation of plants, including seedlings or saplings.

44. Allowed non-organic raw materials: Natural or synthetic substances accepted by the applicable regulations on their use in the production, preparation and/or management or intermediation of organic products.

45. Mulch: A layer or cushion on the soil made up by materials such as wood chips, leaves or straw, or any other material, synthetic or not, such as shredded newspapers or plastics that help to stop weeds from growing, moderate the soil temperature or preserve its humidity.

46. Technical regulations: Rules made official by the Ministry of Agriculture's decree.

47. Organic, biologic or ecologic: The equivalent terms used in the labeling, identification, description or sale of products produced and managed in compliance with the rules of organic production.

48. Genetically modified organism (GMO): An organism, with the exception of humans, whose genetic material has been modified in a way it would not appear naturally through pairing nor through natural recombination.

The known techniques for genetic modification are, among others:

- 1) Techniques of deoxyribonucleic acid (DNA) recombination that include forming new combinations of genetic materials through inserting molecules of nucleic acid obtained from any source outside an organism, in a virus, a bacterial plasmid or another vector system and incorporating it in a host organism in which it is not naturally found but can keep reproducing.
- 2) Techniques that require taking genetic material prepared outside an organism and directly introducing it into that organism. This includes micro-injection, macro-injection and micro-encapsulation.
- 3) Cellular fusion techniques (including protoplast fusion) or hybridization in which living cells are formed with new combinations of genetic hereditary materials through the fusion of two or more cells using methods that do not occur naturally.

49. Operator: An operator is a natural or legal person who has signed a certification agreement on organic products with a certification body or an organization of ecological farmers registered with the Agriculture and Livestock Service and is allowed to produce, process and/or sell organic products and has the responsibility to ensure that these processes comply with the certification requirements. Likewise, the national sellers who do not take part in any production or processing and who are directly inspected by the Service and also have to comply with the stipulations of the applicable regulation are considered to be operators.

50. Transition period: The time that has to pass before the certification body can certify the product's organic character and during which all of the production standards have been applied without exception.

51. Pest: Any organism that is alive or of special character that, because of its presence and dispersion, constitutes a serious risk for the health conditions of the plants or its products, such as insects, microorganisms, weeds, nematodes, fungus and parasites, among others.

52. Pesticide: A chemical, organic or inorganic compound or natural substance that is used to fight weeds, diseases or pests and could possibly cause damage in organisms or objects.

53. Organic management plan (OMP): A program of annual tasks and activities that are carried out in the production or processing unit and guarantee that the obtained product is in compliance with the national organic regulation.

54. Preparation: The preserving, classifying, selecting and/or processing operations of a farm product, including slaughter and cutting meat in animal products, packaging the resulting products and the modifications made to the initial labeling regarding the presentation of the organic product and the preservation methods for fresh or processed products.

55. Processing: The operation of cooking, roasting, curing, heating, drying, mixing, sifting, whipping, separating, extracting, cutting apart,

cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, cooling or another way of manufacturing including packaging and canning (preserves) of food as well as bottling in jars or other forms of enclosing food in a container.

56. Production: All of the combined operations in the context of forestry, agriculture or livestock that include the genesis as such, the packaging and the original labeling of a product.

57. Animal production: The production of domestic or domesticated animal species, including insects.

58. Extensive animal production: The system of animal production that enables the requirements of cattle, herds or others to be fulfilled with the resources from the production unit itself without depending on external sources.

59. Organic production: The holistic system for production management in forestry, agriculture or livestock, which fosters and improves the health of the agroecosystem and particularly the soil's biodiversity, biological cycles and biological activity. This production must be performed in compliance with Act No. 20089 and the applicable technical regulations.

60. Parallel production: A simultaneous production in the same production unit of conventional and organic, or organic in transition, crops or animals.

61. Bulk products: When a product is presented to the consumers, intermediaries or the retailers without individual packaging in a way that the units adapt to the space in which they are contained, allowing the choice of determining the product's units, quantities or volumes.

62. Natural or non-synthetic product: A substance derived from mineral, vegetable or animal material which has not been the object of synthesis.

63. Organic agricultural product: A forestry, agricultural or livestock product that has been harvested, produced, processed, manipulated and/or sold in compliance with the regulations for organic production and is of vegetable, animal, beekeeping or fungal origin.

64. Organic in transition product: A product obtained in a production unit in which the technical rules for organic production have been applied for a specified time but are not yet sufficient to fulfill the period stipulated in this Regulation to be considered organic as such.

65. Producer: A legal or natural person involved in the production of food, fibers, forages and other farm products for consumption.

66. Primary organic products: Products and by-products of vegetable, animal, beekeeping or fungal origin in their natural state, without altering their organic condition.

67. Processed organic products: Products and by-products of vegetable, animal, beekeeping or fungal origin which have undergone marketing processes that have modified their original nature but not their organic condition.

68. Wild product: A plant or part of a plant or fungus that has been gathered or harvested in an area that has not been cultivated or under any agricultural management for at least the last 3 years.

69. Synthetic product: A substance that was made artificially through a chemical process.

70. Prophylaxis: The prevention or combination of measures to avoid an illness.

71. Slurry: A mixture of excrements and water produced when cleaning the stables.

72. Stubble: The plant residue or remnants which are left in the field

after harvesting a crop. This includes canes, stems, leaves, roots, fruits and herbs.

73. Natural resources of the operation: The physical, hydrologic and biological aspects of a producing operation, including soil, water, wetlands, forested areas and wildlife.

74. Record: Any information which is necessary or sufficient, be it in written, visual or digital form that documents the activities performed by the producer, intermediary or certification body in compliance with the specifications stipulated in this Regulation and by the Competent Authority.

75. Residues: The presence of any substance or trace that can reliably be observed, found in a sample or by approved analysis methods.

76. Crop rotation: The practice of alternating crops on one specific piece of land, in a programmed pattern or sequence of successive yearly crops so that the crops of the same species or families do not grow repeatedly on the same soil without interruption. The systems of perennial crops apply similar formulas based on associated crops, intercropping and hedges to introduce biodiversity.

77. Label: All written, printed or graphic data on the farm product that identifies it in storage, transport and the sales outlets.

78. System: The National Certification System for Organic Agricultural Products.

79. Food supplement: A food or a combination of various elements added to a ration for animal consumption with the purpose of improving the nutritional balance, the acceptability parameters or the results of the entire ration. These can be:

- a) integrated into the other food when it is given to the animals;
- b) offered as a free option, separated from the other rations; and
- c) completely integrated and mixed to produce a complete meal.

80. Active substance in a pesticide: The component that gives a pesticide its expected biological effect or modifies the effect of another.

81. Allowed substances: Those determined in accordance with the criteria defined in the annexes of this Regulation.

82. Prohibited substances: Elements, compounds or matter of which the use, in any aspect of the production or preparation of an organic product, has not been authorized by the Competent Authority.

83. Sustainable: The capacity of meeting current needs without compromising the capacity that future generations will have to meet their own needs.

84. Tolerance: The maximum legal levels permitted for a specific chemical residue, pesticide or any other chemical product, present in a natural agricultural product, raw material or processed food.

85. Traceability: The capacity to follow the history, the application or localization of everything that is under consideration. When considering an organic product, traceability is related to the origin of the materials and the parts, the productive processes, the distribution and the localization of the product after delivery.

86. Organic production unit or unit of organic production: The clearly delineated area or surface in which vegetable, animal, beekeeping and or fungal products are produced, processed or harvested in compliance with the rules for organic production and that has separate traceability, including records on each unit's production, processes and marketing activities. These must be included in the management plan.

87. Buffer area, buffering zone or buffer zone: The area or space located between an organic production unit or a part of it and an adjacent area that is not kept under organic management. The buffer zone should be large enough and have other features to prevent accidental contact from substances that are used on land adjacent to the area that is part of an organic production unit. Buffers zones must not receive conventional treatments.

HEADING 4

General requirements for organic production

Article 4. In order to use the term 'organic' in the name of a primary or prepared product and/or in some or all of its ingredients, depending on the case, it shall be required to comply with the following requirements, apart from the applicable legal regulations:

- a) Be produced exclusively by methods listed in the current regulation.
- b) Not use sludge, household sludge or other residues from the process of treating wastewater or industrial wastewater.
- c) Not include organic and non-organic types of a same ingredient.
- d) Only use the allowed substances which can be found in the annexes of this regulation and for the purposes indicated.

Article 5. The only products that can be certified as organic are primary and processed products coming from production units that have applied the technical regulations for organic production during the periods specified in this Regulation. To determine this transition period it shall be considered that the operator has been registered in the System on the day that the first inspection visit is performed.

Article 6. The use of genetically modified organisms in organic production and products derived from them is prohibited. Examples of these are: food products and ingredients (including additives and flavorings); processing aids (including extraction solvents); animal feed; compound feed; raw materials for animal feed; additives in animal feed; processing aids in animal feed; certain products used in animal feed (such as amino acids; proteins obtained from microorganisms; algae; by-products from antibiotics manufactured through fermentation; ammonium salts and by-products of the amino acids manufactured through fermentation); animals; pesticides; fertilizers; soil conditioners; seeds and vegetative propagation materials.

The operator must request a sworn statement from the supplier on any of the inputs or products referred to in the preceding paragraph or any other affidavit that specifies to the certification body or Competent Authority that it is GMO-free.

The certification bodies must evaluate the affidavits mentioned in the preceding paragraph and shall be able to authorize inputs or products, taking into account the guidelines of the Competent Authority. The operator must produce explicit records of the authorization for using inputs or products in the organic management plan.

Article 7. The parallel production of organic and conventional products is prohibited. However, exceptionally and for a period of 3 years starting from the registration of the production unit in the System, parallel production will be allowed. The operator must submit a conversion plan demonstrating compliance with the stipulations of Article 11 of this Regulation, with prior authorization from the certification body. The content of this Article is without prejudice to what is indicated in the first paragraph of Article 30 of this Regulation.

Article 8. Hydroponics is prohibited in organic production.

Article 9. It is prohibited to use fire to destroy stubbles, trimmings or similarly produced leftovers from the production unit, with the exception that it may be used to contain the spread of pests and diseases, or those indicated as a mandatory control method.

Article 10. Transformed surfaces must not shift between organic and conventional production. Otherwise, they shall lose their organic status until they comply with the organic production requirements again.

Article 11. Organic farming production must be performed in production units or parts thereof, with production separated from the conventional production by a buffer zone of at least 6 meters of space to ensure that it shall not be possible for direct or indirect contaminants to be present. The certification body must verify the buffer zone, and request any additional measures when appropriate.

Article 12. The operator must prepare an organic management plan (OMP) to establish the conditions during the transition period, in production, preparation practices, handling and management according to the applicable regulations. This plan must be updated annually to record in the management system what problems were encountered during the implementation and what measures were taken to overcome these problems.

The OMP must include a production or processing description that includes updated written plans of all the aspects described in Heading 11 of this Regulation.

Article 13. Agricultural machinery used on organic lands must be used exclusively for organic production. Exceptionally, if there is no exclusive machinery, the machines must be appropriately cleaned and they must be registered as stipulated under Heading 11 of this Regulation.

The operator must have a separate and enclosed space that has been designated for storage of agricultural inputs used on organic lands.

In case of conventional and organic production in the same production unit, the operator must prove that he/she has taken all precautionary measures to avoid contaminants in the organic lands.

HEADING 5

Specific rules for organic vegetable production

Article 14: General principles.

1. Only vegetables, primary and processed products from production units that have applied the technical standards of organic agriculture for a period of at least 36 months before the first harvest can be certified as organic.

2. Certification bodies may request the Competent Authority to extend or reduce the periods indicated in Paragraph 1 above according to the previous use of the production unit provided that it has the appropriate records. For the purpose of reducing the term, the production unit must be at least 3 years without the use of prohibited substances provided the unit has been registered for at least 12 months in the System. The criteria for assessing these applications shall be determined by the Competent Authority.

3. Unprocessed vegetable products obtained in a production unit which has applied this Regulation for at least 12 months and which do not comply with the periods stipulated in Paragraphs 1 and 2 of this Article shall be called Organic in Transition Products. This condition must be verified by the certification body, which shall issue a certificate of said condition and moreover, shall assess the labeling requirements in accordance with Article 68 of this Regulation.

Article 15. Origin of the seeds and propagating material

1.- Only seeds or other organic propagating materials must be used except:

a) Untreated seeds or other conventional propagating materials or those treated with the products listed in Annex A, Table 2 of this Regulation when it is proven to the satisfaction of the certification body that it is impossible to obtain seeds or other organic propagating materials in the required quantity, species and relevant varieties on the market. This exception does not apply to the production of edible shoots.

b) Seeds or other materials mentioned in the previous paragraph in the event of natural disasters or agricultural emergencies as declared by the authorities which prevent obtaining organic seeds and reproduction materials. The use of these seeds or other materials must be approved by the Competent Authority by means of a reasoned decision as a temporary measure and for specific species-varieties.

c) Seeds or other conventional propagating materials treated with products other than those authorized for use in organic agriculture in the event that the authority of phytosanitary control requires a mandatory inspection of the entire species for health reasons.

2.- Where applicable, the production of seeds and propagating material must comply with the following requirements:

a) For the production of seeds and propagating material, the female parent material in the case of seeds and the parent material in the case of vegetative reproduction material must have been produced in accordance with the rules laid down in this Regulation for at least one generation or in the case of perennial crops for two growing seasons.

b) The certification bodies must inform the Competent Authority about the available producers of seeds and propagating material, the species and quantities.

c) Regarding the propagating material that is used to replace plants, the following conditions must be fulfilled, in the following order of priority:

1.- Before starting to replace plants, the operator must seek approval from the certification body and in no case after the execution of the work.

2.- The propagating material must originate from a plant nursery registered with the Agriculture and Livestock Service.

3.- The propagating material used to replace plants must be organically managed for at least one year before being harvested as such.

d) The propagation material used to make seedlings must comply with Paragraph 1 of this Article and during the period growing in seedbeds it must comply with the stipulations of this Regulation. The use of conventional seedlings is not allowed.

e) When choosing the species and/or varieties to grow several factors must be considered, such as: the preservation of genetic diversity; saving local varieties; varieties adapted to agro-ecological conditions; and vulnerability to pests and diseases. The use of genetically modified seeds, other propagating material or replacement plants is not allowed.

f) If phytosanitary regulations established by the Competent Authority require the use of unauthorized substances in the organic production of seeds, annual seed plants and nursery plants, as an exception, their use for organic production shall be permitted.

Article 16. Irrigation.

1. Irrigation water must comply with current regulations and must not endanger the organic condition of the production unit. When circumstances suggest the presence of contamination or contaminants the certification body or Competent Authority may require an analysis to verify compliance with the aforementioned regulations.

2. The irrigation system's design and management should avoid degradation of natural resources which shall have to be evaluated by the certification body.

3. The water resources should be used efficiently without affecting the sustainability of the ecosystem.

Article 17. Managing soil fertility.

Both the fertility and the biological activity of the soil must be preserved or increased by the following procedures, where appropriate:

a) Minimum tillage which maintains or increases the soil's biological activity and improves its physical characteristics.

b) The cultivation of legumes, green fertilizer or deeply rooted plants, in accordance with a suitable rotation program.

c) The producer must implement a crop rotation system that aims to preserve or increase the level of organic matter; prepare a basis for pest and disease management of annual and permanent crops; manage deficits or excesses of plant nutrients and offer systems for erosion control.

d) The introduction of organic material into the soil coming from

production units applying the standards of organic agriculture. They may use byproducts of cattle rearing such as composted manure, in accordance with the criteria laid down in annex A of this Regulation.

e) The introduction of products and by-products of vegetable or animal origin from conventional extensive sources, provided that these have been previously composted under the criteria and conditions set forth in this Regulation and that the absence of contaminants has been verified. The restrictions on the use of fresh manure are described in Article 26 of this Regulation.

f) The use of appropriate microorganisms or preparations of vegetable, animal and/or mineral origin (such as biodynamic, homeopathic and Ayurvedic preparations) under the criteria and conditions set forth in this Regulation to activate compost and soil. To that end the use of nitrogen compounds is also authorized.

g) The introduction of fertilizers and/or soil conditioners as described in Table 1 of Appendix A of this Regulation, only when adequate vegetable nutrition is not possible through crop rotation or soil conditioning.

h) The addition of nitrogen through the permitted systems will be limited to a maximum of 170 kg/ha/year, preventing the possible contamination of the respective groundwater aquifers.

The organic quality of the fertilizer must be emphasized and in case of doubt the appropriate analyses must be performed, such as analysis for heavy metals, salinity, and electrical conductivity, among others, to ensure that these do not affect the production system's conditions.

Article 18. Pest control.

1. Pests should be handled by one of the following measures or a combination thereof, in a proper manner:

- a) The improvement and preservation of biodiversity.
- b) The selection of agro-ecologically adapted species and varieties giving priority to the local and/or resistant ones.
- c) A program of crop rotation and sowing season.
- d) Mechanical and manual cultivation means such as plows, harrows, cultivators, chisel plows, hoes and other means for similar purposes.
- e) The protection of the natural controllers through measures that favor them (e.g. hedges, nests and trap crops).
- f) Trimming and thermal weed control.
- g) Mechanical control mechanisms such as traps, barriers, light and sound.
- h) Biological control, use of native biological control agents and/or exotic ones, authorized in accordance with applicable regulations.
- i) Ground covering materials such as mulch, straw, stubble and fine gravel or even living protective coverage.
- j) Animal grazing.
- k) Thermal treatment (with vapor, soil solarization and flashover).
- l) Soil maintenance with balanced fertility and high levels of biological activity.
- m) Traps using pheromones and sexual confounders or using food lure authorized in accordance with applicable regulations; and
- n) The removal of diseased tissues from cultivation areas.

2. When the practices described in Paragraph 1 of this Article are

insufficient to control pests, pesticides with permitted natural and active substances can be applied in compliance with the requirements and general conditions provided for such substances which have been approved according to the applicable regulations.

If a product with an active natural substance is not available products with active synthetic substances are allowed to be used as long as they are permitted under this Regulation and comply with the requirements and general considerations provided for such substances which have been approved according to the applicable regulations.

3. The organic agricultural production unit must be separated from the conventional production unit by a distance of no less than six meters. The certification body shall require the installation of appropriate barriers and precautionary measures to minimize the risk of contamination or contaminants by drifting or other causes.

4. When an accident occurs that alters the organic condition of the production area this must be registered in the records of the production unit, communicated to the certification body within a maximum period of 24 hours after the event, the affected areas must be identified and the compromised products separated from the rest of the production.

In the event that inputs are used which are not included in Table 2 of Annex A of this Regulation, this event must be recorded, for reasons of mandatory controls by the Competent Authority, in the respective records and communicated to the certification body within 24 hours of the event. The affected products and areas must be identified and the compromised products separated from the rest of the production. These products may not be certified as organic.

In the cases mentioned in the preceding paragraph, the affected area may preserve its organic certification status by prior approval of the Competent Authority at the request of the party involved.

Article 19. Products of wild origin.

1. Wild products stemming from systems without sources of contamination or contaminants can be qualified as organic.

2. A system of wild harvesting is considered organic when harvesting plants, parts of them or edible mushrooms growing in wild areas, native forests and agricultural areas, the latter without productive use for at least 3 years, meets the following conditions:

- a) The gathering areas have not been affected by the use of products other than those listed in Annex A, for a period of 36 months before the harvest; and
- b) The harvest does not disturb the stability of the natural habitat nor the preservation of existing species in the area in which it is performed.

The wild harvesting system must have an organic management plan and its content shall be defined by the Competent Authority to ensure, at least, sustainability and compliance with the conditions set forth in points a) and b) above.

Compliance with these requirements must be verified by a certification body which must delineate the harvesting area and approve the respective management plan.

HEADING 6

Specific rules for organic livestock production.

Article 20. General principles.

1. The only products that can be certified as organic are animal products, meat products, eggs, hides, fibers, wool, hair and by-products (organic residue) primary and processed produced in accordance with this Regulation.

2. When organically produced animals are kept these must be an integral part of the agricultural production unit and be kept in accordance with this Regulation. It shall be allowed to keep animals treated under the principles of this Regulation and conventional ones in one and the same production unit, with the prior authorization of the certification body and only if they belong to different species and if the facilities where they are kept are clearly separated from each other.

3. As a first exception, it is determined that animals whose rearing does not meet the stipulations of this Regulation are allowed to use, with prior authorization of the certification body, for a limited period of time each year the pasture of units that are subject to this Regulation and only if said animals come from extensive livestock production and are not in those pastures or grassland at the same time as animals which are subject to the requirements of this Regulation.

4. As a second exception, it is determined that the animals whose rearing does comply with this Regulation may graze on land and/or common pastures. This will be possible provided that such land or pastures have not been treated with products other than those authorized in Appendix A, Table 1 and 2 of this Regulation within a period defined by the certification body and as long as they are not on said pastures or grasslands at the same time as animals which are not subject to the requirements of this Regulation.

5. It is prohibited to sell, label or present as organic:

- a) Animals or derived edible products that have been removed from an organic system and then afterwards managed under a conventional system; and
- b) Slaughtered breeding or dairy cattle that has not been under continuous organic management from the last third of the gestation period.

6. The animals intended for organic production must be selected with preference given to their physical constitution, the race's distinguishing characteristics and its capacity to adapt to natural conditions of management, breeding and of resistance to diseases.

7. The use of genetically modified organisms is not allowed.

8. It is only allowed to breed animals associated with a land surface area corresponding with the stipulations of Article 27, Paragraph 5 of this Regulation.

Article 21. Transition.

1. If it is the intention to use those certified agricultural lands to initiate a certified organic livestock production the animals will have to be bred in compliance with this Regulation for a minimum period of:

- a) 12 months in the case of equine, bovine and South American camelid

animals intended for meat production and in any case during three quarters of their lifetime;

- b) 6 months in the case of small ruminants (ovine and caprine) and pigs;
- c) 6 months in the case of animals intended for milk production;
- d) 10 weeks for poultry intended for meat production and introduced into the System before their 3rd day of life; and
- e) 6 weeks for egg production.

2. The certification body with the consent of the Competent Authority may extend in some cases the periods indicated in Paragraph 1 of this Article, depending on the previous use of the respective production unit.

3. As an exception to the aforementioned provisions of this Article, when the transition affects the whole production unit simultaneously including the animals, pasture lands and/or any land used for animal feed within the property the total transition period for animals, pastures and/or any land used for animal feed shall be reduced to 24 months and is subject to the following conditions:

- a) This shall only apply to the existing animals and their offspring and to the land used for animal feed and pastures before starting the transition; and
- b) The animals shall primarily have to be fed with products from the production unit.

It is possible to request a reduction of the transition period when at least 12 months under the System have passed. The certification body may grant or reject this request with prior authorization from the Competent Authority.

Article 22. Origin of the animals.

1. The animals must come from an organic production system and this must be maintained throughout the animal's entire lifetime.

2. As a first exception, each year it is acceptable to incorporate animals from non-organic sources representing no more than 10% of the animal population of each species for the purpose of expansion or replacement.

3. As a second exception, animals shall also be considered to be organic if, where appropriate, they comply with the following requirements regarding their origin:

- a) Calves incorporated into the organic operation up to the age of 14 days which have received colostrum and do not come from livestock markets.
- b) Breeding cattle stemming from extensive farms. When the females are incorporated into the organic farm they must not yet have bred for the first time.
- c) Milk-producing animals must be under organic management conditions from the third month of pregnancy; and
- d) Birds must have been under continuous organic management conditions from the second day of their life. For the eggs of laying birds to be considered organic they must correspond to the egg-laying of birds kept for at least 6 weeks under organic conditions.

4. To make use of these exceptions an authorization from the certification body must be requested.

Article 23. Food.

1. All of the animal production systems must reach the optimal level in which 100% of the food system is compliant with this Regulation (See Annex A; Tables: 4.1; 4.2; 4.3; 4.4 and 4.5). However, under extreme climate conditions or other circumstances of force majeure as declared by the Competent Authority and with its authorization the use of conventional feed shall be allowed in a quantity of no more than 10% for ruminants and 20% for non-ruminants. This circumstance must be recorded and a program of progressive introduction of certified feed must be applied.

2. When the basis of the animal's diet is grazing the meadows that are used to that end must comply with the principles laid down in Heading 5 of this Regulation and when it is forage this must originate from production units that comply with the same principles.

3. Keeping the livestock in nourishment conditions that can cause malnutrition is not permitted. The operator must feed the cattle with a diet composed by agricultural products, including grasses and forage which have been produced and managed organically. For the usual feed, it is only allowed to use supplements such as: salt, trace elements, vitamins and minerals of natural origin. The use of nutritional supplements of synthetic origin shall be subject to authorization by the Competent Authority, provided there is adequate justification for health reasons. During the lactation period milk substitutes are allowed to be used provided all of the components are organic.

4. The nourishment of animals reared in an organic system includes a wide range of products which must be generated and managed in accordance with this Regulation in order to be considered acceptable in the diet of poultry, bovine, porcine and caprine livestock, among others. The origin and the main foodstuffs considered are the following (see Annex A, Tables: 4.1; 4.2; 4.3; 4.4 y 4.5) :

- a) Food of vegetable origin: cereals, grains, its derived products and by-products. Oil seeds, legumes, tubers, root vegetables, other seeds and fruits, forage and other plants (See Annex A, Table 4.1).
- b) Food of animal origin: sustainably produced milk and dairy products, fish and other marine animals; fish oils and unrefined oils from fish liver; shellfish or crustaceans and fishmeal (See Annex A, Table 4.2).
- c) Food of mineral origin: food additives, traces of iron, iodine, cobalt, copper, manganese, zinc, molybdenum, selenium (See Annex A, Table 4.3); and
- d) Food that can originate from one or several of the groups above: enzymes, microorganisms, preservation substances, agglutinants, coagulants, softeners and adjuvants (See Annex A, Tables: 4.4 and 4.5).

5. In the case of herbivores, rearing systems shall be based on the maximum use of pastures according to the availability of these pastures during the different seasons. At least 60% of the dry matter in daily rations will consist of common, fresh, dried or ensiled forage. Concerning animals for milk production the certification body may, however, authorize that said percentage is reduced to 50% for a maximum period of 3 months at the start of the lactation.

6. The producer of an organic operation must not:

- a) use drugs for animal use including hormones to stimulate growth,

production, reproduction control or for other purposes;

- b) perform force-feeding or provide food supplements or additives in quantities that exceed the necessary amounts for the species' adequate nutrition and health at that specific stage of its life;
- c) feed with plastic pellets;
- d) use formulas that contain urea or manure;
- e) use by-products from the slaughter of mammals or birds to feed mammals or birds; or
- f) use any other type of food that is not listed in this Regulation.

7. Where necessary when milk from the biological mother is not available newborn animals may be reared artificially by feeding them with mother's milk of organic origin or colostrum preserved in accordance with organic methods. For caprine and ovine animals the use of organically produced cow milk is allowed.

Article 24. Prophylaxis and veterinary care.

1. Only animals which are in a good state of health must be certified as organic. The producers must keep respective records that are up to date and record all injuries or illnesses the animals have suffered as well as treatments applied and the results obtained.

2. Veterinary prescriptions must clearly define the name of the drugs, the name of the active ingredients, the details of the diagnosis, the dosage, the route of administration, the duration of the treatment and the period of care. Everything mentioned above should be recorded.

3. The use of chemically produced allopathic medicines, antibiotics, anabolics or similar products is not allowed. However, when a sick animal does not respond to the treatments prescribed by this Regulation, and if it is crucial to administer treatment to avoid unnecessary suffering or distress to the animal or if there is a public health risk, the use of chemically produced allopathic veterinary medicine or antibiotics shall be allowed under the responsibility of a veterinarian. The care period equal to twice the time determined by the Agriculture and Livestock Service must be respected and it must be for a minimum of 48 hours.

4. With the exception of vaccinations, antiparasitic treatments and control programs or mandatory eradication schemes, when an animal or group of animals receive more than three treatments with chemically produced allopathic veterinary medicine or antibiotics within a period of 12 months (or more than one treatment if their productive lifecycle is less than one year), animals or products derived from them may not be sold as organic products and these animals shall be subject to the transition periods set out in Article 21.

5. Protecting animals against diseases and pests and maintaining hygiene in the premises where they live must be done exclusively with the techniques and products listed in Annex A, Table 3. Preference must be given to phytotherapy, using extracts of natural plants (excluding antibiotics) and essential oils. Likewise, homeopathic, biodynamic and Ayurvedic products derived from plants, animals or minerals must be used.

6. In the event of an accident which alters organic conditions, or if unauthorized products are applied due to force majeure as declared by the Competent Authority, this event must be registered in the respective records and must be communicated to the certification body within 24 hours of the event. The contaminated products must be identified and separated from the rest of the production. These may not be sold as organic as long

as the transition period, which for these cases is determined by Paragraph 2 of this article, has not been completed.

Article 25. Methods for zootechnical management, transportation and animal product identification.

1. The organic production system favors natural mating and allows the use of artificial insemination. The use of other forms of artificial or assisted reproduction, such as embryo transfer, is not allowed.

2. The producer must set up and maintain preventive measures to promote animal welfare, drastically minimizing the actions that inflict pain or cause stress, especially:

- a) Mutilation is not allowed with the exception of castrations, tail amputations for ovine species, dehorning and ringing. These activities must be recorded.
- b) It is prohibited to file, cut or extract teeth, cut wings, cut beaks and perform any practice other than those mentioned as acceptable which inflicts suffering or damage to the animal's natural constitution.
- c) All cases of necessary amputations must be duly justified to the certification body; and
- d) In any case such necessary mutilations must be performed by qualified personnel using appropriate systems to avoid any suffering by the animals.

3. Weaning should occur at the minimum age of:

- a) Ovine y porcine animals : 35 days
- b) Caprine animals : 60 days
- c) Bovine animals : 90 days
- d) South American camelids : 180 days.

4. The minimum age for birds to be slaughtered:

Birds	Minimum age to be slaughtered (days)
Chickens	81
Capons	150
Ducks	90
Hens	94
Turkeys	140
Geese	140
Ostriches	300
Emus	300
Rhea	240
Quails	50

Producers who use races of greater precocity must record that fact in their management plan and receive authorization from the Competent Authority to slaughter at earlier ages.

5. Organic production animals must be identified individually or by batch in the case of poultry so that their traceability can be reliably determined from birth to slaughter and during the sale of their products and by-products.

6. Certification bodies may establish areas of transhumance for organic animal feeding.

Article 26. Manure.

1. The producer of organic animals must handle manure in such a way that it does not contribute to the contamination of crops, soil and/or water, through plant nutrients, heavy metals and/or pathogens. Likewise, efforts must be made to optimize nutrient recycling.

2. Regardless of the stipulations of Article 27 of this Regulation livestock density should be determined in such a way that the nitrogen excreted by the animals on the used agricultural area does not exceed the limit of 170 kg of nitrogen per hectare per year. The surplus manure, preferably composted, must be removed from the used agricultural area and may be used in other operations.

3. Fresh animal manure, originating from extensive farming, must be composted to be used on croplands, unless:

- a) It is applied on lands used for crops that are not meant for human consumption.
- b) It is introduced into the soil with a minimum of 120 days before harvesting a product whose edible part has direct contact with the soil surface or with soil particles.
- c) It is introduced into the soil with a minimum of 90 days before harvesting a product whose edible part has no contact with the soil surface or with soil particles.

Article 27. Stables, outdoor areas and animal accommodation.

1. In order to isolate organic livestock production and safeguard its status as such it is essential that the pastures' fences are kept in good condition and are of materials which are not toxic for animals.

2. The structures where animals intended for organic production are kept must cover the basic needs of the species concerned and allow them to express their patterns of behavior such as marking territory, resting, foraging, developing their gregarious instincts, establishing hierarchies or other similar activities. Animals must have easy access to food and water.

3. The buildings must be insulated and have a functional design that allows proper management of temperature levels and natural ventilation, air circulation, control over the level of dust, humidity, gas concentration and offer access to natural light. The animals should have free choice to stay inside the buildings or outside of them. To that end openings of a size and location suited to the characteristics of each species must be available to facilitate exit and entry.

4. The number of animals must be in line with the surface area of the operation, the nature of the species in question, the aim of production and the management systems used.

5. The maximum animal density allowed per hectare of pasture on an organic operation is as follows:

Type of animal	Number of animals/hectare
Equine animals older than six months	2
Fattening calves	5
Bovine animals younger than one year	5

Bovine males between one and two years	3.3
Bovine females between one and two years	3.3
Bovine males older than two years	2
Steers or heifers	2.5
Fattening steers	2.5
Dairy cows	2
Dry cows	2
Other cows	2.5
Rabbits	100
Caprine and ovine animals	13.3
Piglets	74
Fattening pigs and other pigs	14
Birds, chickens, ducks, geese	580

6. The minimum indoor and outdoor surfaces and other characteristics of the accommodations for different species and types of production must not be less than:

6.1. Bovines, Ovines and Pigs

	Covered area (Available surface area per animal)		Open area (exercising surface not including pastures)
	Minimum live weight (kg)	m ² /head	m ² /head
Breeding and fattening cattle (bovine and equine)	up to 100	1.5	1.1
	up to 200	2.5	1.9
	up to 300	4.0	3
	more than 350	5 with a minimum of 1m ² /100 kg	3.7 with a minimum of 0.75 m ² /100 kg
Dairy cows		6	4.5
Breeding bulls		10	30
Sheep and goats		1.5 sheep/goat	2.5
		0.35 lamb/kid	2.5 with 0.5 per lamb/kid
Farrowing sows with piglets of up to 40 days		7.5	2.5
Fattening pigs	up to 50	0.8	0.6
	up to 85	1.1	0.8
	more than 85	1.3	1
Piglets	Older than 40 days and up to 30 kg	0.6	0.4
Breeding pigs		2.5 female	1.9
		6.0 male	8.0

6.1. Poultry

	Covered area			Open air space
	Available surface area per animal			Available area when rotating/head (m ²)
	Number of animals/m ²	cm of perch/animal	Number of animals/nest	
Laying hens	6	18	Eight laying hens per nest or, if it concerns a common nest, 120 cm ² per bird	4 Provided the limit of 170 kg N/ha/ year is not exceeded.
Fattening poultry (in permanent accommodation)	10, with a maximum of 21 live kg/m ²	20		4 meat chickens 4.5 ducks 10 turkeys 15 geese The limit of 170 kg N/ha/year should not be exceeded for any of the species above.
Chicks being fattened in mobile accommodations	16* mobile accommodations with a maximum weight of 30 kg live weight/m ²			2.5 Provided the limit of 170 kg/N/ha/year is not exceeded.
Quails	28	18	A maximum of seven if the space is 50 by 50 cm	4 Provided that the limit of 170 kg/N/ha/year is not exceeded.
* Exclusively for mobile accommodations that do not exceed 150 m ² of available area and do not remain covered by night.				

7. When livestock production systems with specific characteristics do not comply with the densities listed in the tables above, the certification body shall be able to examine each case and authorize other densities as long as the general principles for organic livestock production of this Regulation are not violated.

8. The conditions of animal welfare must comply with the applicable regulations on the matter in particular the stipulations of Act No. 20380 on Animal Protection and its complementary regulation, regardless of the production system's design. The organic livestock production must take into account the specific needs of the animals' natural health and welfare and meet the following requirements:

- a) Appropriate cleanliness.
- b) Bedding that does not affect health and does not inhibit the species' natural behavior. If it is part of the usual diet of the species in question, it must meet the requirements for organic feed.
- c) Specifically designed shelter and protection from different climates

so that while maintaining the animals' natural behavior conditions and normal exercise an appropriate level of temperature, ventilation and air circulation is ensured, depending on the species in question. This is so that there is a reduced risk of damage to the animals and so that thermal stress is avoided.

- d) Smooth not slippery floors with at least 50% made of solid construction. The use of slats or grates as flooring is not allowed; and
- e) Free access to clean water sources for their welfare and hygiene.

9. Keeping animals tethered is not allowed except temporarily for health or welfare reasons. The animals must be kept in groups. Calves of more than one week old must not be left in individual boxes. Birds must be kept in open spaces and the use of individual cages that inhibit the access to outdoor areas is not allowed. Pregnant sows are an exception to this rule. They must be isolated during the last part of their pregnancy and after childbirth, during suckling.

10. Only rearing organic animals in an extensive system is allowed. Pigs and lambs for breeding may be kept in pens for a maximum period that does not exceed one fifth of their lifespan and never for more than 3 months.

11. A temporary confinement can be set up in the following cases:

- a) due to inclement weather conditions
- b) because the phase in the breeding cycle requires it
- c) due to special conditions that constitute a risk to the animals' health, welfare and/or security and
- d) due to specific risks caused by unexpected changes in soil and/or water quality.

Article 28. Animal slaughter.

1. Without prejudice to the stipulations of the applicable legislation, slaughtering animals of organic production and processing their meat, must be performed in accordance with this Regulation.

2. Traceability must be ensured for organic products by means of documents from the origins and through the processes such as slaughter, taking into account all intrinsic unit operations, packaging and labeling. The appropriate steps must be taken to prevent mix-ups and/or mistakes with conventional products.

3. Compliance with the applicable regulations on animal welfare and transportation must be ensured.

4. The slaughter and butchering of animals of organic production must be done separately from those originating from conventional farms and each of them must be identified in such a way that said identification is maintained throughout the slaughtering process.

5. In the event that an accident occurs during the slaughtering process which alters the organic condition of an item or batch this must be registered in the records of the company within 24 hours of the event and the non-organic products must be identified and separated from the rest of the production. The accident must be reported to the certification body or the Competent Authority.

6. The substances and procedures used when cleaning the facilities and instruments and when disinfecting, removing insects, and exterminating rats in the enclosures must be the ones listed in Annex A of this Regulation.

HEADING 7

Specific regulations for organic bee production.

Article 29. General principles

1. Beekeeping is an important activity that is consistent with the basic principles of organic farming and contributes through pollination by bees to environmental protection and the sustainable production of agroforestry ecosystems.

2. Organic bee product certification is only possible for honey, pollen, royal jelly, wax and propolis obtained in accordance with this Regulation.

3. Parallel bee production is not permitted. However, exceptionally and by authorization of the certification body, where the organic production unit is affected by climate, geographic or structural constraints the operator may have non-organic bee production units for pollination purposes provided that the requirements of this Regulation are met, apart from the provisions concerning the location of the beehives or apiaries laid down in Article 32 of this Regulation. Products obtained from non-organic bee production units may not be sold as organic. The operator shall ensure traceability and differentiated control over both production systems.

Article 30. Transition period.

1. The transition period from the conventional to the organic system is 12 months. Certification as organic produce is only possible for primary and processed bee products after the first season.

2. The certification body with the consent of the Competent Authority may extend the periods indicated in point 1 of this Article, in some cases, depending on the previous use of the concerned production unit.

Article 31. Origin of bees.

1. The organic bee production unit may be formed by packaged bees, hives, natural and/or artificial swarms or nucleus colonies.

2. In beekeeping preference shall be given to hardy, local species which have adapted to the environment with particular emphasis on their strength and disease-resistance.

3. Hives shall be renewed or augmented by dividing them or the purchase of queen bees, packages of bees and/or nucleus colonies, having obtained all of them from organic production units. Replacement shall be possible of up to 10% per annum of queen bees, bee packages or swarms by others from non-certified hives and these shall be placed in hives with honeycombs or sheets of beeswax from organic production units. To that end the operator shall record both the origin of and the hives containing these bees and/or queen bees in the relevant organic production unit.

4. In the case of serious mortality of bees owing to disease, pests, disaster, or an agricultural emergency as declared by the Competent Authority, the latter may authorize the re-establishment of apiaries where no hives that meet organic beekeeping standards are available. Hives affected by such a situation shall remain in transition.

Article 32. Location of apiaries/bee hives.

1. The apiaries to be used for organic bee production shall be located in places with sources of nectar, honeydew and pollen obtained predominantly from wild vegetation or crops treated with methods and products that do not affect the organic status of bee production.

2. They shall be located at a minimum distance of three kilometers from conventional apiaries.

3. The apiaries shall be located at a minimum distance of three kilometers from areas exposed to the use of methods, products or activities that may affect the organic status of bee production, such as towns and cities, industrial areas and landfill sites. This requirement also applies to cases of transhumance of hives subject to the organic production conditions.

Article 33. Food

1. Bees must have easy access to abundant sources of clean water.

2. Where hives are deprived of food reserves due to a climate emergency or disaster as declared by the Competent Authority and this endangers the survival of the hives, bees may be artificially fed honey and/or pollen of organic origin, sugar syrup, organically produced sugar or foodstuffs authorized for organic beekeeping by the Competent Authority. Withdrawal of the reserve honey from within the brood chamber or its replacement with syrup, molasses, honey by-products or other sugary substances is not permitted.

3. At the end of the production season, abundant reserves of honey and pollen shall be left in the hives for the bees' hibernation in the hives. In the case of artificial feeding of the hives for purposes of supplementation or conservation, honey and/or pollen of organic origin or products authorized for beekeeping in this Regulation may be used between the last honey harvest of the season and the two weeks before the first nectar flow.

4. The circumstances in which artificial feeding occurred shall be recorded including the reason, product utilized and its origin, the dates and the hives or apiaries treated.

Article 34. Prophylaxis and veterinary treatment

1. Treatments to maintain the health of the hives using the products indicated in Annex A, Table 5 of this Regulation are authorized. Preventive treatment with allopathic medication is prohibited. The preventive approach shall focus particularly on systematic checks of the hives for timely detection of health anomalies and control of the causes. Priority shall be given to disinfection of materials and equipment, the elimination of contaminated matter, regular replacement of the beeswax, and checks to ensure an adequate reserve of honey and pollen in the hives.

2. In the case of disease, affected hives shall be separated and moved away from the rest of the apiary. Antibiotics of synthetic origin or sulfonamides may not be used. The approach to be used in the case of

parasitic disease and varroosis is to follow and utilize the practices and methods described in Annex 1, Table 5 of this Regulation.

Article 35. Zootechnical management and identification.

1. The operator shall record the location(s) of the apiaries and the identification of the respective hives.

2. The operator shall inform the certification body of the date and place to which the hives are changed or moved. The certification body shall convey this information to the Competent Authority in a timely fashion.

3. In the event of an accident occurring which alters the organic status or an application of unauthorized products for reasons of force majeure as declared by the Competent Authority this situation must be noted in the relevant records and the certification body must be informed within 24 hours of the event. The apiaries and/or production batches affected must be identified and separated from the remainder of the output, and may not be sold as organic.

4. Chemical repellents must not be utilized when handling bees.

5. Harvesting from frames with young bees is not permitted.

6. Any action is prohibited that could undermine the physical welfare, or cause the death of bees in circumstances such as:

- a) Killing the bees when brushing the frames during harvesting and
- b) Mutilating the insects such as clipping the wings of the queen bee.

7. Notwithstanding point 6 of this Article the following is permitted:

- a) Killing an old or faltering queen bee during a replacement operation.
- b) Destroying the cells of immature males during operations to eliminate varroosis.
- c) Destroying undesired royal cells; and
- d) Killing bees and/or young bees for the purposes of sampling or sanitary control alone.

Article 36. Characteristics of hives and of equipment used in beekeeping.

1. Hives utilized for organic production shall be made of wood or other traditional materials. Hives made of plastic, fiber glass or of other materials of synthetic chemical origin are not permitted. The interior shall not be coated with paint, varnish or other similar products. The treatment of hives with pesticides is not permitted either and during their replacement only products listed in Annex A, Table 5 of this Regulation is permitted. The use of vegetable oil or non-synthetic and/or unleaded paint alone is permitted for the coating of exterior surfaces.

2. The sheets in the frames shall be of pure, recycled, organically-sourced beeswax. The addition of paraffin or substitutes to natural wax is prohibited. For wax preservation refrigeration, sulphur and biological control are permitted. Chemical products must not be used to treat or preserve wax. The quantity of wax produced shall be recorded along with the extraction and processing methods. Where external stamping of wax sheets is required the method, place, time of year and identity of the provider of the wax sheet stamping service shall be recorded and it may only be performed using wax from organic hives. The certification body shall check

to ensure that the wax employed by the operator during organic production is free from prohibited substances by sampling the stamped sheets.

3. Only products of vegetable origin which do not compromise the organic status of the honey, pollen, royal jelly, propolis and wax may be utilized as smoker fuel.

Article 37. Bee products.

The following requirements must be fulfilled for organic certification of the following bee products:

1. Honey

- a) This must come from hives managed in accordance with this Regulation.
- b) Uncapping shall be carried out at a temperature not exceeding 35°C during the procedure.
- c) The extraction and storage of honey shall be done using stainless steel recipients and machinery or those coated in food-grade epoxy paint. Plastic, galvanized or bare metal recipients must not be utilized.
- d) The maximum temperature to which honey may be warmed for extraction is 70°C for no longer than two seconds or failing this a temperature in excess of 40°C must not be employed.
- e) Merchandizing containers shall be food grade and preferably made of recyclable glass with hermetic seals.
- f) Extraction shall be carried out in harvesting rooms authorized by the certification body without prejudice to current legal requirements.
- g) The traceability requirements established by the Competent Authority shall be fulfilled.
- h) The containers or drums from a production batch to be used to artificially feed the hives must be identified; and
- i) A monthly record shall be kept of production and sales per apiary, pursuant to Heading 11 of this Regulation.

2. Pollen

- a) Pollen must be collected from hives managed in accordance with the specifications in this Regulation.
- b) Pollen must be dried using heat sources not exceeding 35°C and with no direct exposure to sunlight.
- c) It must be kept in hermetically sealed and refrigerated containers or in dry, well-ventilated and preferably dark places.
- d) Pollen extraction must be carried out in the period when hives are producing honey (raised) to prevent nutritional detriment to the hive;
- e) A monthly record shall be kept of production and sales per apiary; and
- f) The containers with the respective quantity of pollen stored in each, to be used for the artificial feeding of the hives must be recorded, pursuant to Heading 11 of this Regulation.

3. Royal Jelly

- a) Royal jelly must be extracted from hives managed in accordance with the specifications in this Regulation.
- b) Queen cells for the production of royal jelly must be made of beeswax or, if artificial, be covered in this.
- c) The hives must be fed with honey and/or organically produced pollen and stimulation with honey or pollen substitutes is not permissible.
- d) Royal jelly produced must be refrigerated and kept in food-grade containers and must not be allowed to be affected by daylight; and

- e) A record of monthly production and sales per hive must be kept, pursuant to Heading 11 of this Regulation.

4. Propolis

- a) Propolis must be extracted from hives managed in accordance with the specifications in this Regulation.
- b) Regarding extraction of propolis from the hive, food-grade plastic traps, stainless steel nets or scraping of this matter from the hive are permitted.
- c) It must be stored in hermetically-sealed and refrigerated recipients or in dry and well-ventilated places; and
- d) A monthly production record must be kept with a breakdown per extraction method for each apiary or hive, as appropriate, as well as a monthly sales record per apiary pursuant to Heading 11 of this Regulation.

5. Wax

- a) Wax must be extracted from beehive frames managed according to the specifications in this Regulation.
- b) For extraction of wax from the frames, steam, hot water or solar radiation treatments are permitted. Containers shall be used that will not contaminate the wax, preferably made of stainless steel.
- c) The wax must be kept in closed containers in dry and well-ventilated places.
- d) Annual production and monthly sales records must be kept, pursuant to Heading 11 of this Regulation; and
- e) Only substances authorized in Annex A of this Regulation must be used to make embossed wax sheets and the product's organic quality must be guaranteed throughout.

HEADING 8

Specific regulations for organic fungi production

Article 38. Organic certification can only be granted for primary, processed physical products obtained pursuant to this Regulation during a period equivalent to the species' natural cycle from preparation of the substrate to complete development of the infrastructure.

Article 39. In some cases the certification body may extend the periods indicated in the preceding article, depending on the prior use of the production unit.

Article 40. There must be no residues of banned substances in the organic fungi production unit.

Article 41. To avoid cross contamination or contamination between conventional and organic fungi production areas the air and water used must be properly isolated. If this were not possible, parallel production must not be carried out.

Article 42. The propagation material used must have been produced in premises that fulfil the above-mentioned conditions and it must not be

genetically modified. Where grains (wheat, oats, millet etc.) are used to produce the inoculum these must be organic and in the case of the use of wooden pegs the wood must not have been treated with chemicals.

Article 43. The substrate used during the production phase must be obtained in accordance with organic production standards.

Article 44. Pest and disease prevention must be effected by managing environmental conditions (temperature, humidity, concentrations of gases, light and so on) in ranges appropriate to the requirements of each species of fungi being grown. Physical methods may also be used, such as nets, traps and thermal treatments which foster aseptic conditions in premises associated with the production process (composting, pasteurization, sowing, incubation, production, packaging and storage). Entry by people into these premises must not endanger these aseptic conditions and this shall be ensured through the use of special clothing (gowns, gloves and clean footwear exclusively for indoor use).

Article 45. Contamination by bacteria, mold, other organisms or contaminants at any stage of the production process must be controlled by physical, biological or mechanical means such as heat and the physical elimination of the product. If this were not possible one of the products indicated in Annex A, Table 2 of this Regulation may be applied. The application of chlorine is permitted in extreme cases, provided that the concentration does not exceed 3mg/L (3ppm) of free chlorine.

Article 46. In the case of a change in the organic status this fact must be registered in the respective records and communicated to the certification body within 24 hours of the event. Contaminated products must be identified and separated from the remainder of the product. Said produce may not be sold as organic.

HEADING 9.

Specific regulations for organic processed products.

Article 47. General Points.

1. An organic processed product is considered to be a primary, organic product which has been subject to one or more of the following individual operations: cooking, blanching, drying, mixing, grinding, beating, separating, extracting, cutting, preparing for retail or whole-sale merchandising, freezing, concentrating or another individual operation that makes it possible to manufacture or process a foodstuff or change its physical characteristics. The container is also included.

2. The following are not deemed to be individual industrial processing operations: selection, washing with water, refrigeration, or any other treatment that only delays or accelerates the natural maturation or decomposition process provided that it is carried out at the same farm.

Article 48. Raw materials, additives and processing aids.

1. The following applies to raw materials, additives and processing aids used in the manufacture of processed products:

- a) Organically certified raw materials must be utilized.
- b) Additives, aids, and colorants used to make the product must be included in Annex B of this Regulation.
- c) Processing aids used to make the product must be included in Annex C of this Regulation; and

d) The water used as an ingredient must meet the current standards.

2. Restrictions concerning raw materials, additives and processing aids for the manufacturing of processed products:

- a) The use of an organic raw material alongside a non-organic raw material is not acceptable.
- b) Synthetic colorants, preservatives and flavorings are forbidden.
- c) Raw materials of synthetic chemical origin, as well as sulphites, nitrites and nitrates shall not be added during the production stage or during handling or in the product's subsequent preparation other than in the case of wines containing added sulphites, in accordance with this Regulation; and
- d) Raw materials contaminated with heavy metals and/or pesticides must not be included.

3. Where ingredients are not available on the domestic market in sufficient quantity and they cannot be developed organically and are essential for formulation of the product, as an exception non-organic farming ingredients constituting up to 5% of the product's weight may be used, apart from water and salt. Fulfilment of the provisions of points 6 and 7 of Article 49 of this Regulation shall be demonstrated.

Article 49. Processing.

1. The ingredients and products themselves must not be subjected to ionizing radiation treatments.

2. Water to be used during processing which comes into contact with the foodstuffs without being an ingredient in the product must be of drinking quality.

3. Organic processing must be effected in a complete series. Commencement of the process of manufacturing the organic products must be communicated to the certifying body.

4. Whenever the processing of organic and conventional products is carried out this must be done at different times and must fulfil the conditions for cleaning prior to commencement of organic processing. Every precaution must be taken to avoid cross contamination or contaminants in the organic products and the procedures and records demonstrating fulfilment of these measures must be available.

5. Organic production batches must be adequately identified and it is necessary to ensure that these are not mixed with conventional products. At the same time, traceability of the inputs and/or raw materials in the production batches must be ensured.

6. In the event that a batch or item is accidentally contaminated during processing this must be registered in the records of the organic production unit and this fact must be communicated within 24 hours of the event to the certifying body. The contaminated product must be identified and separated from the rest of the production and may only be certified with the express authorization of the Competent Authority once it has properly assessed the particular situation.

7. Ingredients of non-organic farming origin.

When an organic ingredient is required for processing a foodstuff and it is not produced in sufficient quantities in accordance with organic production standards or cannot be imported, an ingredient of non-organic farming origin may be used if the following provisions are met:

- a) The Competent Authority has authorized its use, after evaluation by the certification body.
- b) Where the Competent Authority has provisionally authorized its use for a maximum of 12 months having verified that the ingredients with organic status in question are unavailable; and
- c) Where the conditions that gave rise to authorization being granted for the use of the ingredient in question have not changed, the Competent Authority may extend the authorization set out in point b) above up to three times for periods of 12 months.

The procedure for authorizing the use of ingredients of non-organic farming origin shall be established by the Competent Authority.

Article 50. Special conditions governing processing facilities.

1. Establishments manufacturing organic products and conventional products must have segregated, different and identified facilities to store organic raw materials separately from conventional ones as well as for products manufactured with each of these two types of products.

2. Establishments where organic products are manufactured or processed must have a system to impede cross contamination or contamination between organic and conventional products.

3. In respect of the cleaning of equipment and utensils, the products listed in Annex A, Table 6 of this Regulation are permitted.

4. Among pest and disease control treatments (disinfection, insect removal and rat extermination) the following may be utilized in processing facilities: physical barriers, sound, ultrasound, light, ultraviolet light, traps (including pheromone and fixed bait traps), temperature controls, and controlled atmosphere (only CO₂ and N₂), without prejudice to stipulations by the Competent Authority.

5. Establishments processing organic products for export are not exempt from the certification obligation set out in this Regulation.

HEADING 10

Specific standards for organic wine

Article 51. General principles.

1. Organic wine must comply with current legal standards relevant in this area.

2. A system must be established to ensure traceability of the product from the outset to the final product.

3. On arrival in the winery the raw material must be clearly identified to prevent mixing with conventional grapes.

4. The principles of recycling of residues and by-products of viticulture and wine-making processes must be respected in the production unit.

5. Processes involving excessive use of water and energy must be avoided

6. The use of sulphur dioxide must be kept to an absolute minimum; and

7. The use must be avoided of any material or substance which by reason of its manufacture, utilization and/or disposal could constitute a health and/or environmental hazard.

Article 52. Raw materials and harvesting.

1. Only grapes obtained through organic farming which are grown in accordance with the standards in this Regulation may be used.
2. Grape harvesting may be manual or mechanical.
3. The following containers must be used to transport the harvested grapes to the winery: easily cleanable and stackable boxes or bins, trailers or tubs fitted with covered receptacles of a maximum depth of 1.2 meters. The grapes must not be allowed to come into contact with metal (other than stainless steel) or wood.

Article 53. The cleaning of harvesting equipment.

1. To perform manual harvesting or grape-picking, the harvesting tools and transportation equipment must be cleaned on every occasion at the beginning of this operation. The products authorized in this Regulation may be utilized for the purposes of cleaning and disinfection.
2. In the case of mechanical grape harvesting, in organically-managed areas the machinery must be thoroughly cleaned before commencing. Cleaning agents authorized in this Regulation must be used.
3. Where plastic containers are utilized to hold and transport freshly harvested grapes, before harvesting commences these must be cleaned with agents authorized in this Regulation and then rinsed to avoid residues.

Article 54. Wine-making

All stages in the operation and grape-processing measures as well as the preparation of the juice for organic wine shall have the following objectives:

1. Juice extraction must be carried out by mechanical means.
2. The use of wine-making machinery and vessels made of or coated with materials that could leach toxic substances or any undesirable substance into the must or wine is prohibited.
3. The following operations, for example, that are inherent in the wine-making process are permitted: racking, pumpovers; topping up, and punch downs.
4. Fermentation must be carried out preferably with yeasts occurring naturally in the must prepared as starters or with selected indigenous yeasts. It is acceptable to utilize pure yeast strains, lactic bacteria and pectolytic enzymes.
5. The use of yeasts, bacteria and/or enzymes obtained from genetically modified fruit or micro-organisms is prohibited, in accordance with Article 6 of this Regulation.
6. The use of refrigeration techniques is permitted in accordance with the terms of this Regulation for the thermal conditioning of the grape harvest, control of fermentation temperatures, conservation, and cold stabilization of wine and halting fermentation in the manufacture of sweet and semi-sweet wines.
7. All organic matter from residues and/or by-products of the manufacturing process must be treated to prevent it from contaminating the environment.
8. For vinification the use is permitted of containers such as wood barrels and casks and/or bottles and untreated oak chips and staves.

Article 55. Wine-making processes.

1. Acidity control
It is preferable to achieve acidification by adding highly acidic must or wines obtained at early harvest.

Acidification by means of acids is only permitted in the case of the addition of naturally occurring I (+) tartaric acid.

2. Enrichment

In the case of sweet and semi-sweet wines, the addition of organic must with a high sugar content obtained from sun-dried or semi-dried and partially fermented or unfermented grapes is permitted.

In the case of sparkling wines, the addition of organic sucrose, grape sugar or concentrated organic required for their manufacture is permitted.

3. Clarification and stabilization

Sedimentation should preferably be achieved naturally.

The products listed in Annex A, Table 7 of this Regulation may be utilized. Where it can be shown that it is impossible to obtain such products of organic origin, the certifying body may authorize the use of conventional products listed in Annex A, Table 7 of this Regulation.

The use of silver, potassium ferrocyanide, calcium phytate, metatartaric acid, polyvinylpyrrolidone (PVVP) and/or bovine blood is prohibited.

4. Filtration

Filtration must be carried out using membrane filters or filters made of perlite or diatomaceous earth (kieselguhr) or other substances that do not imbue the wine with a smell or flavor nor contain heavy metals, and which are authorized by the certifying body.

5. Blending

Blending is only permitted of wines which have been produced organically.

6. Sulphiting

Combustion using pure sulphur tablets as a disinfectant and sulphur wicks on cellulose bases is permitted only in empty recipients not containing must or wine.

The addition of 100% pure sulfur dioxide (SO₂) in gas form or in watery SO₂ solutions (k metabisulfate) is permitted.

The total SO₂ content (mg/L) in the finished product must be as low as possible and must not exceed the limits established in the following table:

MAXIMUM TOTAL SO₂ CONTENT

Products	Maximum total SO ₂ content (mg/L)
Red wines	100
White or rosé wines	
a) dry	120
b) sweet and semi-sweet	150
c) fortified or liqueur wines	150
d) sparkling	100

In cases of exceptional farming/climate circumstances, the Competent Authority shall be empowered to authorize SO₂ levels higher than those established in the above table within the terms of the current legislation with a maximum limit of 160mg/L for red wine and 210mg/L for white wine and rosé.

7. Pasteurization.

The use of flash pasteurization techniques and amicrobic filtration with inert membrane filters is permitted as a means of avoiding the utilization of sulphur dioxide and in cases where this is required and technically justified.

8. Ageing

The maturation and ageing of wine is permitted by means of natural systems in wood containers and/or bottles, as well as the utilization of untreated oak wood chips and staves.

9. Storage

The conservation of organic wines must ensure traceability from the outset.

Storage vessels must be made of stainless steel, wood or enameled steel for winemaking or be cement vats or vats made of reinforced masonry coated on the inside with epoxy paints that contain no solvents.

In order to conserve wines in an inert atmosphere the use of nitrogen and CO₂ gases is permitted.

The use of enamels that contain lead in the vats is prohibited.

10. Other wine making processes

Where required for the final product, the addition of or dilution with carbon dioxide is permitted.

Where required technically, the treatment of the wines is permitted with purified carbon or washed activated carbon that contains no toxic substances for deodorizing purposes.

The following treatments are prohibited in wine-making processes: the elimination of sulphur dioxide (SO₂) by means of physical processes; electro dialysis treatment and cation exchange treatment to stabilize the tartaric acid in the wine; partial dealcoholisation of the wine; filtration employing pores of less than 0.2 µm in diameter; the use of electro-membranes and in the case of thermal treatments, temperatures must not exceed 70°C.

The use is prohibited of sorbic acid and salts thereof as preservatives.

11. Sales packaging and containers

Properly washed and recyclable glass bottles must be used. Tops or covers made of inert material or natural pure cork must be used. Tops made with a mixture of cork and cork board may be used provided that it is the natural cork that remains in contact with the wine.

The use of corks printed using natural inks is permitted. Heat affixing is allowed.

In the case of whole cork and cork board the resin used must be of high purity. They must not contain solvents or formalin.

The washing of corks must be carried out without adding chlorine or disinfectants which are not authorized in this Regulation. Sterilizing the cork using ionizing radiation is prohibited.

The use of capsules containing lead, tin or polystyrene is prohibited.

The use of polystyrene for transport packaging is prohibited.

The use of glues containing polyvinyl chloride (PVC) is prohibited.

12. Labelling

All wines made with 100% organic grapes, made and bottled in accordance with this Regulation, may be labeled as organic wine on the main label of the bottle when this is permitted under current legal regulations.

Wines not manufactured using organic must or grapes may not be labelled organic wine.

The label at the back must show the name of the body certifying the process in respect of obtainment of the organic grapes, the wine-making and the product's bottling and packaging.

The use of paper and pigments containing heavy metals is not permissible for the labels.

13. Cleaning and disinfection

All detergents and disinfectants containing chlorine are prohibited. Cleaning and disinfection shall be carried out with a view to optimal environmental conservation conditions using products authorized in this Regulation.

HEADING 11

Records

Article 56. Production units and establishments must keep records necessary to demonstrate to the certifying body and the Competent Authority their fulfilment of the relevant technical standards for organic agriculture. The files shall be tailored to the production system for which they desire certification. They must contain sufficient information concerning all field activities and transactions to facilitate verification and auditing and they must be kept for at least five years from their date of creation.

In the case of production or processing units also carrying out conventional activities, a record of these operations must be kept and be made available, when required, to the certifying bodies and the Competent Authority.

Article 57. The producer of an organic livestock operation must store sufficient information to preserve the identity of all organically managed

animals as well as the edible and non-edible animal products produced in the operation.

Article 58. The producer should ensure strict written, documented and updated accounting, keeping verification documents to back up the statements of the origin, nature and quantities for all raw materials, animals, products and inputs purchased and/or introduced into the system, as well as the use thereof. A similar system should be in place to record all sales. When selling directly to the public, these sales must be recorded daily in the register. All this information must remain available for inspection, certification, verification and clarification of irregular situations detected by the certification body and/or the Competent Authority.

Article 59. To comply with this regulation, the operator shall maintain records and relevant supporting documents relating to entries and details of organic utilization, production, preparation and handling of farming products. The operator has to guarantee the organic integrity of the product through continuous traceability from the receipt of raw materials until product release.

The records must allow to trace the origin, nature and quantities of the organic products that have been delivered in the production unit.

HEADING 12 Labeling.

Article 60. All organic products must be labeled in accordance with current national regulations and, additionally, the requirements of this Heading.

Article 61. Primary and processed organic products should be labeled, where appropriate, with the expressions '100% organic'; 'organic'; 'Produced with organic ingredients'; or 'contains less than 70% organic ingredients', immediately after the description of the product. The label must be authorized by the certification body, and this body shall be identified on the final product's label.

Article 62. The term organic can only be used in the labeling of natural or processed farming products, including ingredients that have been produced, handled and marketed in accordance with the specifications stipulated by this Regulation. The term organic may not be used to describe a product that modifies a nonorganic ingredient.

Article 63. Livestock meat products may be labeled as 'meat produced from animals raised under organic production' if these have been produced from certified organic animals. This description must be authorized by the certification body.

Article 64. To label a product as '100% organic', it must consist of 100% organically produced ingredients, expressed in weight (mass) or

volume, excluding the water and salt contained.

Article 65. To label a product as 'organic', it must consist of at least 95% organically produced ingredients expressed in weight (mass) or volume, excluding the water and salt contained. The label must identify the 3 main organic ingredients in the product.

Article 66. To label a product as 'produced with organic ingredients', it must consist of at least 70% organically produced ingredients expressed in weight (mass) or volume, excluding the water and salt contained. The label must identify the 3 main organic ingredients in the product.

Article 67. To label a product as 'contains less than 70% organic ingredients', it must consist of organically produced ingredients in a percentage less than 70% expressed in weight (mass) or volume, excluding water and salt. The organic ingredients need not be specifically identified on the label.

Article 68. In the case of the 'organic in transition products', the label must mention such status, provided that:

- a) A transition period of at least 12 months has been applied before harvesting; and
- b) The indication is written in the same color, size and font.

This type of labeling is only permitted for fresh products in transition.

Article 69. Containers with products certified as organic must meet the legal provisions on the use of the official seal as determined by the Competent Authority.

Article 70. The use of graphic elements, when labeling containers, to identify the product by any of the degrees of organic, requires the producer, intermediary or seller to keep records showing these certificates, where appropriate so that, if necessary, the organic condition of the product can be corroborated, recorded on the label and its ingredients identified as such.

Article 71. All products using names that include the term organic should state by numeric expression the total percentage of organic ingredients in the final product. In this regard, characters similar in size and prominence should be used as those used in the product name.

Article 72. In transport operations for organic products, external packaging should be labeled, registering the name and address of the producer, the name and address of the intermediary, if there is one, and the name and address of the consignee.

Article 73. Export products produced and certified under foreign organic standards or under conditions of foreign buyers, different from the requirements of this Regulation must be labeled in accordance with the specific requirements of the destination country. Likewise, a document is required for these products to indicate the status of compliance with this Regulation, issued by a certification body registered with the Agriculture and Livestock Service.

Article 74. When there is an agreement of equivalence or recognition of standards with other countries for export companies that send products to said countries certification under this Regulation shall be mandatory.

Article 75. The containers used for dispatching or storing the final product and those that do not reach the final consumer should be labeled with the following:

- a) Product identification as organic using the specific name that corresponds according to the percentage of organic ingredients contained.
- b) Name and address of the unit of origin of the product.
- c) Batch number of the product, if applicable; and
- d) Identification of the certification body.

Article 76. The product labels must include, at least, the following indications:

- a) Product identification as organic using the specific name that corresponds according to the percentage of organic ingredients contained.
- b) The name and address of the last production or processing unit in which the product was handled.
- c) The product's batch number and the month and year of harvest, if applicable.
- d) Identification of the certification body; and
- e) The stamp of the 'National Certification System for Organic Products'.

Article 77. The percentages of organic ingredients which are included in the labeling of primary or processed products must be certified.

Article 78. When calculating the percentage of organic constituents of a product, the figures that include decimals must be rounded down to the nearest whole number.

Article 79. The containers used to transport organic products to foreign markets must be labeled according to the requirements of the specific market and the transportation companies, if these differ from the stipulations of this Regulation. In this case, the legend 'For Export Only' must be added.

HEADING 13

Storage, containers, packaging and marketing

Article 80. Organic products may not be mixed with conventional products.

Article 81. In the case that only a part of the production unit is dedicated to organic production, the non-organic products must be stored and handled separately.

Organic products must be clearly identified.

Article 82. Bottling or wrapping facilities for organic products may be located outside the production unit where the raw materials are

obtained. If organic and conventional products are bottled or packaged in the same facility, these processes must be performed separately.

Article 83. Storing organic and conventional products in the same place shall only be allowed if these two types of products are properly packaged, clearly identified and appropriately separated or there is another system to prevent any cross-contamination or contact with contaminants.

Article 84. Warehouses for organic products in bulk should be separated from the conventional ones and be clearly identified for this purpose.

Article 85. Before using storage sites, the lack of contamination or the absence of contaminants must be demonstrated in relation to any type of product not permitted by this Regulation.

Article 86. The places meant for storage must be thoroughly cleaned by applying methods suited for the product that is to be stored and only with substances permitted by this Regulation.

Article 87. Among the treatments to control pests and diseases in storage sites the following is allowed to be used: physical barriers, sound, ultrasound, light, ultraviolet light, traps (including pheromones and fixed bait traps); temperature control, controlled atmosphere (only CO₂, O₂ and N₂) and diatomaceous earth.

Article 88. The materials used when packing organic products should not contain synthetic chemicals such as pesticides, preservatives or additives. In addition, these materials must comply with the applicable technical standards and relevant regulatory requirements.

Article 89. For the containers of organic products, the use of any materials that have previously been in contact with any substance that could compromise the organic status of the product is not allowed.

Article 90. Packaging materials containing lead, PVC or other chlorinated plastics must not be used.

Article 91. The products must only be transported to wholesale markets and/or retailers in proper containers and sealed in such a way that they prevent the replacement of the product contained. During transport operations of organic products, in which both the dispatcher and the consignee are subject to inspection of the organic production system, it is not mandatory to use sealed containers as described above.

Article 92. Sales establishments and street markets that sell organic products do not require certification if these do not process the product. However, these are required to have all the necessary documentation for selling and the advertising used must be clear and not mislead consumers.

Sales establishments and street markets must allow the Agriculture and Livestock Service to access its facilities and documentation for inspection.

2. - Let Decree No. 17 of 2007 of the Ministry of Agriculture be repealed.

Let this be recorded, acknowledged and published.- MICHELLE BACHELET JERIA, President of the Republic.- Carlos Furche G., Minister of Agriculture.

This I transcribe for your knowledge.- Sincerely, Claudio Ternicier G., Undersecretary for Agriculture.

ANNEX A

Permitted inputs and general conditions of use in organic production.

1. Criteria for the introduction, modification or disposal of active substances, compounds and/or procedures in the tables of this Annex.

1.1 Active substances, compounds and/or procedures that may be used in organic farming are indicated in this Annex as follows:

- a) Fertilizers and soil conditioners.
- b) Pesticides and pest control procedures.
- c) Inputs and procedures to control pests and animal diseases.
- d) Raw materials and additives for animal feed.
- e) Inputs and/or procedures to control pests and diseases affecting apiculture.
- f) Inputs and procedures to clean and disinfect.
- g) Inputs and their general conditions of use in the production of organic wine.

The active substances, compounds and biological organisms, may be used as long as they are authorized in accordance with current legislation, where appropriate.

1.2 The authorization of active substances, compounds and procedures that point 1.1 refers to is subject to the general requirements in Heading 4 of this Regulation and to the following criteria which will be evaluated as a whole to protect the integrity of the organic production:

1.2.1 The use of active substances and compounds originating from organic agriculture, natural substances or derivatives of natural substances and mineral fertilizers with low solubility is allowed.

1.2.2 All active substances and active compounds must be of vegetable, animal, microbial or mineral origin, unless there is insufficient substance or compound available from these sources, the quality is not acceptable or no alternatives are available.

1.2.3 Its use must be necessary for a sustainable production and they must be essential to the end that they are intended for.

1.2.4 The manufacture, use and disposal of the active substance or compound must neither have, nor contribute to harmful effects on the health of people, animals or the environment.

1.2.5 Active fertilizing and soil conditioning substances.

The use of these inputs must be essential to achieve or maintain soil fertility or to meet specific nutritional needs of crops or for specific soil conditioning purposes.

1.2.6 Active pesticide substances for Organic Agriculture.

a) Its use must be essential to control a harmful organism or a particular disease for which there is no other biological, physical or selection alternative, or other effective cultivation or management practice.

b) If the active substances and compounds are not of vegetable, animal, microbial or mineral origin and are not identical to those that occur in nature these will only be allowed or restricted if their conditions of use avoid all direct contact with the edible parts of the crop, and provided that compliance with point 1.2.4 of this Annex is observed.

1.2.7 Raw materials and Additives for Animal Feed.

For the products mentioned in the tables 4.1, 4.2, 4.3, 4.4 and 4.5, the following criteria will apply:

- a) They must prove necessary to maintain animal health, welfare and vitality and contribute to a suitable diet that meets the physiological and behavioral needs of the species, or if without the use of said substances it is impossible to produce or preserve such feed.
- b) Feed made up by minerals, trace elements, vitamins or pro-vitamins shall be of natural origin. Should these substances not be available, it shall be permitted to use chemically defined analogous substances for use in organic production as listed in this Annex.

1.3 Determination of the conditions for use and modification or disposal of active substances, compounds and/or procedures from the tables.

1.3.1 This Annex contains the conditions and limits (manner of use, dosage, the time limits for use and contact with farming products, among others) concerning farming products on which it is allowed to use the active substances, compounds and/or procedures referred to in point 1.1, shall be those contained in this Annex.

1.3.2 By amending this Decree on reasonable grounds it shall be allowed to introduce or delete active substances, compounds and/or procedures referred to in point 1.1 from the tables or modify their use as referred to in point 1.3.1.

2. General requirements and considerations for the assessment and authorization of inputs for organic agriculture.

The Agriculture and Livestock Service will be responsible for assessing and authorizing formulated products containing the substances listed in Annex A of this Regulation.

In the evaluation process, the Agriculture and Livestock Service may request documentation and technical background to support compliance with the criteria laid down in this Regulation.

2.1 Any input (active substance, substance, compound, formulated product among others) and/or any procedure used in organic production either for fertilizing and soil conditioning, pest control, to ensure livestock health and the quality of animal products or for the preparation, preservation and storage of a food product must be adapted to the requirements of the relevant national legislation.

2.2 The active substances, compounds and permitted or restricted inputs for organic production should be used with caution. This is because even permitted or restricted substances, if used improperly, can negatively modify the natural resources of the productive units.

2.3 In formulated products the permitted or restricted active substances must be accompanied by natural co-formulants. As an exception, the use of a synthetic co-formulant which does not cause adverse effects on human health, to animals or to the environment may be accepted.

2.4 During the authorization process for inputs for organic agriculture of the Agricultural and Livestock Service, it must be ensured that the permitted or restricted active substances be treated by physical, chemical, biological/enzymatic and/or microbial processes and with substances

(reagents or solvents) whose use does not produce impurities that cause adverse effects on human health, to animals or to the environment.

2.5 The conditions of use (volume, frequency of application, specific purpose, among others) must be respected for inputs, substances, compounds and biological organisms listed in this Annex and specified by the Agriculture and Livestock Service.

2.6 Inputs, active substances, compounds and biological organisms included in this Regulation's tables may only be used so far as their use or the products containing them has been authorized, in accordance with current legislation.

2.7 Fertilizers and soil conditioners.

2.7.1 It shall only be allowed to use active substances of vegetable, animal microbial or mineral origin, listed in this Annex.

Exceptionally, the use of active substances identical to the natural or synthetic ones in compliance with the criteria set out in Annex A and detailed in Table 1 shall be permitted.

2.7.2 The co-formulants must be of vegetable, animal, microbial or mineral origin.

2.7.3 Chelating and complexing agents used in the manufacture of fertilizers may be natural substances such as seaweed, amino acids, organic acids, gluconic acids, humic and fulvic acids, flavonoids and polyflavonoids.

Lignin sulfonate (lignosulfonic acid, calcium lignosulfonate and sodium lignosulfonate) is allowed as a chelating agent. Ammonium lignosulfonate is prohibited.

2.7.4 Regarding compost preparation, the following conditions must be considered:

- a) The raw materials used in the preparation of compost must be listed in Table 1 of this Annex and meet the described conditions of use.
- b) The origin of prepared compost must be demonstrated. Its raw materials must not come from sources that endanger the organic production system (for containing organisms of significance to public health, heavy metals, persistent organic contaminants, synthetic pesticides and their residues, antibiotic substances, plastic remnants or other inert synthetic substances, among others).
- c) Genetically modified organisms or products derived from them must not be used.
- d) During compost preparation the temperature must be checked periodically following the guidelines found in Table 1 of this Annex, in order to ensure the death of pathogens and possible biological contaminants.
- e) The use of sludge is prohibited.
- f) If the compost is prepared on other premises, it is preferable to use materials from the destination site to prevent contaminants from entering the production unit. The certification body may request background information to verify the quality of the compost, where necessary.
- g) Commercial compost must not exceed the maximum levels accepted for compost in accordance with the evaluation procedures for inputs determined by the Competent Authority regarding the parameters for heavy metals, fecal coliforms, Salmonella Sp. and viable helminth eggs as listed in Table 1 of this Annex. The Competent Authority may request additional background

information than what is specified by this Regulation to verify the quality of compost.

2.7.5 Imported fertilizing products that contain raw materials, substances or compounds of animal origin in their composition must be authorized beforehand by the Competent Authority.

2.7.6 Based on the criteria of this Regulation, the Competent Authority may authorize the use of commercial products in national organic production, provided that the indications on the respective labels are respected.

2.8 Pesticides

The instructions for pesticide use will be indicated on the label that the Agriculture and Livestock Service authorizes during the registration of these products.

In accordance with specific restrictions, the following inputs may be used in organic production.

Table 1 – Fertilizers and soil conditioners.

It is allowed to use products that only contain the substances listed in the following table and to use them in accordance with the conditions indicated for each one of them:

Product or active substance	Description, composition and conditions of use
Foliar fertilizer	Of natural origin
Bran	
Seaweeds and seaweed products	The seaweeds must come from sustainable resource gathering. As long as these are obtained directly through physical methods, including dehydration, freezing and grinding, or are extracted with water or acid/alkaline aqueous solutions, or by fermentation. Its use is subject to necessity, verified by the certification body.
Clay (bentonite, perlite, vermiculite, zeolite and kaolins)	
Sawdust, vegetable crusts, wood shavings and wood residues from sawmills	Originating from wood that was not treated with chemicals after felling.
Elemental sulfur	Its use is subject to necessity, verified by the certification body.
Biostimulants	Extracts of natural origin (vegetable, microbial or animal)
Biofertilizers	Of natural origin. It is allowed to use products containing nitrogen fixing microbial strains, mycorrhizal fungi, phosphorus solubilizing fungi, yeasts and, in general, organisms that enhance various nutrients or produce active ingredients which are used on seeds or on the soil.
Calcium carbonate of natural origin (chalk, marlstone, ground limestone, calcareous sand, phosphate chalk, among others)	
Calcium and magnesium carbonate (magnesium chalk, ground magnesium limestone, among others)	

Rice husk	
Wood ashes	Originating from wood that was not treated with chemicals after felling.
Calcium chloride	Of natural origin. It may be used in case of nutrient deficiency and physiological disorders. It should not cause salt accumulations in the soil due to repeated application. Its use is subject to necessity, verified by the certification body.
Sodium chloride	Only rock salt. Its use is subject to necessity, verified by the certification body.
Compost	<p>During the process a minimum temperature of 55°C must be reached for 3 consecutive days or of 45°C for 12 consecutive days. Furthermore, the compost pile must be turned, in order to ensure the death of any pathogenic microorganisms and possible microbiological contaminants in the food. The raw materials used for compost for own as well as other lands must comply with the provisions of point 2.7.4 of the General requirements and considerations for evaluation and authorization of inputs for Organic Agriculture, of this Annex.</p> <p>Maximum concentration in mg/kg dry matter: Arsenic: 15 ; Cadmium: 0.7 ; Copper: 70 ; Chrome (total):70; Chrome(VI): 0 ; Mercury: 0.4 ; Nickel: 25 ; Lead: 45 ; Zinc: 200</p> <p>Viable helminth eggs:<1 in 4gr of compost, dry base.</p>
	Salmonella sp.:< 3 MPN in 4gr of compost, dry base Fecal coliforms: < 1000 MPN per gr of compost, dry base
Compost tea	Must be obtained from compost that meets the criteria mentioned above.
Shells and shell fragments	
Organic derivatives of food products and industrial textiles	These must not contain contaminating substances. Its use is subject to necessity, verified by the certification body.
Earthworm feces (earthworm hummus) and insect feces	
Slags	Restricted according to the heavy metal content. Its use is subject to necessity, verified by the certification body.
Composted manure	<p>Products made up by a mixture of animal excrements and vegetable materials (beds), with the indication from which animal these come.</p> <p>Its use is subject to necessity, verified by the certification body.</p> <p>The raw materials used for compost for own as well as other lands must comply with the provisions of point 2.7.4 of the General requirements and considerations for evaluation and authorization of inputs for Organic Agriculture, of this Annex.</p> <p>Prohibited if it originates from intensive livestock production.</p>
Dried manure and dehydrated poultry manure (poultry droppings)	The species of origin must be identified. Its use is subject to necessity, verified by the certification body. Prohibited if it originates from intensive livestock production.
Liquid animal excrements (half liquid manure, urine, slurry, etc.)	May be used after controlled fermentation or acceptable dilution. The species of origin must be identified. Its use is subject to necessity, verified by the certification body. Prohibited if it originates from intensive livestock production.

Product or active substance	Description, composition and conditions of use
Aluminum-calcium phosphate	Must have a cadmium content inferior or equal to 90 mg/kg of P ₂ O ₅ . Its use is limited to alkaline soils (pH above 7.5). Restricted according to the heavy metal content.

Natural soft phosphate	Must have a cadmium content inferior or equal to 90 mg/kg of P ₂ O ₅ . Restricted according to the heavy metal content.
Coastal guano	Its use is subject to necessity, verified by the certification body. The use of white coastal guano is prohibited.
Guano from other birds	Its use is subject to necessity, verified by the certification body. The use of guano from birds fed with GMOs is prohibited.
Blood meal	Only allowed if it has been sterilized.
Fish meal and other products derived from fish	Without the addition or presence of ethoxyquin, synthetic chemical substances and/or chemical treatments. Liquid products derived from fish may be adjusted in pH by (by order of preference): organic vinegar, organic citric vinegar, phosphoric acid. The amount of acid used should not exceed the necessary minimum to reach a pH of 3.5.
Earthworm and insect humus (vermicompost)	Final product from the decomposition of organic matter through the activities of earthworms. Must be used when stabilized and of verified composition.
Humates, humic acid, fulvic acid	Permitted if they are extracted by microbial fermentation or potassium hydroxide. The levels of potassium hydroxide used in the extraction process, should not exceed the quantity required for the extraction. Restricted according to the heavy metal content.
Natural inoculants	Products based on microorganisms.
Bark mulch	Wood that was not treated with chemicals after felling.
Mulch from solid animal excrements, including guano from hens and composted manure	Indication of the animal species. Prohibited if it originates from intensive livestock production. Its use is subject to necessity, verified by the certification body. The raw materials used for compost for own as well as other lands must comply with the provisions of point 2.7.4 of the General requirements and considerations for evaluation and authorization of inputs for Organic Agriculture, of this Annex.
Mulch from earthworm composting	Its use is subject to necessity, verified by the certification body.
Fungi mulch	The initial composition of the substrate must be limited to products mentioned in this table.
Mixture of vegetable materials	Its use is subject to necessity, verified by the certification body.
Micronutrients (boron, copper, iron, manganese, molybdenum, zinc, cobalt)	Its use is subject to necessity, verified by the certification body. Nutritional deficiency should be documented. These should not be used as defoliants, herbicides or drying agents. Use copper with caution to prevent its accumulation in the soil and to protect water resources.
Natural biologic organisms (earthworms and others)	
Pulverized rocks	Its use is subject to necessity, verified by the certification body. Restricted according to the heavy metal content.
Biodynamic, homeopathic preparations	Compost, soil and plant activators and/or biostimulators, natural balance restorers.
Ayurvedic preparations, Homa ashes	Compost, soil and plant activators and/or biostimulators, natural balance restorers.
Products and by-products of animal origin mentioned here: blood meal, dried blood, hoof meal, horn meal, bone meal or dust or degelatinized bone dust, fish meal, meat meal, feather meal, wool, skin and hair agglomerates, hairs, dairy products, hydrolyzed proteins.	Its use is subject to necessity, verified by the certification body. For hairs and hair and skin agglomerates, these must have a hexavalent chromium content of Cr (VI) =0 mg/kg dw. Blood meal may only be used if it has been sterilized, fish meal may be used if it is free of ethoxyquin, synthetic chemical substances and/or chemical treatments. Hydrolyzed proteins should not be applied on the edible parts of the crops.

Products based on microorganisms	Its use is permitted for compost, plants, seeds, soils and other components of the organic productive process.
Chitin, chitosan	Its use is subject to necessity, verified by the certification body.
Calcined aluminum-phosphate rock	Restricted according to the heavy metal content.
Magnesium rock and magnesium limestone (dolomite)	Restricted according to the heavy metal content.
Natural phosphate (superphosphate)	Restricted according to the heavy metal content.

Product or active substance	Description, composition and conditions of use
Crude natural potassium salt (kainite, sylvinit, among others)	Its use is subject to necessity, verified by the certification body.
Calcium chloride solution	Only of natural origin. Leaf treatment for fruit bearing plants with calcium deficit. Its use is subject to necessity, verified by the certification body.
By-products from industrial production of ingredients originating from organic agriculture.	Its use is subject to necessity, verified by the certification body.
Calcium sulfate (gypsum)	Only of natural origin.
Magnesium sulfate (kieserite, Epsom salt)	Only of natural origin. Its use is subject to necessity, verified by the certification body.
Potassium sulfate, which may contain magnesium salt	Product of physical crude potassium salt extraction. Its use is subject to necessity, verified by the certification body.
Diatomaceous earth	
Vinasse or vinasse extract	Ammonium vinasses are excluded.

Table 2 – Pesticides and procedures for pest control.

It will be permitted to use products if they only contain the active substances listed in the following table and if they are used in accordance with the conditions indicated for each one of them.

Table 2.1 – Active substances of vegetable or animal origin.

Product or active substance	Description, composition and conditions of use
Essential vegetable oils (mint, caraway, thyme, lavender, pine, eucalyptus, citrus, among others)	Insecticides, acaricides, fungicides and sprout inhibitors.
Vegetable oils (linseed, soy, among others)	Insecticides, acaricides, among others.
<i>Azadirachta indica</i> (Nimtree) extract or azadirachtin	Insecticide. Its use is subject to necessity, verified by the certification body.
Casein	
Beeswax	Agent used when pruning.
<i>Chrysanthemum cinerariaefolium</i> extract or pyrethrins	Insecticide. Its use is subject to necessity, verified by the certification body.
Fungal extract (Shiitake mushrooms)	
Natural plant extracts (nettle, chili, garlic, quillai, citrus, among others)	Excluding tobacco.
Lecithin	Fungicide.
Propolis	Its use is subject to necessity, verified by the certification body.
Hydrolyzed proteins	Attracting agent. Only when used in combination with other suited products from this table

<i>Quassia amara</i> . Extract or quassin	Insecticide and repellent. Its use is subject to necessity, verified by the certification body.
Chitosan	
<i>Ryania speciosa</i> . Extract or ryanodine	Its use is subject to necessity, verified by the certification body.

Table 2.2 – Organisms used for biological pest control.

Product or active substance	Description, composition and conditions of use
Male, sterile insects	Not genetically modified.
Organisms and preparations based on microorganisms (bacteria, fungi, yeasts, nematodes and viruses)	Only products derived from organisms that have not been genetically modified.

Table 2.3 – Active substances only used in traps and/or dispensers

Product or active substance	Description, composition and conditions of use
Pheromones	Attracting agents; confusing agent for mating disruption. Only in traps and dispensers.
Diammonium phosphate	Attracting agent. Only in traps.

Table 2.4 – Other active substances, typically used in organic agriculture

Product or active substance	Description, composition and conditions of use
Natural paraffinic oils	Insecticide and acaricide. Its use is subject to necessity, verified by the certification body.
Potassium alum (Kalinite)	Inhibits ripening in bananas.
Quartz sand	Repelling agent.
Sulfur	Fungicide, acaricide, repellent. Its use is subject to necessity, verified by the certification body.
Sodium bicarbonate	

Product or active substance	Description, composition and conditions of use
Potassium bicarbonate	
Natural calcium chloride	
Copper: copper compounds in the form of Bordeaux mixture, copper hydroxide, copper oxychloride, copper sulfate, tribasic copper sulfate	Fungicide, bactericide. Limited to a maximum of 6 kg of copper/ha/year. Use copper with caution to avoid accumulation in the soil and to protect water resources. Its use is subject to a possible future replacement by alternative substances.
Ethylene	Degreening.
Pyrethrins	From natural extraction from chrysanthemum.
Lime sulfur	Fungicide, insecticide or acaricide. Necessity has to be verified by the certification body.
Pulverized rock	
Potassium salt, rich in fatty acids (mild soap)	Insecticide.
Sodium silicate	
Aluminum silicate (Kaolin)	
Iron(III) phosphate	Molluscicide.
Vinegar	

Table 2.5 – Other treatments permitted in organic agriculture

Type of treatment	Description, composition and conditions of use
Atmosphere controlled with O ₂ , CO ₂ , N ₂ and inert gasses	Post-harvest.
Physical barriers, sound and ultrasound	
Weeding with fire	Only using liquefied gas.
Light and ultraviolet light	
Mulch	Mulch of organic residue from genetically modified organisms is not allowed. Sawdust and wood shavings must stem from wood that was not treated with chemicals. The use of paper and newspaper printed with color ink is prohibited. Non-biodegradable or semi-biodegradable plastic coverings must be withdrawn before its degradation or physical disintegration sets in, ensuring that no fragments remain on the land. Biodegradable plastics may remain on the land if they do not contain contaminating substances. PVC is prohibited in mulch.
Herbal preparations	
Biodynamic and homeopathic preparations	
Ayurvedic preparations, Homa ashes or Homa therapy	
Cooling treatment	Preparing seedlings. Post-harvest.
Water vapor treatment	
Thermal treatment	
Use of seaweeds, seaweed extract and meal, only when gathered with a sustainable management plan, marine salts and sea water.	
Vacuum, hypobaric atmosphere	Post-harvest.

Table 2.6 – Active substances, produced by microorganisms

Product or active substance	Description, composition and conditions of use
Espinosaad	Insecticide. Only if measures are taken to minimize the risk of important parasitoids and the development of resistance.

Table 3 – Permitted inputs and procedures to control pests and animal diseases

It will be permitted to use products if they only contain the substances listed in the following table and if they are used in accordance with the conditions indicated for each one of them.

Product or active substance	Description, composition and conditions of use
Fish liver oil	
Sodium acetylsalicylate	
Acetic acid	
Acetylsalicylic acid	
Lactic acid (fermented skimmed milk, whey, among others)	
Simple mineral acids (nitric or phosphoric)	Following prolonged rinsing with water. Restricted use: only sporadic use and duly diluted.
Denatured alcohol	

Sulfur	
Sodium bicarbonate	
Lime	Restricted use: only to disinfect buildings.
Carbasalate calcium	

Product or active substance	Description, composition and conditions of use
Sprouted cereals	
Magnesium chloride	In drinking water. Restricted use: only on specific instructions of veterinarian.
Biodegradable detergents	
D.L. lysine from acetylsalicylic acid (Dextrorotatory-Levorotatory)	
Quassia extract	
Natural plant extracts obtained through infusion	Excluding tobacco.
Dicalcium phosphate	Precipitation stemming from bones.
Mono and defluorinated dicalcium phosphates	Of mineral origin
Crude soaps	
Brewer's yeast	
Micronized lithothamnion	
Magnesium peroxide (MgO ₂)	Restricted use: only in periods of high deficiency risk.
Trace elements in biochemical form	
Chemical trace elements	Simple minerals. Restricted use: only as a cure and in case of limited deficiency.
Mineral oxidants	
Potassium permanganate at 1%	
Salt rocks	Should not have incorporated flavor enhancers, urea or other non-mineral additives.
Natural pyrethrins	
Medicinal plants	
Pollen	
Diatomaceous dust	
Biodynamic, homeopathic or Ayurvedic preparations	
Salt (NaCl)	Ground rock salt and unrefined sea salt.
Sediments of marine plankton	
Potassium hydroxide soda	Following prolonged rinsing with water. Restricted use: only for sporadic use.
Copper sulfate at 1%	
Sodium sulfate	
Potassium and sodium sulfite	
Natural therapies, aroma therapy, isopathy, homeopathy and similar.	
Adhesive traps; electrical traps	
Thermal treatments (e.g.: 90°C water or disinfecting with vapor)	
Use of attenuated microbes	In treatments when they help to avoid using chemical products and antibiotics.
Use of sterile organisms	
Use of attenuated parasites	
Vaccines	Legally mandatory.
Natural vitamins	
Iodine	To prevent infections.

List 4 – Raw materials and additives for animal feed

Table 4.1 – Raw materials of vegetable origin

Cereals, seeds (their products and by-products)	Oat (<i>Avena sativa</i>) in grains, flakes, middling, hulls and bran
	Rice (<i>Oriza sativa</i>) in grains, broken, rice bran and press cake of rice sprouts.
	Barley (<i>Hordeum vulgare</i>) in grains, protein and middling.
	Rye (<i>Secale cereale</i>) in grains, middling, forage meal and bran.
	Spelt (<i>Triticum aestivum</i>) in grains.
	Maize (<i>Zea mays</i>) in grains, middling, bran, sprout press cake and gluten.
	Millet (<i>Panicum miliaceum</i>) in grains.
	Malt culms.
	Dried brewing residues.
	Sorghum (<i>Sorghum bicolor</i>) in grains.
	Wheat (<i>Triticum aestivum</i>) in grains, middling, forage meal, gluten feed, gluten and sprouts.
	Triticale (<i>Triticale secale</i>) in grains.
Forages	Alfalfa/lucerne (<i>Medicago sativa</i>) and alfalfa meal.
	Silaged forage.
	Hay.
	Herbs of forage plants and meal of forage herbs.
	Cereal straw.
	Vegetable roots for forage.
Legume seeds (their products and by-products)	Clover (<i>Trifolium sp.</i>) in clover meal.
	Chickpea (<i>Cicer arietinum</i>)
	Broad/fava bean (<i>Vicia faba</i>).
	Sweet lupine (<i>Lupinus albus</i>).
	Kidney bean (<i>Phaseolus vulgaris</i>) in seeds, middling and bran.
Vetches or vicia (<i>Vicia sp.</i>).	

Oil seeds (their products and by-products)	Cotton (<i>Gossypium sp.</i>) in seeds and seed press cake.
	Soy bean (<i>Glycine hispida</i>) in beans, toasted, press cake and husk.
	Olive pomace (<i>Olea europea</i>) pitted (physical extraction of the olive).
	Palm kernel in press cake.
	Squash seeds (<i>Cucurbita pepo</i>) in press cake
	Colza (<i>Brassica sp.</i>) in press cake or husk.
	Linseed (<i>Linum usitatissimum</i>) in seeds and press cake.
	Sunflower seed (<i>Helianthus annuus</i>) in seeds and press cake.
	Turnip rape seed (<i>Brassica napus</i>) in press cake and husk.
Sesame seed (<i>Sesamum indicum</i>) in seeds and press cake.	
Tubers, roots (their products and by-products)	Sweet potato (<i>Ipomoea batatas</i> , in roots.
	Potato (<i>Solanum tuberosum</i>) and potato pulp as starch by-product, potato starch, potato proteins.
	Tapioca protein.
	Sugar beet pulp (<i>Beta vulgaris var. Saccharata</i>).
	Dried beet.
	Yucca roots (Genus <i>Yucca</i>).
	Spices and herbs.

Other plants (their products and by-products)	Vegetable protein extracts (only provided for rearing).
	Seaweed meal (dried and ground seaweed, washed afterwards to reduce its iodine content).
	Molasses, only used to bind compound feeds.
	Plant powders and extracts
Other seeds and fruits (their products and by-products)	Citrus pulp
	Apple pomace (<i>Malus pumilla</i>).
	Tomato pulp (<i>Lycopersicum esculentum</i>).
	Grape pulp (<i>Vitis vinifera</i>).
	Carob pods (<i>Ceratonia siliqua</i>).

Table 4.2 – Raw materials of animal origin

Milk and dairy products	Casein powder.
	Lactose powder.
	Raw milk.
	Skimmed milk and skimmed milk powder.
	Milk powder.
	Buttermilk and buttermilk powder.
	Whey protein powder (through physical treatment).
	Partially lactose-free milk whey powder.
Fish and other marine animals (their products and by-products)	Milk whey and milk whey powder.
	Fish oil, refined fish oil and unrefined fish oil from codfish liver, must come from extraction systems that safeguard the sustainability of the resource.
	Autolysis, hydrolysis and proteolysis of fish, mollusks or crustaceans obtained by enzyme action in soluble or non-soluble form; only for rearing.
	Fish meal.
	Fish.

Table 4.3 – Raw materials of mineral origin

Sulfur	Sodium sulfate.
Calcium	Calcium carbonate.
	Shells of water animals (including cuttlefish bones).
	Calcium gluconate.
	Calcium lactate.
	Lithothamnium and maerl.
Phosphorus	Defluorinated dicalcium phosphate.
	Dicalcium phosphate precipitated from bones.
	Defluorinated monocalcium phosphate.
Magnesium	Magnesium carbonate.
	Anhydrous magnesium.
	Magnesium sulfate.
Sodium	Sodium bicarbonate.
	Sodium carbonate.
	Natural sodium chloride.
	Crude mine rock salt.
	Unrefined sea salt.
	Sodium sulfate.

Table 4.4 – Additives for animal feed

Binding agents, anti-caking agents and coagulants	Kaolinite clays.
	Bentonite.
	Perlite.
	Colloidal silica.
	Diatomaceous earth.
	Vermiculite.
	Sepiolite.
Preserving agents	Acetic acid for silage.
	Formic acid for silage.
	Lactic acid for silage.
	Boric acid for silage.
Enzymes	Of natural origin and/or by natural process. Genetically modified enzymes or derivatives of genetically modified organisms are not permitted.
Microorganisms	Of natural origin and/or by natural process. Genetically modified microorganisms or derivatives of genetically modified organisms are not permitted.
Trace elements	Cobalt: cobalt sulfate monohydrate and/or heptahydrate cobalt sulfate; basic cobalt carbonate monohydrate.
	Copper: copper oxide; basic copper carbonate monohydrate; pentahydrate copper sulfate.
	Iron: iron carbonate; iron sulfate monohydrate; iron oxide.
	Manganese: manganese carbonate; manganous oxide and manganic oxide; manganese sulfate mono- and/or tetrahydrate.
	Molybdenum: Ammonium molybdate; sodium molybdate.
	Selenium: Sodium selenate; Sodium selenite.
	Iodine: anhydrous calcium iodate; calcium iodate monohydrate; potassium iodide.
Zinc: zinc carbonate; zinc oxide; zinc sulfate mono- and heptahydrate.	
Vitamins, pro-vitamins and chemically well-defined substances with equivalent effect	Vitamins of identical synthesis as the natural vitamins may only be used for monogastric animals. For ruminant animals, its use is subject to authorization by the certification body.
	Vitamins, preferably derived from raw materials that are naturally present in the animals' food.

Table 4.5 – Technological auxiliaries, used in animal feed

Products	Conditions
Sugar	If the climate conditions do not allow a suited fermentation, the certification body or the Competent Authority may authorize the use of lactic, formic, propionic and acetic acid to produce silage. Genetically modified bacteria/enzymes or derivatives of genetically modified organisms will not be permitted.
Enzymes	
Cereal flour	
Yeasts	
Molasses and lactic, acetic, formic and propionic acid bacteria	
Sugar beet pulp	
Rock salt	
Sea Salt	
Milk whey	

Table 5 – Permitted inputs and/or procedures to control pests and diseases that affect apiculture

Name of the product/treatment	Description, composition and conditions of use
Water	
Isolating the queen	To halt the egg production.
Kaolin	Propolis extraction.
Capture through chemical attracting agents	
Natural sodium chloride	Contamination or biological contaminant control in fungi cultivations.
Varroosis control	With adhesive traps and the use of vegetable smoke.
Drone brood and eliminating their combs when these are capped	
Disinfecting the hives	
Destroy colonies and combs that have been severely affected	
Selecting a suitable location for the hive	
Syrup with medicinal plant infusions	
Parasites and parasitoids	
Wax renewal	
Queen replacement	
Selecting resistant breeds	
Natural therapies, such as phytotherapy, aromatherapy, homeopathy, isopathy	
Treatment with essential ethereal oils (camphor, eucalyptol, menthol, thymol)	Those of synthetic origin may be used when the natural sources are not available on the market or not in sufficient quantity.
Treatment with oxalic acid	Those of synthetic origin may be used when the natural sources are not available on the market.

Name of the product/treatment	Description, composition and conditions of use
Treatment with sulfur	
Treatment with ether	
Treatment with vegetable coating, such as linseed oil	
Thermal treatment, with vapor or direct flame	
Treatment with acetic acid	
Treatment with formic acid	Those of synthetic origin may be used when the natural sources are not available.
Treatment with lactic acid	
Treatment with one of the following products: lime, quicklime, sodium hypochlorite, alcohol, caustic soda	
Use of <i>Bacillus thuringiensis</i>	
Vinegar	

Table 6 – Permitted inputs and treatments for cleaning and disinfecting

Name of the product/treatment	Description, composition and conditions of use
Citric, acetic, peracetic, formic, oxalic acid	
Nitric and phosphoric acid	Used in milking equipment and in pressurized irrigation systems.
Water and vapor	
Alcohol	
Sodium bicarbonate	
Borax	

Lime and quicklime	
Sodium carbonate	
Chlorine compounds: sodium hypochlorite, calcium hypochlorite or chlorine dioxide	Should not exceed the maximum levels for drinking water.
Biodegradable detergents	
Natural plant essences	
Soda and potassium soap	
Lime milk	
Ozone	To clean irrigation systems, surfaces and equipment.
Hydrogen peroxide	
Cleaning and disinfecting products for teats and the milking equipment	
Caustic potash (potassium hydroxide)	
Caustic soda (sodium hydroxide)	
Vapor	Free of contaminants.

Table 7 – Permitted inputs and general conditions for their application in organic wine production

Product or active substance	Description, composition and conditions of use
Cleaning surfaces and processing equipment	
The use of the following products is permitted to support the use of water, vapor and mechanical means:	
Citric acid	
Peracetic acid	
Sulfurous acid	
Tartaric acid	
Water	Use of dechlorinated water.
Surfactant agents	The ones described in this Regulation.
Ethyl alcohol	
Potassium hydroxide	
Sodium hydroxide	
Ozone	Direct contact with the products is prohibited.
Hydrogen peroxide	Use exclusively for cleaning.
Vinification	
Egg albumin	Of organic origin.
Tartaric acid	L (+) tartaric acid of natural origin.
Sulfur dioxide	To obtain sulfur dioxide it is allowed to use: Sulfur dioxide; potassium bisulfite or potassium metabisulfite.
Lactic bacteria	With certificate for not containing genetically modified organisms.
Potassium bitartrate or cream of tartare	
Bentonites	
Activated carbon	
Casein	
Fresh egg whites	Of organic origin.
Isinglass	
Yeast hulls	Its use is subject to necessity, verified by the certification body.
Silicon dioxide	In gel form or colloidal solution (sol or silicon earth).
Pectolytic enzymes	Peptidase free. Only to prepare grape juice and unfermented reserve.
Beta-gluconase enzyme	
Beta-glucosidase enzyme	

Diammonium phosphate (DAP)	Product used to feed yeasts as a source of nitrogen.
Edible gelatin	Not hydrolyzed.
Gum arabic	Only extracted with water.
Active dry yeasts	Derived from organic raw materials if these are available or from selected native varieties.
Oak wood	Not treated, only for barrel/cask, tanks, chips and staves.
Sucrose	Crystalized sugar from organic production. May only be used in the process of second fermentation (for sparkling wines).
Tannin	
Thiamine	
Filtration	
Diatomaceous earth (Kieselguhr)	
Perlite earth	Inert
Inert membrane filters	
Other purposes	
Carbon dioxide	
Nitrogen	As inert gas.
Silicon dioxide	In gel form or colloidal solution (sol or silicon earth).

ANNEX B

Substances (additives, auxiliaries and colorants) that may be used when preparing processed organic products.

1. Criteria to introduce, modify or dispose of substances in this Annex.

1.1 In the preparation of processed organic products, the use of substances and compounds (additives, auxiliaries and colorants) which are included in the table of this Annex is only allowed provided these comply with current national legislation.

The substances and compounds may be used so far as they are authorized by the Agriculture and Livestock Service in accordance with current legislation, when appropriate.

1.2 To authorize substances and compounds referred to in point 1.1 it will be necessary to comply with the general requirements established in Heading 4, 'General requirements for organic production' of this Regulation and with the following criteria, which will be evaluated as a whole to protect the integrity of the organic product:

1.2.1 The use of substances and compounds originating from organic agriculture and natural substances or derivatives from natural substances shall be allowed.

1.2.2 These substances and compounds shall only be used if it has been demonstrated that without them it is impossible to produce or preserve the foodstuffs, that there are no other technologies that meet these provisions, that these do not diminish the overall quality of the product and that they maintain their authenticity.

1.2.3 They must be essential for the purpose they are intended for.

1.2.4 The substances and compounds may be submitted to the following processes: mechanical/physical, biologic/enzymatic and/or microbial.

1.2.5 The use of synthetic substances and compounds shall be strictly limited to situations in which substances and compounds referred to in point 1.2.1 are not available on the market; they are not available in sufficient quantities through methods and technologies referred to in point 1.2.4; their quality is not acceptable or if the use of the products and substances referred to in point 1.2.1 contributes to harmful or unacceptable environmental effects.

1.2.6 The manufacture, use and disposal of the substance or compound should neither have nor contribute to harmful effects on human health, animal health or the environment.

1.3 This Regulation shall set out the conditions and limits concerning additives, auxiliaries and colorants that can be used in the manufacture of organic products, the manner of use, dosage and the time limits for use.

1.4 By amending this Decree on reasonable grounds, it shall be allowed to introduce or delete active substances and compounds referred to in point 1.1 from the tables or modify their use as referred to in point 1.3.

Substances permitted for manufacturing processed organic products.

Substances and compounds whose functions as an additive, auxiliary and colorant are permitted for use in manufacturing organic products, are listed in the following Table: ANNEX C Processing aids and other products that can be used to manufacture organic products.

Product or active substance	Specific conditions
Alginate acid	

Ascorbic acid	If it is not available in natural form.
Citric acid	Products of fruits and vegetables.
Lactic acid	Fermented products. Entrails or sausage casing.
Malic acid	
DL tartaric acid and L tartaric acid	
Acetic and lactic acid	Of bacterial origin
Essential fatty acids	In accordance with food regulations.
Agar	
Drinking water	
Algae and by-products	
Potassium alginate	
Sodium alginate	
Fenugreek	
Chemically unmodified starch	
Amino acids	In accordance with food regulations.
Argon	
Natural flavorings and preparations of natural flavorings	
Sugar	Of organic origin
Sulfur dioxide	Gasified agent
Bentonite	
Ammonium bicarbonate	
Sodium bicarbonate	
Activated carbon	
Ammonium carbonate	
Calcium carbonate	Dairy products. Its use as a coloring is not permitted.
Magnesium carbonate	
Potassium carbonate	Traces. Cereals, cakes, cookies. Confectionery.
Sodium carbonate	Restriction: not authorized as a colorant.
Carrageenan, carrageenin	Dairy products.
Wood ashes	Wood not chemically treated. Only for livestock and poultry products. Traditional cheese.
Beeswax	
Candelilla wax	
Carnauba wax	
Calcium citrate	
Sodium citrate	Sausages; pasteurization of egg white; dairy products
Calcium chloride	Dairy products; fatty products; meat products; fruits and vegetables; soy products.
Magnesium chloride	Soy products.
Potassium chloride	Frozen fruits and vegetables; fruits and vegetables in preserves; vegetable sauces, ketchup and mustard.
Sodium chloride	Without additives or with aggregates of calcium carbonate as anti-caking agent.
Natural colorants	The use of synthetic colorants is not permitted.
Nitrogenous compounds	In accordance with food legislation.

Sulfur dioxide	Wine products
Carbon dioxide	
Sodium dioxide	Binding agent for herbs and spices.
Magnesium stearate	
Tocopherol-rich extract	Antioxidant in grease and oils.
Vegetable extracts	Not extracted with solvents.
Monocalcium phosphate	Leavening agent in self-rising flour.
Fructose	
Natural gelatins	
Glycerin	Vegetable extracts.
Gum Arabic	Milk and dairy products; fat and fatty products; confectionery products.
Gum karaya	
Carob gum	Dairy products; meat products.
Guar gum	Dairy products; canned meat; egg products.
Tragacanth	
Xanthan gum	Fatty products, fruits and vegetables, salads, patisserie and cookies.
Plant derived gums	
Calcium hydroxide	
Sodium hydroxide	
Lactose	
Smoked yeast, non-synthetic	

Product or active substance	Specific conditions
Brewer's yeast, non-synthetic	With or without lecithin, obtained without bleachers or solvents.
Nutritional yeast, non-synthetic	
Baker's yeast, non-synthetic	
Lecithin	Obtained without using bleaches or organic solvents. Dairy products; dairy based baby foods; fatty products; mayonnaises.
Minerals and trace elements	Accepted by food regulations, typically used to produce foodstuffs.
Mono- and diglycerides	
Nitrogen	
Oxygen	
Pectin	Not modified. Dairy products
Preparations based on microorganisms	Typically used to produce foodstuffs. Excludes genetically obtained/modified microorganisms.
Enzyme preparations	Typically used to produce foodstuffs. Excludes enzymes derived from genetic engineering.
Wood resin	
Natural flavorings, non-synthetic	
Common salt	Having as basic elements sodium chloride and calcium chloride
Whey and its fractions	
Calcium sulfate	Support. Carrier. Patisserie and cookies; soy products; baker's yeast.
Magnesium sulfate	
Potassium tartrate	Cereals/patisserie.

Sodium tartrate	Patisserie/confectionery.
Tocopherols	Mixed natural concentrates.
Vinegar	
Vitamins	In accordance with food legislation.

ANNEX C

Processing aids and other products that can be used to manufacture organic products.

1. Criteria to introduce, modify or delete substances from this Annex.
 - 1.1 In the manufacture of organic products, it shall only be allowed to use processing aids and other products that are included in the table of this Annex, provided that these comply with current national legislation. Processing aids and other products may be used in so far as they have been authorized by the Ministry of Agriculture, after a report from the Agriculture and Livestock Service, in accordance with current legislation, when appropriate.
 - 1.2 The authorization of substances and compounds referred to in point 1.1 is subject to the general requirements established in Heading 4 and to the following criteria, which will be assessed as a whole to protect the organic product's integrity:
 - 1.2.1 The use of substances and compounds from organic agriculture and natural substances or derivatives of natural substances shall be allowed.
 - 1.2.2 Processing aids may only be used if it has been demonstrated that without them it is impossible to produce or preserve the foodstuffs, that there are no other technologies that meet these provisions and that these do not diminish the overall quality of the product.
 - 1.2.3 They must be essential for the purpose they are intended for.
 - 1.2.4 The substances and compounds may be submitted to the following processes: mechanical/physical, biologic/enzymatic and/or microbial.
 - 1.2.5 The use of synthetic substances and compounds shall be strictly limited to situations in which substances and compounds referred to in point 1.2.1 are not available on the market; they are not available in sufficient quantities through methods and technologies referred to in point 1.2.4; their quality is not acceptable or if the use of the products and substances referred to in point 1.2.1 contributes to harmful or unacceptable effects on human health, animal health or the environment.
 - 1.2.6 The manufacture and disposal of the substance should neither have nor contribute to harmful effects to human health, animal health or the environment.
 - 1.3 This Regulation shall set out the conditions and limits concerning processing aids and other products that can be used in the manufacture of organic products, the manner of use, dosage and the time limits for use.
 - 1.4 By amending this Decree on reasonable grounds, it shall be allowed to introduce or delete the products and substances referred to under point 1.1 from the tables or modify their use as referred to in point 1.3.

Processing aids and other products allowed in the manufacture of organic products.

Processing aids and other products whose use is allowed in the production of organic products, are listed in the following table.

Product or active substance	Use
Vegetable oils	Greasing agent, separating agent, releasing or anti-foaming agent
Citric acid	Oil production hydrolysis of starch; pH adjustment
Lactic acid	Dairy products; coagulating agent; pH regulator for the salt bath of cheeses.
Tannic acid	Clarifying agent; filtering agent

Tartaric acid and salts	
Water	
Egg white albumin	
Bentonite	
Kaolin	Extraction of propolis
Activated carbon	
Calcium carbonate	
Potassium carbonate	Drying grapes
Sodium carbonate	Sugar production. Dairy products, as neutralizing agent.
Hazelnut shell	
Casein	
Beeswax	Separating agent; releasing agent
Carnauba wax	Separating agent; releasing agent
Calcium chloride	Coagulating agent. Texture enhancer for cheese manufacturing.
Magnesium chloride (nigari)	Coagulating agent
Isinglass	
Carbon dioxide	
Silicon dioxide	Gel; colloidal solution
Ethanol	Dissolving agent.
Silica gel or colloidal solution of silicon dioxide	
Gelatin	
Rice flour	
Calcium hydroxide	
Potassium hydroxide	pH regulation in sugar production.
Sodium hydroxide	pH regulation in sugar production; rapeseed oil production.
Nitrogen	
Ovalbumin	
Preparations of vegetable crust components	
Preparations of enzymes and microorganisms	Typically used as processing aids in the food industry. Genetically modified microorganisms/enzymes or derivatives of genetically modified organisms are not accepted
Calcium sulfate	Coagulating agent
Talc	
Diatomaceous earth	
Perlite	
Animal casings	