



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2013) XXX draft

ANNEXES 1 to 5

## **ANNEXES**

**to the**

**Proposal for a**

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007**

## ANNEX I

### PRODUCTS REFERRED TO IN ARTICLE 2(1)

- yeasts used as food or feed,
- beer,
- beverages made from plant extracts,
- fruit nectars,
- chocolate and derived products,
- bread, pastry, cakes, confectionery, biscuits and other baker's wares,
- pasta, stuffed pasta,
- soups,
- sauces,
- cooked meals,
- ice cream,
- flavoured yoghurts, yoghurts containing added fruits, nuts or cocoa,
- sea salt,
- natural gums and resins,
- mustard paste,
- pollen,
- beeswax,
- essential oils,
- spirit drinks provided that the ethyl alcohol used for the production of the spirit drinks is exclusively of agricultural origin

## **ANNEX II**

### **PRODUCTION RULES REFERRED TO IN CHAPTER III**

#### **Part I: Plant production rules**

In addition to the production rules laid down in Articles 7 to 10, the rules set out in this Part shall apply to organic plant production.

##### **1. General requirements**

- 1.1. Hydroponic production which is a method of growing plants with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.
- 1.2. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.
- 1.3. Conversion
  - 1.3.1. For plants and plant products to be considered organic, the production rules as referred to in this Regulation must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic production, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.
  - 1.3.2. The competent authority may decide, in the cases where the land has been contaminated with products not authorised for organic production, to extend the conversion period beyond the period referred to in point 1.3.1..
  - 1.3.3. In the case of treatment with a product not authorised for organic production, the competent authority shall require a new conversion period in accordance with point 1.3.1.

That period may be shortened in the following two cases:

- (a) treatment with a product not authorised for organic production as part of a compulsory control measure for pests, diseases or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State;
  - (b) treatment with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.
- 1.3.4. In the cases provided for in points 1.3.2. and 1.3.3., the length of the conversion period shall be fixed taking into account the following factors:
    - (a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;
    - (b) the harvest following the treatment may not be sold with reference to organic production.
  - 1.3.5. The specific conversion rules for land associated with organic livestock production should be as follows:
    - 1.3.5.1. The conversion rules shall apply to the whole area of the production unit on which animal feed is produced.

- 1.3.5.2. Notwithstanding point 1.3.5.1., the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.
- 1.4. Origin of plants including seed and vegetative propagating material
- 1.4.1. For the production of plants and plant products only organically produced seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons.
- 1.4.2. Use of seed or vegetative propagating material not obtained from organic production
- Seed and vegetative propagating material not obtained from organic production may be used only when it comes from a production unit in conversion to organic production or where it is justified for use in research, test in small-scale field trials or for variety conservation purposes agreed by the competent authority of the Member State.
- 1.5. Soil management and fertilisation
- 1.5.1. Organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.
- 1.5.2. The fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production.
- 1.5.3. Where the nutritional needs of plants cannot be met by measures provided for in points 1.5.1. and 1.5.2. only fertilisers and soil conditioners authorised for use in organic production in accordance with Article 18 may be used and only to the extent necessary.
- 1.5.4. The total amount of livestock manure, as defined in Council Directive 91/676/EEC<sup>1</sup>, applied on the holding may not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements.
- 1.5.5. Organic-production holdings may establish written cooperation agreements exclusively with other holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production. The maximum limit as referred to in point 1.5.4., shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.5.6. Preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.
- 1.5.7. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.
- 1.5.8. Mineral nitrogen fertilisers shall not be used.

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<sup>1</sup> Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1).

- 1.6. Pest, disease and weed management
- 1.6.1. The prevention of damage caused by pests, diseases and weeds shall rely primarily on the protection by:
- natural enemies,
  - the choice of species and varieties,
  - crop rotation,
  - cultivation techniques such as biofumigation, and
  - thermal processes such as solarisation and shallow steam treatment of the soil (to a maximum depth of 10 cm).
- 1.6.2. Where plants cannot be protected adequately from pests and diseases by measures provided for in point 1.6.1. or in the case of an established threat to a crop, only products authorised for use in organic production in accordance with Article 18 may be used and only to the extent necessary.
- 1.6.3. The traps and/or dispensers of products other than pheromones, shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed of safely.
- 1.7. Products and techniques used for cleaning and disinfection
- With regard to cleaning and disinfection only the products for cleaning and disinfection in plant production authorised for use in organic production in accordance with Article 18 shall be used.

## **2. Requirements for specific plants or plant products**

### **2.1. Rules on mushroom production**

For the production of mushrooms, substrates may be used, if they are composed only of the following components:

- (a) farmyard manure and animal excrements:
  - (i) either from holdings producing according to the organic production rules;  
or
  - (ii) referred to in point 1.5.3., only when the product referred to in point (i) is not available, provided that these farmyard manure and animal excrements do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;
- (b) products of agricultural origin, other than those referred to in point (a), from holdings producing according to the organic production rules;
- (c) peat not chemically treated;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.5.3., water and soil.

### **2.2. Rules concerning the collection of wild plants**

The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered as organic production provided that:

- (a) those areas have not, for a period of at least three years before the collection, received treatment with products other than those authorised for use in organic production;
- (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

## **Part II: Livestock production rules**

In addition to the production rules laid down in Articles 7, 8, 9 and 11, the rules set out in this Part shall apply to livestock production.

### **1. General Requirements**

- 1.1. Landless livestock production, where the farmer producing livestock does not manage agricultural land and has not established a written cooperation agreement with another farmer is prohibited.
- 1.2. Conversion
  - 1.2.1. The conversion period shall start at the earliest when the farmer has notified his activity to the competent authorities and subjected his holding to the control system in accordance with this Regulation.
  - 1.2.2. Conversion periods specific to the type of animal production are set out in point 2 .
  - 1.2.3. Animals and animal products produced during the conversion period shall not be marketed as organic.
  - 1.2.4. Animals and animal products may be deemed organic at the end of the conversion period if there is simultaneous conversion of the complete production unit, including livestock, pasturage and/or any land used for animal feed.
- 1.3. Origin of animals
  - 1.3.1. Organic livestock shall be born and raised on organic holdings.
  - 1.3.2. Animals existing on the holding at the beginning of the conversion period and their products may be deemed organic after compliance with the applicable conversion period referred to under point 2.
  - 1.3.3. With regard to the breeding of organic animals:
    - (a) reproduction shall use natural methods. Artificial insemination is however allowed;
    - (b) reproduction shall not be induced by treatment with hormones or similar substances, unless as a form of veterinary therapeutic treatment in case of an individual animal;
    - (c) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;
    - (d) appropriate breeds shall be chosen. The choice of breeds shall also contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.
  - 1.3.4. In the choice of breeds or strains, account shall be taken of the capacity of animals to adapt to local conditions, their vitality and their resistance to disease. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production, such as

porcine stress syndrome, pale-soft-exudative (PSE) syndrome, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference is to be given to indigenous breeds and strains.

- 1.3.5. For breeding purposes, non-organically raised animals may be brought onto a holding when breeds are in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006<sup>2</sup> and in that case animals of those breeds must not necessarily be nulliparous.

#### 1.4. Nutrition

##### 1.4.1. General nutrition requirements

The following rules shall apply to livestock production with regard to nutrition:

- (a) feed for livestock shall be obtained primarily from the holding where the animals are kept or from other organic holdings in the same region;
- (b) livestock shall be fed with organic feed that meets the animal's nutritional requirements at the various stages of its development. Restricted feeding is not permitted in livestock production;
- (c) the keeping of livestock in conditions, or on a diet, which may encourage anaemia, is prohibited;
- (d) fattening practices shall be reversible at any stage of the rearing process. Force-feeding is forbidden;
- (e) with the exception of bees, livestock shall have permanent access to pasture or roughage;
- (f) growth promoters and synthetic amino-acids shall not be used;
- (g) suckling animals shall be fed with maternal milk for a minimum period;
- (h) feed materials of mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production in accordance with Article 18.

##### 1.4.2. Grazing of common land and transhumance

###### 1.4.2.1. Organic animals may be grazed on common land, provided that:

- (a) the common land is fully managed in accordance with this Regulation;
- (b) any non-organic animals which use the land concerned are derived from a production system equivalent to those as provided for Article 36(a)(iii) and (iv) of Council Regulation (EC) No 1698/2005<sup>3</sup> or in Articles 28 and 30 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council<sup>4</sup>;

<sup>2</sup> Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 368, 23.12.2006, p. 15).

<sup>3</sup> Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 277, 21.10.2005, p. 1).

<sup>4</sup> Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

- (c) any livestock products from organic animals, whilst using this land, is not regarded as being from organic production, unless adequate segregation from non-organic animals can be proved.
- 1.4.2.2. During the period of transhumance animals may graze on non-organic land when they are being moved on foot from one grazing area to another. The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed for a maximum of 35 days covering both the outward and return journeys.
- 1.4.3. In-conversion feedingstuffs
  - 1.4.3.1. For in-conversion holdings, up to 15 % of the total average amount of feedingstuffs fed to livestock may originate from the grazing or harvesting of permanent pastures, perennial forage parcels or protein crops, sown under organic management on lands in their first year of conversion, provided that they are part of the holding itself. Feedingstuffs in their first year of conversion may not be used for the production of processed feed. When both in-conversion feedingstuffs and feedingstuffs from parcels in their first year of conversion are being used, the total combined percentage of such feedingstuffs shall not exceed the maximum percentages fixed in point 1.4.3.2.
  - 1.4.3.2. For organic holdings, up to 20 % on average of the feed formula of rations may comprise in-conversion feedingstuffs, namely feedingstuffs from the second year of conversion. For in-conversion holdings, when the in-conversion feedingstuffs come from the holding itself, this percentage may be increased to 100.
  - 1.4.3.3. The figures in points 1.4.3.1. and 1.4.3.2. shall be calculated annually as a percentage of the dry matter of feedingstuffs of plant origin.
- 1.4.4. Use of certain feed materials, products and substances in feedingstuffs

Only organic feed materials of animal origin as well as feed materials and feed additives authorised for use in organic production in accordance with Article 18 may be used in the processing of organic feed and in the feeding of organic animals.
- 1.5. Health care
  - 1.5.1. Disease prevention
    - 1.5.1.1. Disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions.
    - 1.5.1.2. The use of immunological veterinary medicines is allowed.
    - 1.5.1.3. The use of chemically synthesised allopathic veterinary medicinal products or antibiotics for preventive treatment is prohibited.
    - 1.5.1.4. The use of substances to promote growth or production (including antibiotics, coccidiostats and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), is prohibited.
    - 1.5.1.5. Where livestock is obtained from non-organic units, special measures such as screening tests or quarantine periods may apply, depending on local circumstances.

With regard to cleaning and disinfection, only the products for cleaning and disinfection in livestock buildings and installations authorised for use in organic production in accordance with Article 18 shall be used.

- 1.5.1.6. Housing, pens, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Faeces, urine and uneaten or spilt feed shall be removed as often as necessary to minimise smell and to avoid attracting insects or rodents. Rodenticides (to be used only in traps), and the products authorised for use in organic production in accordance with Article 18 may be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.
- 1.5.2. Veterinary treatment.
  - 1.5.2.1. Where despite preventive measures to ensure animal health animals become sick or injured they shall be treated immediately.
  - 1.5.2.2. Disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions and under the responsibility of a veterinarian, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined.
  - 1.5.2.3. Feed materials of mineral origin and nutritional additives authorised for use in organic production in accordance with Article 18 and phytotherapeutic and homeopathic products shall be used in preference to chemically-synthesised allopathic veterinary treatment or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.
  - 1.5.2.4. With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically- synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, shall not be sold as organic products, and the livestock shall undergo the conversion periods mentioned in points 1.2 and 2.
  - 1.5.2.5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours.
  - 1.5.2.6. Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.
- 1.6. Housing conditions and husbandry practices
  - 1.6.1. Insulation, heating and ventilation of the building shall ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which are not harmful to the animals. The building shall permit plentiful natural ventilation and light to enter.
  - 1.6.2. Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors.

- 1.6.3. The stocking density in buildings shall provide for the comfort, the well-being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The density shall ensure the animals' welfare by providing them with sufficient space to stand naturally, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.
- 1.6.4. The minimum surface for indoor and outdoor areas, and other characteristics of housing for different species and categories of animals, shall be as set out in points 2.1.4., 2.2.4., 2.3.4. and 2.4.5.
- 1.6.5. Open air areas may be partially covered. Verandas shall not be considered as open air areas.
- 1.6.6. The stocking density shall fulfil the following requirements:
  - 1.6.6.1. The total stocking density shall be such as not to exceed the limit of 170 kg of organic nitrogen per year and hectare of agricultural area.
  - 1.6.6.2. To determine the appropriate density of livestock referred to under point 1.6.6.1., the competent authority shall set out the livestock units equivalent to the limit referred to under point 1.6.6.1., following the figures laid down in each of the specific requirement by animal production.
- 1.7. Animal welfare
  - 1.7.1. Personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals.
  - 1.7.2. Husbandry practices, including stocking densities and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met.
  - 1.7.3. The livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Union legislation.
  - 1.7.4. The number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure.
  - 1.7.5. Where Article 7(1)(b) and point 1.4.2.1. of this Part apply, organic livestock shall be kept separate from other livestock.
  - 1.7.6. Tethering or isolation of livestock shall be prohibited
  - 1.7.7. Duration of transport of livestock shall be minimised.
  - 1.7.8. Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
  - 1.7.9. Mutilation is prohibited.
  - 1.7.10. Operations such as attaching elastic bands to the tails of sheep, tail-docking, cutting of teeth, trimming of beaks, toe clipping spur removal and dehorning shall not be carried out routinely in organic production.

- 1.7.11. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.
- 1.7.12. Physical castration is allowed in order to maintain the quality of products and traditional production practices but only under adequate anaesthesia and/or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.
- 1.7.13. Loading and unloading of animals shall be carried out without the use of any type of electrical stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, is prohibited.

## **2. Requirements for specific livestock species**

### **2.1. Production of bovine, ovine and caprine animals**

#### **2.1.1. Conversion**

For bovine, ovine and caprine animals and their products to be considered organic, the production rules set out in this Regulation must have been applied for at least:

- (a) 12 months in the case of bovine animals for meat production, and in any case at least three quarters of their lifetime;
- (b) six months in the case of ovine and caprine animals and of animals for milk production.

#### **2.1.2. Nutrition**

The following rules shall apply with regard to nutrition:

- (a) bovine, ovine and caprine animals shall have access to pasturage for grazing whenever conditions allow;
- (b) notwithstanding point (a), male bovine animals over one year old shall have access to pasturage or an open air area;
- (c) in cases where bovine, ovine and caprine animals have access to pasturage during the grazing period and where the winter- housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived;
- (d) except during the period each year when the animals are under transhumance as mentioned in point 1.4.2.2., at least 90 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in cooperation with other organic farms in the same region;
- (e) rearing systems for bovine, ovine and caprine animals shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations of bovine, ovine and caprine animals shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation is allowed;
- (f) all suckling bovine, ovine and caprine animals shall be fed in preference on maternal milk for a minimum period of three months for bovine animals and 45 days for ovine and caprine animals.

#### **2.1.3. Specific housing conditions**

The following rules shall apply with regard to the housing conditions:

- (a) housing of bovine, ovine and caprine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for bovine, ovine and caprine animals set out in point 2.1.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production in accordance with Article 18;
- (c) Notwithstanding Article 3(1)(a) of Council Directive 2008/119/EC<sup>5</sup> the housing of calves in individual boxes shall be forbidden after the age of one week.

#### 2.1.4. Stocking density

The number of bovine, ovine and caprine animals per hectare shall respect the following limits.

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Calves for fattening	5
Other bovine animals less than one year old	5
Male bovine animals from one to less than two years old	3,3
Female bovine animals from one to less than two years old	3,3
Male bovine animals two years old or over	2
Breeding heifers	2,5
Heifers for fattening	2,5
Dairy cows	2
Cull dairy cows	2
Other cows	2,5
Goats	13,3
Ewes	13,3

The minimum surface areas indoors and outdoors and other characteristics of housing of bovine, ovine, and caprine animals shall be as follows:

<sup>5</sup> Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7).

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Breeding and fattening bovine animals	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3
	over 350	5 with a minimum of 1 m <sup>2</sup> /100 kg	3,7 with a minimum of 0,75 m <sup>2</sup> /100 kg
Dairy cows		6	4,5
Bulls for breeding		10	30
Ovine and caprine animals		1,5 sheep/goat	2,5
		0,35 lamb/kid	2,5 with 0,5 per lamb/kid

## 2.2. Production of equine animals

### 2.2.1. Conversion

For equine animals and their products to be considered organic, the production rules of this Regulation must have been applied for at least:

- (a) 12 months, for meat production, and in any case at least three quarters of their lifetime;
- (b) six months in the case of animals for milk production.

### 2.2.2. Nutrition

The following rules shall apply with regard to nutrition:

- (a) equine animals shall have access to pasturage for grazing whenever conditions allow;
- (b) in cases where equine animals have access to pasturage during the grazing period and where the winter- housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived;
- (c) except during the period each year when the animals are under transhumance as mentioned in point 1.4.2.2., at least 90 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in cooperation with other organic farms in the same region;
- (d) rearing systems for equine animals shall be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations of equine animals shall consist of roughage, fresh or dried fodder, or silage;

- (e) all suckling equine animals shall be fed in preference on maternal milk, for a minimum period of three months.

### 2.2.3. Specific housing conditions

The following rules shall apply with regard to the housing conditions:

- (a) housing of equine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for equine animals set out in point 2.2.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production in accordance with Article 18.

### 2.2.4. Stocking density

The number of equine animals per hectare shall respect the following limit:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Equine animals over six months old	2

The minimum surface areas indoors and outdoors and other characteristics of housing equine animals shall be as follows:

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Breeding and fattening equine animals	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3
	over 350	5 with a minimum of 1 m <sup>2</sup> /100 kg	3,7 with a minimum of 0,75 m <sup>2</sup> /100 kg

### 2.3. Production of porcine animals:

#### 2.3.1. Conversion

For porcine animals and their products to be considered organic, the production rules of this Regulation must have been applied for at least six months.

#### 2.3.2. Nutrition

The following rules shall apply with regard to nutrition:

- (a) at least 60 % of the feed shall come from the farm itself or in case this is not feasible, be produced in the same region in cooperation with other organic farms or feed operators;
- (b) all suckling porcine animals shall be fed in preference on maternal milk , for a minimum period of 40 days;
- (c) roughage, fresh or dried fodder, or silage shall be added to the daily ration for pigs.

### 2.3.3. Specific housing conditions

The following rules shall apply with regard to the housing conditions:

- (a) housing of porcine animals shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in the table on minimum surface areas for porcine animals set out in point 2.3.4., shall be solid, that is, not of slatted or of grid construction;
- (b) the housing of porcine animals shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised as fertiliser or soil conditioner for use in organic production in accordance with Article 18.
- (c) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period;
- (d) piglets shall not be kept on flat decks or in piglet cages;
- (e) exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

### 2.3.4. Stocking density

The number of porcine animals per hectare shall respect the following limits:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Piglets	74
Breeding sows	6,5
Porcine animals for fattening	14
Other porcine animals	14

The minimum surface areas indoors and outdoors and other characteristics for housing porcine animals shall be as follows:

	Indoors area (net area available to animals)	Outdoors area (exercise area, excluding pasturage)

	Live weight minimum (kg)	M <sup>2</sup> /head	M <sup>2</sup> /head
Farrowing sows with piglets up to 40 days		7,5 sow	2,5
Fattening porcine animals	up to 50	0,8	0,6
	up to 85	1,1	0,8
	up to 110	1,3	1
Piglets	over 40 days and up to 30 kg	0,6	0,4
Brood porcine animals		2,5 female	1,9
		10 m <sup>2</sup> /boar	8,0

## 2.4. Production of poultry

### 2.4.1. Conversion

For poultry and their products to be considered organic, the production rules of this Regulation must have been applied for at least:

- (a) 10 weeks for poultry for meat production, brought in before they are three days old;
- (b) six weeks in the case of poultry for egg production.

### 2.4.2. Origin of poultry

Poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains as defined by the competent authority. Where slow-growing poultry strains are not used by the farmer the minimum age at slaughter shall be as follows:

- (a) 81 days for chickens;
- (b) 150 days for capons;
- (c) 49 days for Peking ducks;
- (d) 70 days for female Muscovy ducks;
- (e) 84 days for male Muscovy ducks;
- (f) 92 days for Mallard ducks;
- (g) 94 days for guinea fowl;
- (h) 140 days for male turkeys and roasting geese; and
- (i) 100 days for female turkeys.

### 2.4.3. Nutrition

The following rules shall apply with regard to nutrition:

- (a) at least 60 % of the feed shall come from the farm itself or in case this is not feasible, be produced in the same region in cooperation with other organic farms or feed operators;

- (b) roughage, fresh or dried fodder, or silage shall be added to the daily ration.

#### 2.4.4. Specific housing conditions

The following rules shall apply with regard to the housing conditions:

- (a) poultry shall not be kept in cages;
- (b) water fowl shall have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements;
- (c) poultry shall have access to an open air area for at least one third of their life. Open air areas for poultry shall be mainly covered with vegetation and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking and feeding troughs;
- (d) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs;
- (e) buildings for all poultry shall meet the following conditions:
  - (i) at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;
  - (ii) in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens shall be available for the collection of bird droppings;
  - (iii) poultry shall have perches of a size and number commensurate with the size of the group and of the birds as laid down in the table on the minimum surface areas indoors and outdoors and other characteristics of housing for poultry production set out in point 2.4.5.;
  - (iv) the external boundary of the house, i.e. including a possible veranda, shall have exit/entry pop-holes of a size adequate for the birds, and those pop-holes shall have a combined length of at least 4 m per 100 m area of the house available to the birds. Where a veranda is present, the internal pop-holes between the house and the veranda shall have a combined length of 2 m per 100 m area of the house. Twenty-four hour access to the veranda must be allowed;
  - (v) poultry houses shall be constructed in a manner allowing all birds easy access to open air area, i.e. the maximum distance from any point within the house to the nearest external pop-hole shall not be more than 15 m;
  - (vi) multi-layer systems shall have no more than three levels of usable area including the ground floor. There shall be no more than 1 m between levels or intermediate areas, such as nesting areas. Higher tiers shall be capable of having manure removed by an automated system;
- (f) natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours;

- (g) buildings shall be emptied of livestock between each batch of poultry reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty during a period to be established by the Member States in order to allow vegetation to grow back. These requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam, throughout the day.

#### 2.4.5. Stocking density

The maximum number of animals per hectare shall respect the following limits:

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Table chickens	580
Laying hens	230

The minimum surface area indoors and outdoors and other characteristics of housing for birds of the species *Gallus gallus* shall be as follows:

	<i>Breeders/ parents</i>	<i>Young stock</i>		<i>Fattening birds</i>		<i>Capons</i>	<i>Layers</i>
Age	Breeding birds	Pullets 0-8 weeks	Pullets 9-18 weeks	Starter 0-21 days	Finisher 22 to 81 days	22-150 days	Laying hens from 19 weeks
In house stocking rate (birds per m2 of usable area) for fixed and mobile houses	6 birds	24 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	15 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	20 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	10 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	10 birds with a maximum of 21 kg liveweight/m <sup>2</sup>	6 birds
Perch space (cm)							18
Multi-layer systems additional limits/m2 of ground floor area (including veranda if 24h access)	9 birds	36 birds excluding veranda area	22 birds	Not normally applicable			9 birds
Flock size limits	3.000 including	10,000*	3,300**	10,000*	4,800	2,500	3,000

	males						
Open-air run stocking rates (m <sup>2</sup> /bird), provided that the limit of 170 kg of N/ha/year is not exceeded	4	1	4	1	4	4	4

\* sub-dividable to produce 3x3000 or 2x4800 batches with

\*\* allowance for mortality and surplus sold to smaller farmers

The minimum surface areas indoors and outdoors and other characteristics of housing for birds of species other than *Gallus gallus* shall be as follows:

	<i>Turkeys</i>		<i>Geese</i>	<i>Ducks</i>				<i>Guinea fowl</i>
Type	Male	Female	All	Peking	Male Muscovy	Female Muscovy	Mallard	All
In house stocking rate (birds per m <sup>2</sup> of usable area) for fixed and mobile houses	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>	10 with a maximum of 21 kg liveweight/m <sup>2</sup>
Perch space (cm)	40	40	Not normally applicable	Not normally applicable	40	40	Not normally applicable	20
Flock limits	2,500	2,500	2,500	4,000 females 3,200 males	3,200	4,000	3,200	5,200
Open air stocking rate (m <sup>2</sup> /bird) provided that the limit of 170 kg of N/ha/year is not exceeded	10	10	15	4.5	4.5	4.5	4.5	4

#### 2.4.6. Access to open air areas

The following rules shall apply with regard to access to open air areas:

- (a) poultry shall have access to an open air area for at least one third of their life. In particular, continuous daytime open air access shall be provided from as

early an age as practically possible, whenever physiological and physical conditions allow, except in the case of temporary restrictions imposed on the basis of Union legislation;

- (b) open air areas for poultry shall be mainly covered with vegetation composed of a diverse range of plants and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking troughs. The vegetation on the open-air area must be harvested and removed at regular intervals to reduce the potential for nutrient surpluses. The open air areas shall not extend beyond a radius of 150 m from the nearest pop-hole of the poultry house. However an extension of up to 350 m from the nearest pop-hole of the poultry house is permissible provided that a sufficient number of shelters and drinking troughs are evenly distributed throughout the whole open-air area with at least four shelters per hectare;
- (c) under conditions where feed availability from the range area is limited, due for instance to long term snow cover or arid weather conditions, supplementary feeding of roughage must be included as part of poultry diets;
- (d) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs.

#### 2.4.7. Animal welfare

The following rules shall apply with regard to animal welfare:

- (a) live plucking of poultry is prohibited;
- (b) if beak-trimming or comb-clipping are considered necessary by competent authorities under general legislation to control aggression between breeding males, such practices shall be restricted to breeding males and carried out on one day old chicks only.

#### 2.5. Beekeeping

##### 2.5.1. Conversion

Beekeeping products may be sold with references to organic production only when the organic production rules set out in this Regulation have been complied with for at least one year.

During the conversion period the wax shall be replaced with wax coming from organic beekeeping.

##### 2.5.2. Origin of bees

Preference shall be given to the use of *Apis mellifera* and their local ecotypes.

##### 2.5.3. Nutrition

The following rules shall apply with regard to nutrition:

- (a) at the end of the production season hives shall be left with sufficient reserves of honey and pollen to survive the winter;
- (b) the feeding of bee colonies shall only be permitted where the survival of the hives is endangered due to climatic conditions. Feeding shall be with organic honey, organic sugar syrups, or organic sugar.

#### 2.5.4. Specific rules on disease prevention and veterinary treatment in beekeeping

The following rules shall apply with regard to disease prevention and veterinary treatment:

- (a) for the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides (to be used only in traps), and appropriate products authorised for use in organic production in accordance with Article 18 are permitted;
- (b) physical treatments for disinfection of apiaries such as steam or direct flame are permitted;
- (c) the practice of destroying the male brood is permitted only to isolate the infestation of *Varroa destructor*;
- (d) if despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies may be placed in isolation apiaries;
- (e) formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with *Varroa destructor*;
- (f) if a treatment is applied with chemically synthesised allopathic products, during such a period, the colonies treated shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of one year laid down in point 2.5.1. shall apply to those colonies;
- (g) point (f) shall not apply to products authorised for use in organic production in accordance with Article 18.

#### 2.5.5. Specific housing conditions in beekeeping

The following rules shall apply with regard to the housing conditions:

- (a) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods;
- (b) apiaries shall be kept at sufficient distance from sources that may lead to the contamination of beekeeping products or to the poor health of the bees;
- (c) the siting of the apiaries shall be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops and/or spontaneous vegetation and/or crops treated with low environmental impact methods equivalent to those as provided for under Article 36(a)(iii) and (iv) of Regulation (EC) No 1698/2005 or in Articles 28 and 30 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council which cannot affect the qualification of beekeeping production as being organic. These requirements do not apply where flowering is not taking place, or the hives are dormant;
- (d) the hives and materials used in beekeeping shall be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products;

#### 2.5.6. Specific rules on practices in beekeeping

The following rules shall apply with regard to beekeeping practices:

- (a) the beeswax for new foundations shall come from organic production units;
- (b) only natural products such as propolis, wax and plant oils may be used in the hives;
- (c) the use of chemical synthetic repellents is prohibited during honey extraction operations;
- (d) the use of brood combs is prohibited for honey extraction;
- (e) beekeeping shall not be considered as organic when practiced in regions or areas designated by Member States as regions or areas where organic beekeeping is not practicable.

#### 2.5.7. Animal welfare

The following rules shall apply with regard to animal welfare:

- (a) the destruction of bees in the combs as a method associated with the harvesting of beekeeping products is prohibited;
- (b) mutilation such as clipping the wings of queen bees is prohibited.

### **Part III: Production rules for seaweed and aquaculture animals**

#### **1. Definitions**

For the purposes of this Part, the following definitions shall apply:

- (1) 'closed recirculation aquaculture facility' means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilise the environment for the aquaculture animals;
- (2) 'energy from renewable sources' means renewable non-fossil energy sources: wind, solar, geothermal wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;
- (3) 'hatchery' means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;
- (4) 'nursery' means a place where an intermediate production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle with the exception of species undergoing a smoltification process;
- (5) 'pollution' means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2000/60/EC of the European Parliament and of the Council<sup>6</sup> and in Directive 2008/56/EC of the European Parliament and of the Council<sup>7</sup>, in the waters where those Directives apply respectively;

<sup>6</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

<sup>7</sup> Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

- (6) 'polyculture' means the rearing of two or more species usually from different trophic levels in the same culture unit;
- (7) 'production cycle' means the lifespan of an aquaculture animal or seaweed from the earliest life stage to harvesting;
- (8) 'locally grown species' means those species which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007<sup>8</sup>; it includes the species listed in Annex IV to that Regulation;
- (9) 'stocking density' means the live weight of aquaculture animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface.

## 2. Requirements for seaweed

In addition to the general production rules laid down in Article 7, 8, 9 and 12, the following rules shall apply to the collection and production of seaweed and *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

### 2.1. Conversion

- 2.1.1. The conversion period for a seaweed harvesting site shall be six months.
- 2.1.2. The conversion period for a seaweed cultivation unit shall be the longer of six months or one full production cycle.
- 2.1.3. During the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards seaweed production, the same species may be involved, provided that there is adequate separation between the units.

### 2.2. Production rules for seaweed

- 2.2.1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as organic production provided that:
  - (a) the growing areas are of high ecological quality as defined by Directive 2000/60/EC and, of a quality equivalent to designated waters under Directive 2006/113/EC of the European Parliament and of the Council<sup>9</sup>, and are not unsuitable from a health point of view. Wild edible seaweeds shall not be collected in areas which would not meet the criteria for Class A or Class B areas as defined in Annex II to Regulation (EC) No 854/2004 of the European Parliament and of the Council<sup>10</sup>[*to be repealed by new official controls regulation*];
  - (b) the collection does not affect the long term stability of the natural habitat or the maintenance of the species in the collection area.

<sup>8</sup> Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p. 1).

<sup>9</sup> Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters (OJ L 376, 27.12.2006, p. 14).

<sup>10</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

- 2.2.2. The production of seaweeds shall take place in coastal areas with environmental and health characteristics at least equivalent to those outlined in point 2.2.1 in order to be considered organic. In addition the following production rules shall apply:
- (a) sustainable practices shall be used in all stages of production, from collection of juvenile seaweed to harvesting;
  - (b) to ensure that a wide gene-pool is maintained, the collection of juvenile seaweed in the wild shall take place on a regular basis to supplement indoor culture stock;
  - (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose.
- 2.3. Suitability of aquatic medium and sustainable management plan in seaweed production
- 2.3.1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for use in organic production, or pollutants that would compromise the organic nature of the products.
- 2.3.2. Organic and non-organic production units shall be separated adequately and in accordance with the minimum separation distances set by Member States, where such minimum separation distances have been set. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Seaweed production shall not be considered as organic when practiced at locations or in areas designated by Member State authorities as locations or areas which are unsuitable for organic aquaculture or seaweed harvesting.
- 2.3.3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control authority or control body. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU of the European Parliament and of the Council<sup>11</sup>. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
- 2.3.4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.
- 2.3.5. The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.
- 2.3.6. Aquaculture and seaweed business operators shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy

<sup>11</sup> Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

from renewable sources. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

#### 2.4. Seaweed cultivation

2.4.1. Seaweed culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.

2.4.2. In facilities on land where external nutrient sources are used the nutrient levels in the effluent water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin authorised for use in organic production in accordance with Article 18 may be used.

2.4.3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.

2.4.4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.

#### 2.5. Sustainable harvesting of wild seaweed

2.5.1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with this Regulation.

2.5.2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.

2.5.3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

### 3. Requirements for aquaculture animals

In addition to the general production rules laid down in Article 7, 8, 9 and 12, the rules set out in this Section shall apply to species of fish, crustaceans, echinoderms and molluscs, as referred to in point 3.1.5.6., and they apply *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

#### 3.1. General rules

##### 3.1.1. Conversion

3.1.1.1. The following conversion periods for aquaculture production units shall apply for the following types of aquaculture facilities including the existing aquaculture animals:

- (a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;
- (b) for facilities that have been drained, or fallowed, a conversion period of 12 months;
- (c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;

- (d) for open water facilities including those producing bivalve molluscs, a conversion period of three months.
- 3.1.1.2. During the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards the production of aquaculture animals, the same species may be involved provided that there is adequate separation between the units.
- 3.1.1.3. The competent authority may decide to recognise retroactively as being part of the conversion period any previously documented period in which the facilities were not treated or exposed to products not authorised for organic production.
- 3.1.2. Origin of aquaculture animals
  - 3.1.2.1. The following rules shall apply with regard to the origin of the aquaculture animals:
    - (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;
    - (b) locally grown species shall be used and breeding shall aim to give strains which are more adapted to production conditions, good health and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for the control authority or control body;
    - (c) species shall be chosen which can be produced without causing significant damage to wild stocks;
    - (d) wild caught or non-organic aquaculture animals may be brought into a holding with a view to improving genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding.
  - 3.1.2.2. The following rules shall apply with regard to breeding:
    - (a) the use of hormones and hormone derivates is prohibited;
    - (b) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;
    - (c) the appropriate strains shall be chosen;
    - (d) species-specific conditions for broodstock management, breeding and juvenile production shall be established.
- 3.1.3. Nutrition
  - 3.1.3.1. The following rules shall apply with regard to feed for fish and crustaceans:
    - (a) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
    - (b) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from sustainable exploitation of fisheries;
    - (c) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under this Regulation;
    - (d) growth promoters and synthetic amino-acids shall not be used;

3.1.3.2. The following rules shall apply with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:

- (a) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
- (b) they shall be grown in waters which meet the criteria for Class A or Class B areas as defined in Annex II to Regulation (EC) No 854/2004;
- (c) the growing areas shall be of high ecological quality as defined by Directive 2000/60/EC and of a quality equivalent to designated waters under Directive 2006/113/EC.

3.1.3.3. The following rules shall apply with regard to feed for fish, crustaceans and echinoderms:

- (a) feeding regimes shall be designed with the following priorities:
  - (i) animal health;
  - (ii) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;
  - (iii) low environmental impact;
- (b) only the feed materials of mineral origin authorised for use in organic production in accordance with Article 18 may be used in organic aquaculture.
- (c) only the feed additives, certain products used in animal nutrition and processing aids as referred to in point 1.4.4. of Part II may be used in organic aquaculture.

#### 3.1.4. Health care

##### 3.1.4.1. Disease prevention

The following rules shall apply with regard to disease prevention:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;
- (b) the use of immunological veterinary medicines is allowed;
- (c) an animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish;
- (d) holding systems, equipment and utensils shall be properly cleaned and disinfected;
- (e) bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm;
- (f) only substances for cleaning and disinfection of equipment and facilities authorised for use in organic production in accordance with Article 18 may be used.

- (g) With regard to fallowing the following rules shall apply:
  - (i) the competent authority shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea.
  - (ii) it shall not be mandatory for bivalve mollusc cultivation;
  - (iii) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again;
- (h) where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as regards water status quality, minimise disease risks, and to avoid attracting insects or rodents;
- (i) ultraviolet light and ozone may be used only in hatcheries and nurseries;
- (j) for biological control of ectoparasites preference shall be given to the use of cleaner fish.

#### 3.1.4.2. Veterinary treatments

The following rules shall apply with regard to veterinary treatments:

- (a) Disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;
- (b) Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.
- (c) When despite preventive measures to ensure animal health, according to point 3.1.4.1., a health problem arises, veterinary treatments may be used in the following order of preference:
  - (i) substances from plants, animals or minerals in a homoeopathic dilution;
  - (ii) plants and their extracts not having anaesthetic effects; and
  - (iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;
- (d) the use of allopathic treatments is limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the mentioned limits for allopathic treatments are exceeded the concerned aquaculture animals cannot be sold as organic products;
- (e) the use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months;
- (f) the withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (c), including treatments under compulsory

control and eradication schemes, shall be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or in a case in which this period is not specified 48 hours;

- (g) whenever veterinary medicinal products are used, such use is to be declared to the control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

### 3.1.5. Housing conditions and husbandry practices

#### 3.1.5.1. The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their species specific needs, the aquaculture animals shall:

- (a) have sufficient space for their wellbeing;
- (b) be kept in water of good quality with sufficient oxygen levels;
- (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location;

In the case of freshwater fish the bottom type shall be as close as possible to natural conditions.

In the case of carp the bottom shall be natural earth.

#### 3.1.5.2. The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

#### 3.1.5.3. Containment systems shall be designed, located and operated to minimise the risk of escape incidents.

#### 3.1.5.4. If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained

#### 3.1.5.5. For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use seaweeds and/or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.

#### 3.1.5.6. The stocking density shall be as set out in points (a) to (j) by species or group of species. In considering the effects of the stocking density on the welfare of produced fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored.

- (a) Organic production of salmonids in fresh water:

brown trout (*Salmo trutta*) – rainbow trout (*Oncorhynchus mykiss*) – American brook trout (*Salvelinus fontinalis*) – salmon (*Salmo salar*) – charr (*Salvelinus alpinus*) – grayling (*Thymallus thymallus*) – American lake trout (or grey trout) (*Salvelinus namaycush*) – huchen (*Huchohucho*)

Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 60 % oxygen saturation for stock and must ensure their comfort and the
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		elimination of production effluent.
Maximum density	stocking	Salmonid species not listed below 15 kg/m <sup>3</sup> Salmon 20 kg/m <sup>3</sup> Brown trout and Rainbow trout 25 kg/m <sup>3</sup> Arctic charr 20 kg/m <sup>3</sup>

(b) Organic production of salmonids in sea water:

salmon (*Salmo salar*), brown trout (*Salmo trutta*) - rainbow trout (*Oncorhynchus mykiss*)

Maximum density	stocking	10 kg/m <sup>3</sup> in net pens
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(c) Organic production of cod (*Gadus morhua*) and other Gadidae, sea bass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), meagre (*Argyrosomus regius*), turbot (*Psetta maxima* [= *Scophthalmus maximus*]), red porgy (*Pagrus pagrus* [= *Sparus pagrus*]), red drum (*Sciaenops ocellatus*) and other Sparidae, and spinefeet (*Siganus spp.*)

Production system		In open water containment systems (net pens/cages) with minimum sea current speed to provide optimum fish welfare or in open systems on land.
Maximum density	stocking	For fish other than turbot: 15 kg/m <sup>3</sup>  For turbot: 25 kg/m <sup>2</sup>

(d) Organic production of sea bass, sea bream, meagre, mullets (*Liza*, *Mugil*) and eel (*Anguilla spp.*) in earth ponds of tidal areas and coastal lagoons

Containment system		Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas
Production system		There shall be adequate renewal of water to ensure the welfare of the species,  At least 50 % of the dikes must have plant cover  Wetland based depuration ponds required
Maximum density	stocking	4 kg/m <sup>3</sup>

(e) Organic production of sturgeon in fresh water:

species concerned: Sturgeon family (Acipenseridae)

Production system		Water flow in each rearing unit shall be sufficient to ensure animal welfare  Effluent water to be of equivalent quality to incoming water
Maximum density	stocking	30 kg/m <sup>3</sup>

(f) Organic production of fish in inland waters:

species concerned: carp family (Cyprinidae) and other associated species in the context of polyculture, including perch, pike, catfish, coregonids, sturgeon.

Production system	<p>In fishponds which shall periodically be fully drained and in lakes. Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas.</p> <p>The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.</p> <p>Organic and mineral fertilisation of the ponds and lakes shall be carried out with only fertilisers and soil conditioners authorised for use in organic production in accordance with Article 18 with a maximum application of 20 kg nitrogen/ha.</p> <p>Treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters are prohibited.</p> <p>Areas of natural vegetation shall be maintained around inland water units as a buffer zone for external land areas not involved in the production operation in accordance with the rules of organic aquaculture.</p> <p>For grow-out “polyculture” shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.</p>
Production yield	The total production of species is limited to 1500 kg of fish per hectare per year.

(g) Organic production of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.):

Establishment of production unit/s	Location to be in sterile clay areas to minimise environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Mangrove destruction is not permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a produced shrimp.
Broodstock origin	A minimum of half the broodstock shall be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm.
Eyestalk ablation	Is prohibited.
Maximum on farm stocking densities and	Seeding: maximum 22 post larvae/m <sup>2</sup>

production limits	Maximum instantaneous biomass: 240 g/m <sup>2</sup>
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(h) Molluscs and echinoderms:

Production systems	Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets, bouchot poles and other containment systems.  For mussel cultivation on rafts the number of drop-ropes shall not exceed one per square meter of surface area. The maximum drop-rope length shall not exceed 20 m. Thinning-out of drop-ropes shall not take place during the production cycle, however sub-division of drop ropes shall be permitted without increasing stocking density at the outset.
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(i) Tropical fresh water fish: milkfish (*Chanos chanos*), tilapia (*Oreochromis* spp.), siamese catfish (*Pangasius* spp.):

Production systems	Ponds and net cages
Maximum stocking density	Pangasius: 10 kg/m <sup>3</sup>  Oreochromis: 20 kg/m <sup>3</sup>

(j) Other aquaculture animal species: none

3.1.6. Animal welfare

3.1.6.1. Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimise physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.

3.1.6.2. The following restrictions shall apply to the use of artificial light:

- (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of produced animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;
- (b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.

3.1.6.3. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.

3.1.6.4. The use of oxygen is only permitted for uses linked to animal health requirements and critical periods of production or transport, in the following cases:

- (a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution;
- (b) occasional stock management procedures such as sampling and sorting;
- (c) in order to assure the survival of the farm stock.

3.1.6.5. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.

### 3.2. Specific rules

#### 3.2.1. Nutrition

##### 3.2.1.1. Specific rules on feedingstuffs for carnivorous aquaculture animals

Feedingstuffs for carnivorous aquaculture animals shall be sourced with the following priorities:

- (a) organic feedingstuffs of aquaculture origin;
- (b) fish meal and fish oil from organic aquaculture trimmings;
- (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;
- (d) organic feed materials of plant or animal origin.

##### 3.2.1.2. Specific rules on feedingstuffs for certain aquaculture animals

- (a) Aquaculture animals as referred to in point 3.1.5.6. (f), (g) and (i) shall be fed with feedingstuffs naturally available in ponds and lakes;
- (b) Where natural feedingstuffs are not available in sufficient quantities as referred to in point (a), organic feedingstuffs of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feedingstuffs;
- (c) Where natural feedingstuff is supplemented according to point (b) the feed ration of species as referred to in point 3.1.5.6. (g) and of siamese catfish (*Pangasius spp.*) as referred to in point 3.1.5.6 (i) may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

#### 3.2.2. Housing conditions

3.2.2.1. Closed recirculation aquaculture animal production facilities are prohibited, with the exception of hatcheries and nurseries or for the production of species used for organic feed organisms.

3.2.2.2. Rearing units on land shall meet the following conditions:

- (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
- (b) at least five percent of the perimeter ("land-water interface") area shall have natural vegetation.

3.2.2.3. Containment systems at sea shall:

- (a) be located where water flow, depth and water-body exchange rates are adequate to minimise the impact on the seabed and the surrounding water body;
- (b) have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.

3.2.2.4. Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

### 3.2.3. Specific rules for molluscs

#### 3.2.3.1. Origin of seed

The following rules shall apply with regard to the origin of seed:

(a) provided that there is no significant damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit may be used in the case of bivalve shellfish provided it comes from:

(i) settlement beds which are unlikely to survive winter weather or are surplus to requirements; or

(ii) natural settlement of shellfish seed on collectors;

Records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area;

(b) for the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild.

#### 3.2.3.2. Housing conditions and husbandry practices

The following rules shall apply with regard to the housing conditions and husbandry practices:

(a) production may be carried out in the same area of water as organic finfish and seaweed production in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture;

(b) organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means;

(c) organic shellfish farms shall minimise risks to species of conservation interest. If predator nets are used their design shall not permit diving birds to be harmed.

#### 3.2.3.3. Cultivation

The following rules shall apply with regard to cultivation:

(a) cultivation on mussel ropes and other methods listed in point 3.1.5.6 (h) may be eligible for organic production;

(b) bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the control authority or control body. The report shall be added as a separate chapter to the sustainable management plan.

#### 3.2.3.4. Management

- (a) production shall use a stocking density not in excess of that used for non-organic molluscs in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality;
- (b) biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from mollusc farms. Molluscs may be treated once during the production cycle with a lime solution to control competing fouling organisms.

#### 3.2.3.5. Specific cultivation rules for oysters

Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the requirements set out in point 3.1.5.6. (h).

### **Part IV: Processed food and processed feed production rules**

In addition to the general production rules laid down in Articles 7, 9 and 13, the rules set out in this Part shall apply to processed food and processed feed.

#### **1. General requirements for the production of processed food and feed**

- 1.1. Food and feed additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice<sup>12</sup>.
- 1.2. Operators producing processed food or feed shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
- 1.3. The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with the organic production rules.
- 1.4. Operators shall comply with and implement the procedures referred to in point 1.2. In particular, operators shall:
  - (a) take preventive measures to avoid the risk of contamination by unauthorised substances or products;
  - (b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
  - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
- 1.5. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:
  - (a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;
  - (b) store organic products, before and after the operations, separate by place or time from non-organic products;

<sup>12</sup> Good manufacturing practices (GMPs) as defined in the guidelines of the ICH (International Conference on Harmonization)

- (c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;
- (d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
- (e) carry out operations on organic products only after suitable cleaning of the production equipment.

## **2. Requirements for the production of processed food**

- 2.1. The preparation of processed organic food shall be kept separate in time or space from non-organic food.
- 2.2. The following conditions shall apply to the composition of organic processed food:
  - (a) the product shall be produced mainly from agricultural ingredients; in order to determine whether a product is produced mainly from agricultural ingredients, added water and salt shall not be taken into account;
  - (b) only food additives, processing aids, flavourings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses authorised for use in organic production in accordance with Article 18 may be used;
  - (c) an organic ingredient shall not be present together with an ingredient in conversion;
  - (d) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.
- 2.3. Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of those products or that otherwise may be misleading as to the true nature of these products shall not be used.
- 2.4. Use of certain products and substances in processing of food
  - 2.4.1. Only the products and substances authorised for use in organic production in accordance with Article 18 as well as the products and substances mentioned under points (a) to (e) hereunder, may be used in the processing of organic food, with the exception of products and substances of the wine sector, for which point 2 of Part V shall apply and of yeast for which point 1.3 of Part VI shall apply:
    - (a) Preparations of micro-organisms and enzymes normally used in food processing; enzymes to be used as food additives have to be authorised for use in organic production in accordance with Article 18;
    - (b) Substances, and products as defined in Article 3(1)(b) and (d) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council<sup>13</sup> labelled as natural flavouring substances or natural flavouring preparations, in accordance with Articles 15(1)(e) and (16) of that Regulation.

<sup>13</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

- (c) Colours for stamping meat and eggshells in accordance with, respectively, Article 18 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council<sup>14</sup>;
  - (d) Drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
  - (e) Minerals (trace elements included), vitamins, aminoacids, and micronutrients, only authorised as far their use is required in the foodstuffs in which they are incorporated.
- 2.4.2. For the purpose of the calculation referred to in Article 19 the following rules shall apply:
- (a) certain food additives authorised for use in organic production in accordance with Article 18, shall be calculated as agricultural ingredients;
  - (b) preparations and substances referred to in points (a) to (e) of point 2.4.1. shall not be calculated as agricultural ingredients;
  - (c) yeast and yeast products shall be calculated as agricultural ingredients.
- 2.4.3. The following non-organic agricultural ingredients may be used in the processing of organic food:
- (a) animal products:
    - (i) aquatic organisms, not originating from aquaculture, and permitted in non-organic foodstuffs preparation;
    - (ii) gelatin;
    - (iii) whey powder "herasuola";
    - (iv) casings.
  - (b) unprocessed vegetable products as well as products derived therefrom by processing:
    - (i) edible fruits, nuts and seeds:
 

– acorns	<i>Quercus</i> spp.;
– cola nuts	<i>Cola acuminata</i> ;
– gooseberries	<i>Ribes uva-crispa</i> ;
– maracujas (passion fruit)	<i>Passiflora edulis</i> ;
– raspberries (dried)	<i>Rubus idaeus</i> ;
– red currants (dried)	<i>Ribes rubrum</i> .
    - (ii) edible spices and herbs:
 

– pepper (Peruvian)	<i>Schinus molle</i> ;
– horseradish seeds	<i>Armoracia rusticana</i> ;
– lesser galanga	<i>Alpinia officinarum</i> ;
– safflower flowers	<i>Carthamus tinctorius</i> ;

<sup>14</sup>

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

- watercress herb *Nasturtium officinale*.
    - (iii) miscellaneous:
      - algae, including seaweed.
  - (c) processed vegetable products:
    - (i) sugars, starches and other products from cereals and tubers:
      - fructose;
      - rice paper;
      - unleavened bread paper;
      - starch from rice and waxy maize, not chemically modified;
    - (ii) miscellaneous:
      - pea protein *Pisum* spp.;
      - rum, only obtained from cane sugar juice;
      - kirsch prepared on the basis of fruits and flavourings as referred to in point 2.4.1. (b)
- 2.4.4. Fats and oils whether or not refined, but not chemically modified, may be used in their non-organic form if they are derived from plants other than:
- cocoa *Theobroma cacao*;
  - coconut *Cocos nucifera*;
  - olive *Olea europaea*;
  - sunflower *Helianthus annuus*;
  - palm *Elaeis guineensis*;
  - rape *Brassica napus, rapa*;
  - safflower *Carthamus tinctorius*;
  - sesame *Sesamum indicum*;
  - soya *Glycine max*.

### 3. Requirements for the production of processed feed

- 3.1. Production of processed organic feed shall be kept separate in time or space from production of processed non organic feed.
- 3.2. Organic feed materials, or in-conversion feed materials, shall not enter simultaneously with the same feed materials produced by non-organic means into the composition of the organic feed product.
- 3.3. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
- 3.4. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic feed, that correct the results of negligence in the processing or that otherwise may be misleading as to the true nature of those products shall not be used.

## Part V: Wine

## **1. Scope**

- 1.1. This Part lays down specific rules for the organic production of the products of the wine sector as referred to in Article 1(2)(l) of Regulation (EU) No 1308/2013. They apply in addition to the production rules laid down in Articles 7, 8, 9 and 14 of this Regulation.
- 1.2. Commission Regulations (EC) No 606/2009<sup>15</sup> and (EC) No 607/2009<sup>16</sup> shall apply, save as explicitly provided otherwise in this Part.

## **2. Use of certain products and substances**

- 2.1. Products of the wine sector shall be produced from organic raw material.
- 2.2. Only products and substances authorised for use in organic production in accordance with Article 18 may be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EU) No 1308/2013 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.

## **3. Oenological practices and restrictions**

- 3.1. Without prejudice to the Sections 1. and 2. and to specific prohibitions and restrictions provided for in points 3.2 to 3.5, only oenological practices, processes and treatments, including the restrictions provided for in Article 120c and 120d of Regulation (EU) No 1308/2013 and in Articles 3, 5 to 9 and 11 to 14 of Regulation (EC) No 606/2009 and in their Annexes, used before 1 August 2010 are permitted.
- 3.2. The use of the following oenological practices, processes and treatments is prohibited:
  - (a) partial concentration through cooling according to point (c) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007;
  - (b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;
  - (c) electrodialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009;
  - (d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009;
  - (e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.
- 3.3. The use of the following oenological practices, processes and treatments is permitted under the following conditions:
  - (a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed 70 °C;

<sup>15</sup> Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

<sup>16</sup> Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

- (b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0,2 micrometer.
- 3.4. The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before 1 August 2015 with a view to phase out or to further restrict those practices:
  - (a) heat treatments as referred to in point 2 of Annex I A to Regulation (EC) No 606/2009;
  - (b) use of ion exchange resins as referred to in point 20 of Annex I A to Regulation (EC) No 606/2009;
  - (c) reverse osmosis according to point (b) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007.
- 3.5. Any amendment introduced after 1 August 2010, as regards the oenological practice, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after the adoption of the measures necessary for the implementation of the production rules provided for in this Section and, if required, an evaluation according to Article 18 of this Regulation.

#### **Part VI: Yeast used as food or feed**

In addition to the general production rules laid down in Article 7,9 and 15, the rules set out in this Part shall apply to organic yeast used as food or feed.

##### **1. General requirements**

- 1.1. For the production of organic yeast only organically produced substrates shall be used.
- 1.2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
- 1.3. The following substances may be used in the production, confection and formulation of organic yeast:
  - (a) processing aids authorised for use in organic production in accordance with Article 18 ;
  - (b) products and substances referred to in point 2.4.1. (a) and (d) of Part IV of this Annex.

## **ANNEX III**

### **COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS**

#### **1. Collection of products and transport to preparation units**

Operators may carry out simultaneous collection of organic and non-organic products only where appropriate measures are taken to prevent any possible mixture or exchange with non-organic products and to ensure the identification of the organic products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control authority or control body.

#### **2. Packaging and transport of products to other operators or units**

2.1. Operators shall ensure that organic products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by Union law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) the name of the product or a description of the compound feedingstuff accompanied by a reference to organic production;
- (c) the name and/or the code number of the control authority or control body to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the control authority or control body and which permits to link the lot with the records referred to in Article 22.

The information referred to in points (a) to (d) may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier and/or the transporter.

2.2. The closing of packaging, containers or vehicles shall not be required where:

- (a) transportation is direct between an operator and another operator who are both subject to the organic control system; and
- (b) the products are accompanied by a document giving the information required under point 2.1; and
- (c) both the expediting and the receiving operators shall keep documentary records of such transport operations available for the control authority or control body.

#### **3. Special rules for transporting feed to other production/preparation units or storage premises**

When transporting feed to other production or preparation units or storage premises, operators shall ensure that the following conditions are met:

- (a) during transport, organically produced feed, in-conversion feedingstuffs, and non-organic feed shall be effectively physically separated;
- (b) vehicles and/or containers which have transported non-organic products may only be used to transport organic products if:

- (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products; operators shall record these operations;
- (ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with control arrangements and, where necessary, operators shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production;
- (iii) the operator shall keep documentary records of such transport operations available for the control authority or control body;
- (c) the transport of finished organic feed shall be separated physically or in time from the transport of other finished products;
- (d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded.

#### **4. Transport of live fish**

- 4.1. Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
- 4.2. Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.
- 4.3. Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.
- 4.4. Documentary evidence shall be maintained for points 4.1 to 4.3.

#### **5. Reception of products from other operators of units**

On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided for in Section 2.

The operator shall crosscheck the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 22.

#### **6. Special rules for the reception of products from a third country**

Where organic products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot and with the certificate of control for import from third countries as appropriate.

On receipt of an organic product, imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing, shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 26 (1) (b) (ii), shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article 22.

#### **7. Storage of products**

- 7.1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products

and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.

- 7.2. In case of organic plant and livestock production units, storage of input products other than those authorised for use in organic production in accordance with Article 18 is prohibited in the production unit.
- 7.3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in points 1.5.2.2 of Part II and 3.1.4.2(a) of Part III, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 22.
- 7.4. Where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
  - (a) the organic products shall be kept separate from the other agricultural products and/or foodstuffs;
  - (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;
  - (c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.

#### ANNEX IV

#### TERMS REFERRED TO IN ARTICLE 19

BG: биологичен.  
ES: ecológico, biológico.  
CS: ekologické, biologické.  
DA: økologisk.  
DE: ökologisch, biologisch.  
ET: mahe, ökoloogiline.  
EL: βιολογικό.  
EN: organic.  
FR: biologique.  
GA: orgánach.  
HR: ekološki.  
IT: biologico.  
LV: bioloģisks, ekoloģisks.  
LT: ekologiškas.  
LU: biologesch.  
HU: ökológiai.  
MT: organiku.  
NL: biologisch.  
PL: ekologiczne.  
PT: biológico.  
RO: ecologic.  
SK: ekologické, biologické.  
SL: ekološki.  
FI: luonnonmukainen.  
SV: ekologisk.

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**ANNEX V**  
**ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE**  
**NUMBERS**

**1. Logo**

- 1.1. The organic production logo of the European Union shall comply with the model below:

LOGO to be inserted

- 1.2. The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.
- 1.3. The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour:

LOGO to be inserted

- 1.4. If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.
- 1.5. If a logo is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours.
- 1.6. In certain specific situations where there are indications in a single colour on the packaging, the organic production logo of the European Union may be used in the same colour.
- 1.7. The organic production logo of the European Union must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.
- 1.8. The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production, under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in accordance with Article 21. When associated to national or private logos using a green colour different from the reference colour provided for in point 2, the organic production logo of the European Union may be used in that non-reference colour.

**2. Code numbers**

The general format of the code numbers shall be as follows:

AB-CDE-999

Where:

- (a) "AB" is the ISO code for the country where the controls take place;
- (b) "CDE" is a term, indicated in three letters to be decided by the Commission or each Member State, like "bio" or "öko" or "org" or "eko" establishing a link with organic production; and
- (c) "999" is the reference number, indicated in maximum three digits, to be attributed by:

- (i) each Member State's competent authority to the control authorities or control bodies to which they have delegated control tasks;
- (ii) the Commission, to:
  - the control authorities and control bodies recognised by the Commission for the purpose of Article 27;
  - the third countries' competent authorities recognised by the Commission for the purpose of Article 29.

- (6) 'polyculture' means the rearing of two or more species usually from different trophic levels in the same culture unit;
- (7) 'production cycle' means the lifespan of an aquaculture animal or seaweed from the earliest life stage to harvesting;
- (8) 'locally grown species' means those species which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007<sup>8</sup>; it includes the species listed in Annex IV to that Regulation;
- (9) 'stocking density' means the live weight of aquaculture animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface.

## 2. Requirements for seaweed

In addition to the general production rules laid down in Article 7, 8, 9 and 12, the following rules shall apply to the collection and production of seaweed and *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

### 2.1. Conversion

- 2.1.1. The conversion period for a seaweed harvesting site shall be six months.
- 2.1.2. The conversion period for a seaweed cultivation unit shall be the longer of six months or one full production cycle.
- 2.1.3. During the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards seaweed production, the same species may be involved, provided that there is adequate separation between the units.

### 2.2. Production rules for seaweed

- 2.2.1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as organic production provided that:
  - (a) the growing areas are of high ecological quality as defined by Directive 2000/60/EC and, of a quality equivalent to designated waters under Directive 2006/113/EC of the European Parliament and of the Council<sup>9</sup>, and are not unsuitable from a health point of view. Wild edible seaweeds shall not be collected in areas which would not meet the criteria for Class A or Class B areas as defined in Annex II to Regulation (EC) No 854/2004 of the European Parliament and of the Council<sup>10</sup> [*to be repealed by new official controls regulation*];
  - (b) the collection does not affect the long term stability of the natural habitat or the maintenance of the species in the collection area.

<sup>8</sup> Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture (OJ L 168, 28.6.2007, p. 1).

<sup>9</sup> Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters (OJ L 376, 27.12.2006, p. 14).

<sup>10</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

- 2.2.2. The production of seaweeds shall take place in coastal areas with environmental and health characteristics at least equivalent to those outlined in point 2.2.1 in order to be considered organic. In addition the following production rules shall apply:
- (a) sustainable practices shall be used in all stages of production, from collection of juvenile seaweed to harvesting;
  - (b) to ensure that a wide gene-pool is maintained, the collection of juvenile seaweed in the wild shall take place on a regular basis to supplement indoor culture stock;
  - (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose.
- 2.3. Suitability of aquatic medium and sustainable management plan in seaweed production
- 2.3.1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for use in organic production, or pollutants that would compromise the organic nature of the products.
- 2.3.2. Organic and non-organic production units shall be separated adequately and in accordance with the minimum separation distances set by Member States, where such minimum separation distances have been set. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Seaweed production shall not be considered as organic when practiced at locations or in areas designated by Member State authorities as locations or areas which are unsuitable for organic aquaculture or seaweed harvesting.
- 2.3.3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control authority or control body. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU of the European Parliament and of the Council<sup>11</sup>. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
- 2.3.4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.
- 2.3.5. The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.
- 2.3.6. Aquaculture and seaweed business operators shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy

<sup>11</sup> Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

from renewable sources. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

#### 2.4. Seaweed cultivation

- 2.4.1. Seaweed culture at sea shall only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal production, preferably located nearby as part of a polyculture system.
- 2.4.2. In facilities on land where external nutrient sources are used the nutrient levels in the effluent water shall be verifiably the same, or lower, than the inflowing water. Only nutrients of plant or mineral origin authorised for use in organic production in accordance with Article 18 may be used.
- 2.4.3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.
- 2.4.4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.

#### 2.5. Sustainable harvesting of wild seaweed

- 2.5.1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with this Regulation.
- 2.5.2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
- 2.5.3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

### 3. Requirements for aquaculture animals

In addition to the general production rules laid down in Article 7, 8, 9 and 12, the rules set out in this Section shall apply to species of fish, crustaceans, echinoderms and molluscs, as referred to in point 3.1.5.6., and they apply *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

#### 3.1. General rules

##### 3.1.1. Conversion

- 3.1.1.1. The following conversion periods for aquaculture production units shall apply for the following types of aquaculture facilities including the existing aquaculture animals:
  - (a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;
  - (b) for facilities that have been drained, or fallowed, a conversion period of 12 months;
  - (c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;

- (d) for open water facilities including those producing bivalve molluscs, a conversion period of three months.
- 3.1.1.2. During the conversion period, the agricultural holding may be split into clearly separated units which are not all managed under organic production. As regards the production of aquaculture animals, the same species may be involved provided that there is adequate separation between the units.
- 3.1.1.3. The competent authority may decide to recognise retroactively as being part of the conversion period any previously documented period in which the facilities were not treated or exposed to products not authorised for organic production.
- 3.1.2. Origin of aquaculture animals
  - 3.1.2.1. The following rules shall apply with regard to the origin of the aquaculture animals:
    - (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;
    - (b) locally grown species shall be used and breeding shall aim to give strains which are more adapted to production conditions, good health and good utilisation of feed resources. Documentary evidence of their origin and treatment shall be provided for the control authority or control body;
    - (c) species shall be chosen which can be produced without causing significant damage to wild stocks;
    - (d) wild caught or non-organic aquaculture animals may be brought into a holding with a view to improving genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding.
  - 3.1.2.2. The following rules shall apply with regard to breeding:
    - (a) the use of hormones and hormone derivatives is prohibited;
    - (b) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;
    - (c) the appropriate strains shall be chosen;
    - (d) species-specific conditions for broodstock management, breeding and juvenile production shall be established.
- 3.1.3. Nutrition
  - 3.1.3.1. The following rules shall apply with regard to feed for fish and crustaceans:
    - (a) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
    - (b) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from sustainable exploitation of fisheries;
    - (c) in the case of non-organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under this Regulation;
    - (d) growth promoters and synthetic amino-acids shall not be used;

3.1.3.2. The following rules shall apply with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:

- (a) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
- (b) they shall be grown in waters which meet the criteria for Class A or Class B areas as defined in Annex II to Regulation (EC) No 854/2004;
- (c) the growing areas shall be of high ecological quality as defined by Directive 2000/60/EC and of a quality equivalent to designated waters under Directive 2006/113/EC.

3.1.3.3. The following rules shall apply with regard to feed for fish, crustaceans and echinoderms:

- (a) feeding regimes shall be designed with the following priorities:
  - (i) animal health;
  - (ii) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;
  - (iii) low environmental impact;
- (b) only the feed materials of mineral origin authorised for use in organic production in accordance with Article 18 may be used in organic aquaculture.
- (c) only the feed additives, certain products used in animal nutrition and processing aids as referred to in point 1.4.4. of Part II may be used in organic aquaculture.

#### 3.1.4. Health care

##### 3.1.4.1. Disease prevention

The following rules shall apply with regard to disease prevention:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;
- (b) the use of immunological veterinary medicines is allowed;
- (c) an animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish;
- (d) holding systems, equipment and utensils shall be properly cleaned and disinfected;
- (e) bio-fouling organisms shall be removed only by physical means or by hand and where appropriate returned to the sea at a distance from the farm;
- (f) only substances for cleaning and disinfection of equipment and facilities authorised for use in organic production in accordance with Article 18 may be used.

- (g) With regard to fallowing the following rules shall apply:
  - (i) the competent authority shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea.
  - (ii) it shall not be mandatory for bivalve mollusc cultivation;
  - (iii) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again;
- (h) where appropriate, uneaten fish-feed, faeces and dead animals shall be removed promptly to avoid any risk of significant environmental damage as regards water status quality, minimise disease risks, and to avoid attracting insects or rodents;
- (i) ultraviolet light and ozone may be used only in hatcheries and nurseries;
- (j) for biological control of ectoparasites preference shall be given to the use of cleaner fish.

#### 3.1.4.2. Veterinary treatments

The following rules shall apply with regard to veterinary treatments:

- (a) Disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate. In particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;
- (b) Treatments related to the protection of human and animal health imposed on the basis of Union legislation shall be allowed.
- (c) When despite preventive measures to ensure animal health, according to point 3.1.4.1., a health problem arises, veterinary treatments may be used in the following order of preference:
  - (i) substances from plants, animals or minerals in a homoeopathic dilution;
  - (ii) plants and their extracts not having anaesthetic effects; and
  - (iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;
- (d) the use of allopathic treatments is limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of a production cycle of less than a year a limit of one allopathic treatment applies. If the mentioned limits for allopathic treatments are exceeded the concerned aquaculture animals cannot be sold as organic products;
- (e) the use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months;
- (f) the withdrawal period for allopathic veterinary treatments and parasite treatments in accordance with point (c), including treatments under compulsory

control and eradication schemes, shall be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or in a case in which this period is not specified 48 hours;

- (g) whenever veterinary medicinal products are used, such use is to be declared to the control authority or the control body before the animals are marketed as organic. Treated stock shall be clearly identifiable.

### 3.1.5. Housing conditions and husbandry practices

3.1.5.1. The husbandry environment of the aquaculture animals shall be designed in such a way that, in accordance with their species specific needs, the aquaculture animals shall:

- (a) have sufficient space for their wellbeing;
- (b) be kept in water of good quality with sufficient oxygen levels;
- (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location;

In the case of freshwater fish the bottom type shall be as close as possible to natural conditions.

In the case of carp the bottom shall be natural earth.

3.1.5.2. The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

3.1.5.3. Containment systems shall be designed, located and operated to minimise the risk of escape incidents.

3.1.5.4. If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained

3.1.5.5. For aquaculture animal production in fishponds, tanks or raceways, farms shall be equipped with either natural-filter beds, settlement ponds, biological filters or mechanical filters to collect waste nutrients or use seaweeds and/or animals (bivalves and algae) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.

3.1.5.6. The stocking density shall be as set out in points (a) to (j) by species or group of species. In considering the effects of the stocking density on the welfare of produced fish, the condition of the fish (such as fin damage, other injuries, growth rate, behaviour expressed and overall health) and the water quality shall be monitored.

- (a) Organic production of salmonids in fresh water:

brown trout (*Salmo trutta*) – rainbow trout (*Oncorhynchus mykiss*) – American brook trout (*Salvelinus fontinalis*) – salmon (*Salmo salar*) – charr (*Salvelinus alpinus*) – grayling (*Thymallus thymallus*) – American lake trout (or grey trout) (*Salvelinus namaycush*) – huchen (*Huchohucho*)

Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 60 % oxygen saturation for stock and must ensure their comfort and the
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		elimination of production effluent.
Maximum density	stocking	Salmonid species not listed below 15 kg/m <sup>3</sup> Salmon 20 kg/m <sup>3</sup> Brown trout and Rainbow trout 25 kg/m <sup>3</sup> Arctic charr 20 kg/m <sup>3</sup>

(b) Organic production of salmonids in sea water:

salmon (*Salmo salar*), brown trout (*Salmo trutta*) - rainbow trout (*Oncorhynchus mykiss*)

Maximum density	stocking	10 kg/m <sup>3</sup> in net pens
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(c) Organic production of cod (*Gadus morhua*) and other Gadidae, sea bass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), meagre (*Argyrosomus regius*), turbot (*Psetta maxima* [= *Scophthalmus maximus*]), red porgy (*Pagrus pagrus* [= *Sparus pagrus*]), red drum (*Sciaenops ocellatus*) and other Sparidae, and spinefeet (*Siganus spp.*)

Production system		In open water containment systems (net pens/cages) with minimum sea current speed to provide optimum fish welfare or in open systems on land.
Maximum density	stocking	For fish other than turbot: 15 kg/m <sup>3</sup> For turbot: 25 kg/m <sup>2</sup>

(d) Organic production of sea bass, sea bream, meagre, mullets (*Liza*, *Mugil*) and eel (*Anguilla spp.*) in earth ponds of tidal areas and coastal lagoons

Containment system		Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas
Production system		There shall be adequate renewal of water to ensure the welfare of the species,  At least 50 % of the dikes must have plant cover  Wetland based depuration ponds required
Maximum density	stocking	4 kg/m <sup>3</sup>

(e) Organic production of sturgeon in fresh water:

species concerned: Sturgeon family (Acipenseridae)

Production system		Water flow in each rearing unit shall be sufficient to ensure animal welfare  Effluent water to be of equivalent quality to incoming water
Maximum density	stocking	30 kg/m <sup>3</sup>

(f) Organic production of fish in inland waters:

species concerned: carp family (Cyprinidae) and other associated species in the context of polyculture, including perch, pike, catfish, coregonids, sturgeon.

Production system	<p>In fishponds which shall periodically be fully drained and in lakes. Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas.</p> <p>The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.</p> <p>Organic and mineral fertilisation of the ponds and lakes shall be carried out with only fertilisers and soil conditioners authorised for use in organic production in accordance with Article 18 with a maximum application of 20 kg nitrogen/ha.</p> <p>Treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters are prohibited.</p> <p>Areas of natural vegetation shall be maintained around inland water units as a buffer zone for external land areas not involved in the production operation in accordance with the rules of organic aquaculture.</p> <p>For grow-out “polyculture” shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.</p>
Production yield	The total production of species is limited to 1500 kg of fish per hectare per year.

(g) Organic production of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.):

Establishment of production unit/s	Location to be in sterile clay areas to minimise environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Mangrove destruction is not permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a produced shrimp.
Broodstock origin	A minimum of half the broodstock shall be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm.
Eyestalk ablation	Is prohibited.
Maximum on farm stocking densities and	Seeding: maximum 22 post larvae/m <sup>2</sup>

production limits	Maximum instantaneous biomass: 240 g/m <sup>2</sup>
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(h) Molluscs and echinoderms:

Production systems	Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets, bouchot poles and other containment systems.  For mussel cultivation on rafts the number of drop-ropes shall not exceed one per square meter of surface area. The maximum drop-rope length shall not exceed 20 m. Thinning-out of drop-ropes shall not take place during the production cycle, however sub-division of drop ropes shall be permitted without increasing stocking density at the outset.
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(i) Tropical fresh water fish: milkfish (*Chanos chanos*), tilapia (*Oreochromis* spp.), siamese catfish (*Pangasius* spp.):

Production systems	Ponds and net cages
Maximum stocking density	Pangasius: 10 kg/m <sup>3</sup>  Oreochromis: 20 kg/m <sup>3</sup>

(j) Other aquaculture animal species: none

### 3.1.6. Animal welfare

3.1.6.1. Handling of aquaculture animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimise physical damage and stress and under anaesthesia where appropriate. Grading operations shall be kept to a minimum and as required to ensure fish welfare.

3.1.6.2. The following restrictions shall apply to the use of artificial light:

- (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of produced animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;
- (b) abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.

3.1.6.3. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.

3.1.6.4. The use of oxygen is only permitted for uses linked to animal health requirements and critical periods of production or transport, in the following cases:

- (a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution;
- (b) occasional stock management procedures such as sampling and sorting;
- (c) in order to assure the survival of the farm stock.

3.1.6.5. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.

### 3.2. Specific rules

#### 3.2.1. Nutrition

##### 3.2.1.1. Specific rules on feedingstuffs for carnivorous aquaculture animals

Feedingstuffs for carnivorous aquaculture animals shall be sourced with the following priorities:

- (a) organic feedingstuffs of aquaculture origin;
- (b) fish meal and fish oil from organic aquaculture trimmings;
- (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;
- (d) organic feed materials of plant or animal origin.

##### 3.2.1.2. Specific rules on feedingstuffs for certain aquaculture animals

- (a) Aquaculture animals as referred to in point 3.1.5.6. (f), (g) and (i) shall be fed with feedingstuffs naturally available in ponds and lakes;
- (b) Where natural feedingstuffs are not available in sufficient quantities as referred to in point (a), organic feedingstuffs of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feedingstuffs;
- (c) Where natural feedingstuff is supplemented according to point (b) the feed ration of species as referred to in point 3.1.5.6. (g) and of siamese catfish (*Pangasius* spp.) as referred to in point 3.1.5.6 (i) may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

#### 3.2.2. Housing conditions

3.2.2.1. Closed recirculation aquaculture animal production facilities are prohibited, with the exception of hatcheries and nurseries or for the production of species used for organic feed organisms.

3.2.2.2. Rearing units on land shall meet the following conditions:

- (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
- (b) at least five percent of the perimeter ("land-water interface") area shall have natural vegetation.

3.2.2.3. Containment systems at sea shall:

- (a) be located where water flow, depth and water-body exchange rates are adequate to minimise the impact on the seabed and the surrounding water body;
- (b) have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.

3.2.2.4. Artificial heating or cooling of water shall only be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

### 3.2.3. Specific rules for molluscs

#### 3.2.3.1. Origin of seed

The following rules shall apply with regard to the origin of seed:

- (a) provided that there is no significant damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit may be used in the case of bivalve shellfish provided it comes from:
  - (i) settlement beds which are unlikely to survive winter weather or are surplus to requirements; or
  - (ii) natural settlement of shellfish seed on collectors;

Records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area;

- (b) for the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild.

#### 3.2.3.2. Housing conditions and husbandry practices

The following rules shall apply with regard to the housing conditions and husbandry practices:

- (a) production may be carried out in the same area of water as organic finfish and seaweed production in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture;
- (b) organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means;
- (c) organic shellfish farms shall minimise risks to species of conservation interest. If predator nets are used their design shall not permit diving birds to be harmed.

#### 3.2.3.3. Cultivation

The following rules shall apply with regard to cultivation:

- (a) cultivation on mussel ropes and other methods listed in point 3.1.5.6 (h) may be eligible for organic production;
- (b) bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the control authority or control body. The report shall be added as a separate chapter to the sustainable management plan.

#### 3.2.3.4. Management

- (a) production shall use a stocking density not in excess of that used for non-organic molluscs in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality;
- (b) biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from mollusc farms. Molluscs may be treated once during the production cycle with a lime solution to control competing fouling organisms.

#### 3.2.3.5. Specific cultivation rules for oysters

Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the requirements set out in point 3.1.5.6. (h).

### **Part IV: Processed food and processed feed production rules**

In addition to the general production rules laid down in Articles 7, 9 and 13, the rules set out in this Part shall apply to processed food and processed feed.

#### **1. General requirements for the production of processed food and feed**

- 1.1. Food and feed additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice<sup>12</sup>.
- 1.2. Operators producing processed food or feed shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
- 1.3. The application of the procedures referred to in point 1.2. shall guarantee at all times that the produced processed products comply with the organic production rules.
- 1.4. Operators shall comply with and implement the procedures referred to in point 1.2. In particular, operators shall:
  - (a) take preventive measures to avoid the risk of contamination by unauthorised substances or products;
  - (b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
  - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
- 1.5. When non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:
  - (a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;
  - (b) store organic products, before and after the operations, separate by place or time from non-organic products;

<sup>12</sup> Good manufacturing practices (GMPs) as defined in the guidelines of the ICH (International Conference on Harmonization)

- (c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;
- (d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
- (e) carry out operations on organic products only after suitable cleaning of the production equipment.

## **2. Requirements for the production of processed food**

2.1. The preparation of processed organic food shall be kept separate in time or space from non-organic food.

2.2. The following conditions shall apply to the composition of organic processed food:

- (a) the product shall be produced mainly from agricultural ingredients; in order to determine whether a product is produced mainly from agricultural ingredients, added water and salt shall not be taken into account;
- (b) only food additives, processing aids, flavourings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as amino acids and other micronutrients in foodstuffs for particular nutritional uses authorised for use in organic production in accordance with Article 18 may be used;
- (c) an organic ingredient shall not be present together with an ingredient in conversion;
- (d) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.

2.3. Products, substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of those products or that otherwise may be misleading as to the true nature of these products shall not be used.

2.4. Use of certain products and substances in processing of food

2.4.1. Only the products and substances authorised for use in organic production in accordance with Article 18 as well as the products and substances mentioned under points (a) to (e) hereunder, may be used in the processing of organic food, with the exception of products and substances of the wine sector, for which point 2 of Part V shall apply and of yeast for which point 1.3 of Part VI shall apply:

- (a) Preparations of micro-organisms and enzymes normally used in food processing; enzymes to be used as food additives have to be authorised for use in organic production in accordance with Article 18;
- (b) Substances, and products as defined in Article 3(1)(b) and (d) of Regulation (EC) No 1334/2008 of the European Parliament and of the Council<sup>13</sup> labelled as natural flavouring substances or natural flavouring preparations, in accordance with Articles 15(1)(e) and (16) of that Regulation.

<sup>13</sup>

Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

- (c) Colours for stamping meat and eggshells in accordance with, respectively, Article 18 of Regulation (EC) No 1333/2008 of the European Parliament and of the Council<sup>14</sup>;
  - (d) Drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
  - (e) Minerals (trace elements included), vitamins, aminoacids, and micronutrients, only authorised as far their use is required in the foodstuffs in which they are incorporated.
- 2.4.2. For the purpose of the calculation referred to in Article 19 the following rules shall apply:
- (a) certain food additives authorised for use in organic production in accordance with Article 18, shall be calculated as agricultural ingredients;
  - (b) preparations and substances referred to in points (a) to (e) of point 2.4.1. shall not be calculated as agricultural ingredients;
  - (c) yeast and yeast products shall be calculated as agricultural ingredients.
- 2.4.3. The following non-organic agricultural ingredients may be used in the processing of organic food:
- (a) animal products:
    - (i) aquatic organisms, not originating from aquaculture, and permitted in non-organic foodstuffs preparation;
    - (ii) gelatin;
    - (iii) whey powder "herasuola";
    - (iv) casings.
  - (b) unprocessed vegetable products as well as products derived therefrom by processing:
    - (i) edible fruits, nuts and seeds:
 

– acorns	<i>Quercus</i> spp.;
– cola nuts	<i>Cola acuminata</i> ;
– gooseberries	<i>Ribes uva-crispa</i> ;
– maracujas (passion fruit)	<i>Passiflora edulis</i> ;
– raspberries (dried)	<i>Rubus idaeus</i> ;
– red currants (dried)	<i>Ribes rubrum</i> .
    - (ii) edible spices and herbs:
 

– pepper (Peruvian)	<i>Schinus molle</i> ;
– horseradish seeds	<i>Armoracia rusticana</i> ;
– lesser galanga	<i>Alpinia officinarum</i> ;
– safflower flowers	<i>Carthamus tinctorius</i> ;

<sup>14</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

- watercress herb *Nasturtium officinale*.
- (iii) miscellaneous:
  - algae, including seaweed.
- (c) processed vegetable products:
  - (i) sugars, starches and other products from cereals and tubers:
    - fructose;
    - rice paper;
    - unleavened bread paper;
    - starch from rice and waxy maize, not chemically modified;
  - (ii) miscellaneous:
    - pea protein *Pisum* spp.;
    - rum, only obtained from cane sugar juice;
    - kirsch prepared on the basis of fruits and flavourings as referred to in point 2.4.1. (b)

2.4.4. Fats and oils whether or not refined, but not chemically modified, may be used in their non-organic form if they are derived from plants other than:

- cocoa *Theobroma cacao*;
- coconut *Cocos nucifera*;
- olive *Olea europaea*;
- sunflower *Helianthus annuus*;
- palm *Elaeis guineensis*;
- rape *Brassica napus, rapa*;
- safflower *Carthamus tinctorius*;
- sesame *Sesamum indicum*;
- soya *Glycine max*.

### 3. Requirements for the production of processed feed

- 3.1. Production of processed organic feed shall be kept separate in time or space from production of processed non organic feed.
- 3.2. Organic feed materials, or in-conversion feed materials, shall not enter simultaneously with the same feed materials produced by non-organic means into the composition of the organic feed product.
- 3.3. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
- 3.4. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic feed, that correct the results of negligence in the processing or that otherwise may be misleading as to the true nature of those products shall not be used.

## Part V: Wine

## **1. Scope**

- 1.1. This Part lays down specific rules for the organic production of the products of the wine sector as referred to in Article 1(2)(l) of Regulation (EU) No 1308/2013. They apply in addition to the production rules laid down in Articles 7, 8, 9 and 14 of this Regulation.
- 1.2. Commission Regulations (EC) No 606/2009<sup>15</sup> and (EC) No 607/2009<sup>16</sup> shall apply, save as explicitly provided otherwise in this Part.

## **2. Use of certain products and substances**

- 2.1. Products of the wine sector shall be produced from organic raw material.
- 2.2. Only products and substances authorised for use in organic production in accordance with Article 18 may be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EU) No 1308/2013 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.

## **3. Oenological practices and restrictions**

- 3.1. Without prejudice to the Sections 1. and 2. and to specific prohibitions and restrictions provided for in points 3.2 to 3.5, only oenological practices, processes and treatments, including the restrictions provided for in Article 120c and 120d of Regulation (EU) No 1308/2013 and in Articles 3, 5 to 9 and 11 to 14 of Regulation (EC) No 606/2009 and in their Annexes, used before 1 August 2010 are permitted.
- 3.2. The use of the following oenological practices, processes and treatments is prohibited:
  - (a) partial concentration through cooling according to point (c) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007;
  - (b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;
  - (c) electrodialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009;
  - (d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009;
  - (e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.
- 3.3. The use of the following oenological practices, processes and treatments is permitted under the following conditions:
  - (a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed 70 °C;

<sup>15</sup> Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

<sup>16</sup> Commission Regulation (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products (OJ L 193, 24.7.2009, p. 60).

- (b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0,2 micrometer.
- 3.4. The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before 1 August 2015 with a view to phase out or to further restrict those practices:
  - (a) heat treatments as referred to in point 2 of Annex I A to Regulation (EC) No 606/2009;
  - (b) use of ion exchange resins as referred to in point 20 of Annex I A to Regulation (EC) No 606/2009;
  - (c) reverse osmosis according to point (b) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007.
- 3.5. Any amendment introduced after 1 August 2010, as regards the oenological practice, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after the adoption of the measures necessary for the implementation of the production rules provided for in this Section and, if required, an evaluation according to Article 18 of this Regulation.

#### **Part VI: Yeast used as food or feed**

In addition to the general production rules laid down in Article 7,9 and 15, the rules set out in this Part shall apply to organic yeast used as food or feed.

##### **1. General requirements**

- 1.1. For the production of organic yeast only organically produced substrates shall be used.
- 1.2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
- 1.3. The following substances may be used in the production, confection and formulation of organic yeast:
  - (a) processing aids authorised for use in organic production in accordance with Article 18 ;
  - (b) products and substances referred to in point 2.4.1. (a) and (d) of Part IV of this Annex.

## **ANNEX III**

### **COLLECTION, PACKAGING, TRANSPORT AND STORAGE OF PRODUCTS**

#### **1. Collection of products and transport to preparation units**

Operators may carry out simultaneous collection of organic and non-organic products only where appropriate measures are taken to prevent any possible mixture or exchange with non-organic products and to ensure the identification of the organic products. The operator shall keep the information relating to collection days, hours, circuit and date and time of reception of the products available to the control authority or control body.

#### **2. Packaging and transport of products to other operators or units**

2.1. Operators shall ensure that organic products are transported to other operators or units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by Union law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) the name of the product or a description of the compound feedingstuff accompanied by a reference to organic production;
- (c) the name and/or the code number of the control authority or control body to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the control authority or control body and which permits to link the lot with the records referred to in Article 22.

The information referred to in points (a) to (d) may also be presented on an accompanying document, if such a document can be undeniably linked with the packaging, container or vehicular transport of the product. This accompanying document shall include information on the supplier and/or the transporter.

2.2. The closing of packaging, containers or vehicles shall not be required where:

- (a) transportation is direct between an operator and another operator who are both subject to the organic control system; and
- (b) the products are accompanied by a document giving the information required under point 2.1; and
- (c) both the expediting and the receiving operators shall keep documentary records of such transport operations available for the control authority or control body.

#### **3. Special rules for transporting feed to other production/preparation units or storage premises**

When transporting feed to other production or preparation units or storage premises, operators shall ensure that the following conditions are met:

- (a) during transport, organically produced feed, in-conversion feedingstuffs, and non-organic feed shall be effectively physically separated;
- (b) vehicles and/or containers which have transported non-organic products may only be used to transport organic products if:

- (i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products; operators shall record these operations;
- (ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with control arrangements and, where necessary, operators shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production;
- (iii) the operator shall keep documentary records of such transport operations available for the control authority or control body;
- (c) the transport of finished organic feed shall be separated physically or in time from the transport of other finished products;
- (d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded.

#### **4. Transport of live fish**

- 4.1. Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
- 4.2. Before transport of organic fish and fish products, tanks shall be thoroughly cleaned, disinfected and rinsed.
- 4.3. Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.
- 4.4. Documentary evidence shall be maintained for points 4.1 to 4.3.

#### **5. Reception of products from other operators of units**

On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided for in Section 2.

The operator shall crosscheck the information on the label referred to in Section 2 with the information on the accompanying documents. The result of those verifications shall be explicitly mentioned in the records referred to in Article 22.

#### **6. Special rules for the reception of products from a third country**

Where organic products are imported from a third country, they shall be transported in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot and with the certificate of control for import from third countries as appropriate.

On receipt of an organic product, imported from a third country, the natural or legal person to whom the imported consignment is delivered and who receives it for further preparation or marketing, shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 26 (1) (b) (ii), shall check that the certificate of inspection referred to in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the records referred to in Article 22.

#### **7. Storage of products**

- 7.1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products

and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.

- 7.2. In case of organic plant and livestock production units, storage of input products other than those authorised for use in organic production in accordance with Article 18 is prohibited in the production unit.
- 7.3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in points 1.5.2.2 of Part II and 3.1.4.2(a) of Part III, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 22.
- 7.4. Where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
  - (a) the organic products shall be kept separate from the other agricultural products and/or foodstuffs;
  - (b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;
  - (c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.

#### ANNEX IV

#### TERMS REFERRED TO IN ARTICLE 19

BG: биологичен.  
ES: ecológico, biológico.  
CS: ekologické, biologické.  
DA: økologisk.  
DE: ökologisch, biologisch.  
ET: mahe, ökoloogiline.  
EL: βιολογικό.  
EN: organic.  
FR: biologique.  
GA: orgánach.  
HR: ekološki.  
IT: biologico.  
LV: bioloģisks, ekoloģisks.  
LT: ekologiškas.  
LU: biologesch.  
HU: ökológiai.  
MT: organiku.  
NL: biologisch.  
PL: ekologiczne.  
PT: biológico.  
RO: ecologic.  
SK: ekologické, biologické.  
SL: ekološki.  
FI: luonnonmukainen.  
SV: ekologisk.

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**ANNEX V**  
**ORGANIC PRODUCTION LOGO OF THE EUROPEAN UNION AND CODE**  
**NUMBERS**

**1. Logo**

- 1.1. The organic production logo of the European Union shall comply with the model below:

LOGO to be inserted

- 1.2. The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.
- 1.3. The organic production logo of the European Union may also be used in black and white as shown, only where it is not practicable to apply it in colour:

LOGO to be inserted

- 1.4. If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.
- 1.5. If a logo is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the logo can be used to improve contrast with the background colours.
- 1.6. In certain specific situations where there are indications in a single colour on the packaging, the organic production logo of the European Union may be used in the same colour.
- 1.7. The organic production logo of the European Union must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.
- 1.8. The organic production logo of the European Union may be associated with graphical or textual elements referring to organic production, under the condition that they do not modify or change the nature of the organic production logo of the European Union, nor any of the indications defined in accordance with Article 21. When associated to national or private logos using a green colour different from the reference colour provided for in point 2, the organic production logo of the European Union may be used in that non-reference colour.

**2. Code numbers**

The general format of the code numbers shall be as follows:

AB-CDE-999

Where:

- (a) "AB" is the ISO code for the country where the controls take place;
- (b) "CDE" is a term, indicated in three letters to be decided by the Commission or each Member State, like "bio" or "öko" or "org" or "eko" establishing a link with organic production; and
- (c) "999" is the reference number, indicated in maximum three digits, to be attributed by:

- (i) each Member State's competent authority to the control authorities or control bodies to which they have delegated control tasks;
- (ii) the Commission, to:
  - the control authorities and control bodies recognised by the Commission for the purpose of Article 27;
  - the third countries' competent authorities recognised by the Commission for the purpose of Article 29.