

## ANNEX II

### DETAILED PRODUCTION RULES REFERRED TO IN CHAPTER III

#### Part I: Plant production rules

In addition to the production rules laid down in Articles 9 to 12, the rules set out in this Part shall apply to organic plant production.

1. General requirements
  - 1.1. Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock.
  - 1.2. Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.
  - 1.3. By way of derogation from point 1.1, the production of sprouts by moistening of seeds and the obtaining of chicory heads including by dipping in clear water shall be allowed.
  - 1.4. By way of derogation from point 1.1, the following practices shall be allowed:
    - (a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;
    - (b) growing seedlings or transplants in containers for further transplanting.
  - 1.5. By way of derogation from point 1.1, growing crops in demarcated beds shall only be allowed for the surfaces that have been certified as organic for that practice before 28 June 2017 in Finland, Sweden and Denmark. No extension of those surfaces shall be permitted.

That derogation shall expire on 31 December 2030.

By 31 December 2025, the Commission shall present a report to the European Parliament and the Council on the use of demarcated beds in organic agriculture. That report may be accompanied, where appropriate, by a legislative proposal on the use of demarcated beds in organic agriculture.

- 1.6. All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment.
- 1.7. Conversion
  - 1.7.1. For plants and plant products to be considered as organic products, the production rules laid down in this Regulation shall have been applied with respect to the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, during a period of at least two years before its use as organic feed, or, in the case of perennial crops other than forage, during a period of at least three years before the first harvest of organic products.
  - 1.7.2. Where the land or one or more parcels thereof have been contaminated with products or substances not authorised for use in organic production, the competent authority may decide to extend the conversion period for the land or parcels concerned beyond the period referred to in point 1.7.1.

- 1.7.3. In the case of treatment with a product or a substance not authorised for use in organic production, the competent authority shall require a new conversion period in accordance with point 1.7.1.

That period may be shortened in the following two cases:

- (a) treatment with a product or a substance not authorised for use in organic production as part of a compulsory control measure for pests or weeds, including quarantine organisms or invasive species, imposed by the competent authority of the Member State concerned;
- (b) treatment with a product or a substance not authorised for use in organic production as part of scientific tests approved by the competent authority of the Member State concerned.

- 1.7.4. In the cases referred to in points 1.7.2 and 1.7.3, the length of the conversion period shall be fixed taking into account the following requirements:

- (a) the process of degradation of the product or substance concerned must 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 placed on the market as organic or in-conversion products.

- 1.7.4.1. Member States shall inform the Commission and the other Member States of any decision taken by them which lays down compulsory measures related to treatment with a product or a substance not authorised for use in organic production.

- 1.7.4.2. In the case of treatment with a product or a substance which is not authorised for use in organic production, point 1.7.5(b) shall not apply.

- 1.7.5. In the case of land associated with organic livestock production:

- (a) the conversion rules shall apply to the whole area of the production unit on which animal feed is produced;
- (b) notwithstanding point (a), the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species.

- 1.8. Origin of plants including plant reproductive material

- 1.8.1. For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used.

- 1.8.2. To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.

- 1.8.3. When choosing organic plant reproductive material, operators shall give preference to organic plant reproductive material suitable for organic agriculture.

- 1.8.4. For the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as

agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.

All multiplication practices except meristem culture shall be carried out under certified organic management.

1.8.5. Use of in-conversion and non-organic plant reproductive material

1.8.5.1. By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) shows that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material, excluding seedlings, are not met, competent authorities may authorise the use of in-conversion or non-organic plant reproductive material under the conditions laid down in points 1.8.5.3, 1.8.5.4 and 1.8.5.5.

Prior to requesting any such derogation, the operator shall consult the database referred to in Article 26(1) or the system referred to in point (a) of Article 26(2) in order to verify whether his or her request is justified.

1.8.5.2. Control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators in third countries to use in-conversion or non-organic plant reproductive material in an organic production unit when organic plant reproductive material is not available in sufficient quality or quantity in the territory of the third country in which the operator is located, under the conditions laid down under points 1.8.5.3, 1.8.5.4 and 1.8.5.5.

1.8.5.3. Non-organic plant reproductive material shall not be treated with plant protection products other than those authorised for the treatment of seed in accordance with Article 24(1) of this Regulation, unless chemical treatment has been prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authority of the Member State concerned for all varieties of a given species in the area in which the plant reproductive material is to be used.

1.8.5.4. The authorisation to use in-conversion or non-organic plant reproductive material shall be obtained before the sowing of the crop.

1.8.5.5. The authorisation to use in-conversion or non-organic plant reproductive material shall be granted only to individual users for one season at a time, and the competent authority responsible for authorisations shall list the quantities of the authorised plant reproductive material.

1.9. Soil management and fertilisation

1.9.1. In organic plant production, tillage and cultivation practices shall be used that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion.

1.9.2. The fertility and biological activity of the soil shall be maintained and increased:

- (a) except in the case of grassland or perennial forage, by the use of multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops;
- (b) in the case of greenhouses or perennial crops other than forage, by the use of short-term green manure crops and legumes as well as the use of plant diversity; and

- (c) in all cases, by the application of livestock manure or organic matter, both preferably composted, from organic production.
- 1.9.3. Where the nutritional needs of plants cannot be met by the measures provided for in points 1.9.1 and 1.9.2, only fertilisers and soil conditioners that have been authorised pursuant to Article 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records of the use of those products.
- 1.9.4. The total amount of livestock manure, as defined in Directive 91/676/EEC, used in the in-conversion and organic production units shall 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 excrement, including poultry manure, composted farmyard manure and liquid animal excrement.
- 1.9.5. Operators of agricultural holdings may establish written cooperation agreements exclusively with operators of other agricultural holdings and undertakings which comply with the organic production rules, for the purpose of spreading surplus manure from organic production units. The maximum limit referred to in point 1.9.4 shall be calculated on the basis of all of the organic production units involved in such cooperation.
- 1.9.6. Preparations of micro-organisms may be used to improve the overall condition of the soil or to improve the availability of nutrients in the soil or in the crops.
- 1.9.7. For compost activation, appropriate plant-based preparations and preparations of micro-organisms may be used.
- 1.9.8. Mineral nitrogen fertilisers shall not be used.
- 1.9.9. Biodynamic preparations may be used.
- 1.10. Pest and weed management
- 1.10.1. The prevention of damage caused by pests and weeds shall rely primarily on the protection by:
- natural enemies,
  - the choice of species, varieties and heterogeneous material,
  - crop rotation,
  - cultivation techniques such as biofumigation, mechanical and physical methods, and
  - thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm).
- 1.10.2. Where plants cannot adequately be protected from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records proving the need for the use of such products.
- 1.10.3. In relation to products and substances used in traps or in dispensers of products and substances other than pheromones, the traps or dispensers shall prevent the products and substances from being released into the environment and shall prevent contact between the products and substances and the crops being cultivated. All traps, including pheromone traps, shall be collected after use and shall be safely disposed of.
- 1.11. Products used for cleaning and disinfection

Only those products for cleaning and disinfection in plant production authorised pursuant to Article 24 for use in organic production shall be used for that purpose.

#### 1.12. Record-keeping obligation

Operators shall keep records regarding the parcels concerned and the amount of the harvest.

#### 1.13. Preparation of unprocessed products

If preparation operations other than processing are carried out on plants, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply *mutatis mutandis* to such operations.

### 2. Detailed rules for specific plants and 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 excrement:
  - (i) either from organic production units or from in-conversion units in their second year of conversion; or
  - (ii) referred to in point 1.9.3, only when the product referred to in point (i) is not available, provided that that farmyard manure and animal excrement 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 organic production units;
- (c) peat, not treated with chemical products;
- (d) wood, not treated with chemical products after felling;
- (e) mineral products referred to in point 1.9.3, 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) for a period of at least three years before the collection, those areas were not treated with products or substances other than those authorised pursuant to Articles 9 and 24 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 9, 10, 11 and 14, the rules laid down in this Part shall apply to organic livestock production.

### 1. General requirements

1.1. Except in the case of beekeeping, landless livestock production, where the farmer intending to produce organic livestock does not manage agricultural land and has not established a written cooperation agreement with a farmer as regards the use of organic production units or in-conversion production units for that livestock, shall be prohibited.

1.2. Conversion

1.2.1. In the case of simultaneous start of conversion of the production unit, including pasturage or any land used for animal feed, and of the animals existing on this production unit at the beginning of the conversion period of this production unit as referred to in points 1.7.1 and 1.7.5(b) of Part I, animals and animal products may be considered organic at the end of the conversion period of the production unit, even if the conversion period laid down in point 1.2.2 of this Part for the type of animal concerned is longer than the conversion period for the production unit.

By derogation from point 1.4.3.1, in the case of such simultaneous conversion and during the conversion period of the production unit, animals present in this production unit since the beginning of the conversion period may be fed with in-conversion feed produced on the in-conversion production unit during the first year of conversion and/or with feed in accordance with point 1.4.3.1 and/or with organic feed.

Non-organic animals may be introduced into an in-conversion production unit after the start of the conversion period in accordance with point 1.3.4.

1.2.2. Conversion periods specific to the type of animal production are set out as follows:

- (a) 12 months in the case of bovine animals and equine animals for meat production, and in any case no less than three quarters of their lifetime;
- (b) six months in the case of ovine animals, caprine animals and porcine animals and animals for milk production;
- (c) 10 weeks for poultry for meat production, except for Peking ducks, brought in before they are three days old;
- (d) seven weeks for Peking ducks brought in before they are three days old;
- (e) six weeks in the case of poultry for egg production brought in before they are three days old;
- (f) 12 months for bees.

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

However, non-organic beeswax may be used:

- (i) where beeswax from organic beekeeping is not available on the market;
- (ii) where it is proven free of contamination with products or substances not authorised for use in organic production; and
- (iii) provided that it comes from the cap;
- (g) three months for rabbits;
- (h) 12 months for cervine animals.

- 1.3. Origin of animals
- 1.3.1. Without prejudice to the rules on conversion, organic livestock shall be born or hatched and raised on organic production units.
- 1.3.2. With regard to the breeding of organic animals:
- (a) reproduction shall use natural methods; however, artificial insemination shall be allowed;
  - (b) reproduction shall not be induced or impeded by treatment with hormones or other substances with a similar effect, except as a form of veterinary therapeutic treatment in the case of an individual animal;
  - (c) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;
  - (d) the choice of breeds shall be appropriate to the principles of organic production, shall ensure a high standard of animal welfare and shall contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals.
- 1.3.3. When choosing breeds or strains, operators shall consider giving preference to breeds or strains with a high degree of genetic diversity, the capacity of animals to adapt to local conditions, their breeding value, their longevity, their vitality and their resistance to disease or health problems, all without impairment of their welfare. 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, possibly leading to pale-soft-exudative (PSE) meat, sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference shall be given to indigenous breeds and strains.

To choose the breeds and strains in accordance with the first paragraph, operators shall use the information available in the systems referred to in Article 26(3).

- 1.3.4. Use of non-organic animals
- 1.3.4.1. By way of derogation from point 1.3.1, for breeding purposes, non-organically raised animals may be brought to an organic production unit when breeds are in danger of being lost to farming as referred to in point (b) of Article 28(10) of Regulation (EU) No 1305/2013 and acts adopted on the basis thereof. In such case, the animals of those breeds need not necessarily be nulliparous.
- 1.3.4.2. By way of derogation from point 1.3.1, for the renovation of apiaries, 20 % per year of the queen bees and swarms may be replaced by non-organic queen bees and swarms in the organic production unit, provided that the queen bees and swarms are placed in hives with combs or comb foundations coming from organic production units. In any case, one swarm or queen bee may be replaced per year by a non-organic swarm or a queen bee.
- 1.3.4.3. By way of derogation from point 1.3.1, where a flock is constituted for the first time, or is renewed or reconstituted, and where the qualitative and quantitative needs of farmers cannot be met, the competent authority may decide that non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old. Products derived from them may only be considered as organic if the conversion period specified in point 1.2 has been complied with.

1.3.4.4. By way of derogation from point 1.3.1, where the data collected in the system referred to in point (b) of Article 26(2) shows that the qualitative or quantitative needs of the farmer regarding organic animals are not met, competent authorities may authorise the introduction of non-organic animals into an organic production unit, subject to the conditions provided for in points 1.3.4.4.1 to 1.3.4.4.4.

Prior to requesting any such derogation, the farmer shall consult the data collected in the system referred to in point (b) of Article 26(2) in order to verify whether his or her request is justified.

For operators in third countries, control authorities and control bodies recognised in accordance with Article 46(1) may authorise the introduction of non-organic animals into an organic production unit where organic animals are not available in sufficient quality or quantity in the territory of the country where the operator is located.

1.3.4.4.1. For breeding purposes, non-organic young animals may be introduced when a herd or flock is constituted for the first time. They shall be reared in accordance with the organic production rules immediately after they are weaned. In addition, the following restrictions shall apply on the date on which those animals enter the herd or flock:

- (a) bovine animals, equine animals and cervine animals shall be less than six months old;
- (b) ovine animals and caprine animals shall be less than 60 days old;
- (c) porcine animals shall weigh less than 35 kg;
- (d) rabbits shall be less than three months old.

1.3.4.4.2. For breeding purposes, non-organic adult male and non-organic nulliparous female animals may be introduced for the renewal of a herd or flock. They shall be reared subsequently in accordance with the organic production rules. In addition, the number of female animals shall be subject to the following restrictions per year:

- (a) up to a maximum of 10 % of adult equine animals or bovine animals and 20 % of the adult porcine animals, ovine animals, caprine animals, rabbits or cervine animals may be introduced;
- (b) for units with fewer than 10 equine animals, cervine animals or bovine animals or rabbits, or with fewer than five porcine animals, ovine animals or caprine animals, any such renewal shall be limited to a maximum of one animal per year.

1.3.4.4.3. The percentages set in point 1.3.4.4.2 may be increased up to 40 %, provided that the competent authority has confirmed that any of following conditions is fulfilled:

- (a) a major extension to the farm has been undertaken;
- (b) one breed has been replaced with another;
- (c) a new livestock specialisation has been initiated.

1.3.4.4.4. In the cases referred to in points 1.3.4.4.1, 1.3.4.4.2 and 1.3.4.4.3, non-organic animals may only be considered as organic if the conversion period specified in point 1.2 has been complied with. The conversion period laid down in point 1.2.2 shall start, at the earliest, once the animals are introduced into the in-conversion production unit.

1.3.4.4.5. In the cases referred to in points 1.3.4.4.1 to 1.3.4.4.4, non-organic animals shall either be kept separate from other livestock or shall be kept identifiable until the end of the conversion period referred to in point 1.3.4.4.4.

## 1.4. Nutrition

### 1.4.1. General nutrition requirements

With regard to nutrition, the following rules shall apply:

- (a) feed for livestock shall be obtained primarily from the agricultural holding where the animals are kept or shall be obtained from organic or in-conversion production units belonging to other holdings in the same region;
- (b) livestock shall be fed with organic or in-conversion feed that meets the animal's nutritional requirements at the various stages of its development; restricted feeding shall not be permitted in livestock production unless justified for veterinary reasons;
- (c) livestock shall not be kept in conditions or on a diet which may encourage anaemia;
- (d) fattening practices shall always respect the normal nutritional patterns for each species and the animals' welfare at each stage of the rearing process; force-feeding is forbidden;
- (e) with the exception of porcine animals, poultry and bees, livestock shall have permanent access to pasture whenever conditions allow or shall have permanent access to roughage;
- (f) growth promoters and synthetic amino-acids shall not be used;
- (g) suckling animals shall preferably be fed on maternal milk for a minimum period laid down by the Commission in accordance with point (a) of Article 14(3); milk replacers containing chemically synthesised components or components of plant origin shall not be used during that period;
- (h) feed materials of plant, algal, animal or yeast origin shall be organic;
- (i) non-organic feed materials of plant, algal, animal or yeast origin, feed materials of microbial or of mineral origin, feed additives and processing aids may be used only if they have been authorised pursuant to Article 24 for use in organic production.

### 1.4.2. Grazing

#### 1.4.2.1. Grazing on organic land

Without prejudice to point 1.4.2.2, organic animals shall graze on organic land. However, non-organic animals may use organic pasturage for a limited period each year, provided that they have been raised in an environmental friendly way on land supported under Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013 and that they are not present on the organic land at the same time as organic animals.

#### 1.4.2.2. Grazing on common land and transhumance

1.4.2.2.1. Organic animals may graze on common land, provided that:

- (a) the common land has not been treated with products or substances not authorised for use in organic production for at least three years;
- (b) any non-organic animals which use the common land have been raised in an environmental friendly way on land supported under Articles 23, 25, 28, 30, 31 and 34 of Regulation (EU) No 1305/2013;

- (c) any livestock products from organic animals that were produced during the period when those animals grazed on common land are not considered as organic products unless adequate segregation from non-organic animals can be proved.

1.4.2.2.2. During the period of transhumance, organic animals may graze on non-organic land when they are being moved on foot from one grazing area to another. During that period, organic animals shall be kept separate from other animals. The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, shall be allowed:

- (a) for a maximum of 35 days covering both the outward and return journeys; or
- (b) for a maximum of 10 % of the total feed ration per year, calculated as a percentage of the dry matter of feedstuffs of agricultural origin.

#### 1.4.3. In-conversion feed

1.4.3.1. For agricultural holdings that produce organic livestock:

- (a) up to 25 % on average of the feed formula of rations may comprise in-conversion feed from the second year of conversion. This percentage may be increased to 100 % if this in-conversion feed comes from the holding where the livestock is kept; and
- (b) up to 20 % of the total average amount of feed 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 those lands are part of the holding itself.

When both types of in-conversion feed referred to in points (a) and (b) are being used for feeding, the total combined percentage of such feed shall not exceed the percentage fixed in point (a).

1.4.3.2. The figures in point 1.4.3.1 shall be calculated annually as a percentage of the dry matter of feed of plant origin.

#### 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, exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions.

1.5.1.2. Immunological veterinary medicinal products may be used.

1.5.1.3. Chemically synthesised allopathic veterinary medicinal products, including antibiotics and boluses of synthesised allopathic chemical molecules, shall not be used for preventive treatment.

1.5.1.4. Substances to promote growth or production (including antibiotics, coccidiostats and other artificial aids for growth promotion purposes) and hormones and similar substances for the purpose of controlling reproduction or for other purposes (e.g. induction or synchronisation of oestrus) shall not be used.

1.5.1.5. Where livestock is obtained from non-organic production units, special measures such as screening tests or quarantine periods shall apply, depending on local circumstances.

- 1.5.1.6. Only the products for cleaning and disinfection in livestock buildings and installations authorised pursuant to Article 24 for use in organic production shall be used for that purpose.
- 1.5.1.7. 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 products and substances authorised pursuant to Articles 9 and 24 for use in organic production may be used for the elimination of insects and other pests in buildings and other installations where livestock are kept.
- 1.5.2. Veterinary treatment
  - 1.5.2.1. Where animals become sick or injured despite preventive measures to ensure animal health, they shall be treated immediately.
  - 1.5.2.2. Disease shall be treated immediately to avoid suffering of the animal. Chemically synthesised allopathic veterinary medicinal products, including antibiotics, may be used where necessary, 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 authorised pursuant to Article 24 for use in organic production, nutritional additives authorised pursuant to Article 24 for use in organic production, and phytotherapeutic and homeopathic products shall be used in preference to treatment with chemically synthesised allopathic veterinary medicinal products, including antibiotics, provided that their therapeutic effect is effective for the species of animal and for 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 a group of animals receives more than three courses of treatments with chemically synthesised allopathic veterinary medicinal products, including antibiotics, within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, neither the livestock concerned nor produce derived from such livestock shall be sold as organic products, and the livestock shall be subject to the conversion periods referred to in point 1.2.
  - 1.5.2.5. The withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product, including of an antibiotic, under normal conditions of use, and the production of organically produced foodstuffs from that animal shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC, and shall be at least 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 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 ensure the well-being of 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 enabling animals to live outdoors. In such cases, animals shall have access to shelters or shady areas to protect them from adverse weather conditions.
- 1.6.3. The stocking density in buildings shall provide for the comfort, well-being and species-specific needs of the animals, and shall depend in particular 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, to move, to lie down easily, to turn round, to groom themselves, to assume all natural postures and to make all natural movements, such as stretching and wing flapping.
- 1.6.4. The minimum surface for indoor and outdoor areas, and the technical details relating to housing, laid down in the implementing acts referred to in Article 14(3), shall be complied with.
- 1.6.5. Open air areas may be partially covered. Verandas shall not be considered as open air areas.
- 1.6.6. The total stocking density shall not exceed the limit of 170 kg of organic nitrogen per year and hectare of agricultural area.
- 1.6.7. To determine the appropriate density of livestock referred to in point 1.6.6, the competent authority shall set out the livestock units equivalent to the limit referred to in point 1.6.6, following the figures laid down in each of the specific requirements per type of animal production.
- 1.6.8. Cages, boxes and flat decks to raise livestock shall not be used for any livestock species.
- 1.6.9. When livestock is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and shall be provided with straw or appropriate bedding. The animal must be able to turn around easily and to lie down comfortably at full length.
- 1.6.10. Organic livestock may not be reared in a pen on very wet or marshy soil.
- 1.7. Animal welfare
- 1.7.1. All persons involved in keeping animals and in handling animals during transport and slaughter shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals and shall have followed adequate training, as required in particular in Council Regulation (EC) No 1/2005<sup>(1)</sup> and Council Regulation No (EC) 1099/2009<sup>(2)</sup>, to ensure proper application of the rules set out in this Regulation.
- 1.7.2. Husbandry practices, including stocking densities and housing conditions, shall ensure that the developmental, physiological and ethological needs of the animals are met.
- 1.7.3. Livestock shall have permanent access to open air areas that allow the animals to exercise, preferably pasture, whenever weather and seasonal conditions and the state of the ground allow, except where restrictions and obligations related to the protection of human and animal health have been imposed on the basis of Union legislation.

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*Status: This is the original version (as it was originally adopted).*

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- 1.7.4. The number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, and pollution caused by animals or by the spreading of their manure.
- 1.7.5. Tethering or isolation of livestock shall be prohibited, except in relation to individual animals for a limited period and insofar as this is justified for veterinary reasons. The isolation of livestock may only be authorised, and only for a limited period, where workers' safety is compromised or for animal welfare reasons. Competent authorities may authorise the tethering of cattle in farms with a maximum of 50 animals (excluding young stock) where it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have access to pastures during the grazing period, and have access to open air areas at least twice a week when grazing is not possible.
- 1.7.6. Duration of transport of livestock shall be minimised.
- 1.7.7. Any suffering, pain and distress shall be avoided and shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 1.7.8. Without prejudice to developments in Union legislation on animal welfare, tail-docking of sheep, beak trimming undertaken in the first three days of life, and dehorning may exceptionally be allowed, but only on a case-by-case basis and only when those practices improve the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. Disbudding may be allowed only on a case by case basis when it improves the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. The competent authority shall only authorise such operations where the operator has duly notified and justified the operations to that competent authority and where the operation is to be carried out by qualified personnel.
- 1.7.9. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out each operation at only the most appropriate age by qualified personnel.
- 1.7.10. Physical castration shall be allowed in order to maintain the quality of products and traditional production practices, but only under the conditions set out in point 1.7.9.
- 1.7.11. The loading and unloading of animals shall be carried out without the use of any type of electrical or other painful stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, shall be prohibited.
- 1.8. Preparation of unprocessed products

If preparation operations other than processing are carried out on livestock, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply *mutatis mutandis* to such operations.

#### 1.9. Additional general rules

##### 1.9.1. For bovine animals, ovine animals, caprine animals and equine animals

###### 1.9.1.1. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 60 % of the feed shall come from the farm itself or, if this is not feasible or such feed is not available, shall be produced in cooperation with other organic or in-

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conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70 % as from 1 January 2023;

- (b) animals shall have access to pasturage for grazing whenever conditions allow;
- (c) notwithstanding point (b), male bovine animals over one year old shall have access to pasturage or an open air area;
- (d) where animals have access to pasturage during the grazing period and where the winter housing system allows the animals to move freely, the obligation to provide open air areas during the winter months may be waived;
- (e) rearing systems shall be based on maximum use of grazing pasturage, by reference to the availability of pastures in the different periods of the year;
- (f) at least 60 % of the dry matter in daily rations shall consist of roughage, fresh or dried fodder, or silage. This percentage may be reduced to 50 % for animals in dairy production for a maximum period of three months in early lactation.

#### 1.9.1.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) housing shall have smooth, but not slippery floors;
- (b) housing shall be provided with a comfortable, clean and dry laying or rest area of sufficient size, which shall consist 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 that is authorised pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production;
- (c) notwithstanding point (a) of the first subparagraph of Article 3(1) and the second subparagraph of Article 3(1) of Council Directive 2008/119/EC<sup>(3)</sup>, the housing of calves in individual boxes shall be forbidden after the age of one week, unless for individual animals for a limited period, and insofar as this is justified for veterinary reasons;
- (d) when a calf is treated individually for veterinary reasons, it shall be kept in spaces that have a solid floor and shall be provided with straw bedding. The calf must be able to turn around easily and to lie down comfortably at full length.

#### 1.9.2. For cervine animals

##### 1.9.2.1. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 60 % of the feed shall come from the farm itself or, if this is not feasible or such feed is not available, shall be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region. This percentage shall be raised to 70 % as from 1 January 2023;
- (b) animals shall have access to pasturage for grazing whenever conditions allow;
- (c) where animals have access to pasturage during the grazing period and where the winter housing system allows the animals to move freely, the obligation to provide open air areas during the winter months may be waived;

- (d) rearing systems shall be based on maximum use of grazing pasturage by reference to the availability of pastures in the different periods of the year;
- (e) at least 60 % of the dry matter in daily rations shall consist of roughage, fresh or dried fodder, or silage. This percentage may be reduced to 50 % for female cervine animals in milk production for a maximum period of three months in early lactation;
- (f) natural grazing shall be ensured in a pen during the period of vegetation. Pens that cannot provide feed by grazing during the period of vegetation shall not be allowed;
- (g) feeding shall only be allowed in the event of a shortage of grazing due to poor weather conditions;
- (h) farmed animals in a pen shall be provided with clean and fresh water. If a natural source of water that is easily accessible to animals is not available, watering places shall be provided.

#### 1.9.2.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) cervine animals shall be provided with hiding places, shelters and fences that do not harm animals;
- (b) in red deer pens, animals must be able to roll in the mud to ensure skin grooming and body temperature regulation;
- (c) any housing shall have smooth, but not slippery floors;
- (d) any housing shall be provided with a comfortable, clean and dry laying or 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 pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production;
- (e) feeding places shall be installed in areas protected from the weather and accessible both to animals and to persons attending to them. The soil where feeding places are located shall be consolidated, and the feeding apparatus shall be equipped with a roof;
- (f) if permanent access to feed cannot be ensured, the feeding places shall be designed so that all animals can feed at the same time.

#### 1.9.3. For porcine animals

##### 1.9.3.1. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 30 % of the feed shall come from the farm itself or, if this is not feasible or such feed is not available, shall be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region;
- (b) roughage, fresh or dried fodder, or silage shall be added to the daily ration;
- (c) where farmers are unable to obtain protein feed exclusively from organic production, and the competent authority has confirmed that organic protein feed is not available

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in sufficient quantity, non-organic protein feed may be used until 31 December 2025 provided that the following conditions are fulfilled:

- (i) it is not available in organic form;
- (ii) it is produced or prepared without chemical solvents;
- (iii) its use is limited to the feeding of piglets of up to 35 kg with specific protein compounds; and
- (iv) the maximum percentage authorised per period of 12 months for those animals does not exceed 5 %. The percentage of the dry matter of feed from agricultural origin shall be calculated.

#### 1.9.3.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) the housing shall have smooth, but not slippery floors;
- (b) the housing shall be provided with a comfortable, clean and dry laying or 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 pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production;
- (c) there shall always be a bed made of straw or other suitable material large enough to ensure that all pigs in a pen can lie down at the same time in the most space-consuming way;
- (d) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period, during which time the sow must be able to move freely in her pen and her movement shall only be restricted for short periods;
- (e) without prejudice to any additional requirements for straw, a few days before expected farrowing, sows shall be provided with a quantity of straw or other suitable natural material sufficient to enable them to build nests;
- (f) exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting, different substrates may be used.

#### 1.9.4. For poultry

##### 1.9.4.1. Origin of animals

To prevent the use of intensive rearing methods, poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains adapted to outdoor rearing.

The competent authority shall define the criteria of slow-growing strains or draw up a list of those strains and provide this information to operators, other Member States and the Commission.

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.

#### 1.9.4.2. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 30 % of the feed shall come from the farm itself or, if this is not feasible or such feed is not available, be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region;
- (b) roughage, fresh or dried fodder, or silage shall be added to the daily ration;
- (c) where farmers are unable to obtain protein feed exclusively from organic production for poultry species, and the competent authority has confirmed that organic protein feed is not available in sufficient quantity, non-organic protein feed may be used until 31 December 2025, provided that the following conditions are fulfilled:
  - (i) it is not available in organic form;
  - (ii) it is produced or prepared without chemical solvents;
  - (iii) its use is limited to the feeding of young poultry with specific protein compounds; and
  - (iv) the maximum percentage authorised per period of 12 months for those animals does not exceed 5 %. The percentage of the dry matter of feed of agricultural origin shall be calculated.

#### 1.9.4.3. Animal welfare

Live plucking of poultry shall be prohibited.

#### 1.9.4.4. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and shall be covered with a litter material such as straw, wood shavings, sand or turf;
- (b) 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;
- (c) buildings shall be emptied of livestock between each batch of poultry that has been 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. Those requirements shall not apply where poultry are not reared in batches, are not kept in runs and are free to roam throughout the day;
- (d) poultry shall have access to an open air area for at least one third of their life. However, laying hens and finisher poultry shall have access to an open air area for at least one third of their life, except where temporary restrictions have been imposed on the basis of Union legislation;
  - (e) continuous daytime open air access shall be provided from as early an age as practically possible and whenever physiological and physical conditions allow, except where temporary restrictions have been imposed on the basis of Union legislation;
  - (f) by way of derogation from point 1.6.5, in the case of breeding birds and pullets aged under 18 weeks, when the conditions specified in point 1.7.3 as regards restrictions and obligations related to the protection of human and animal health imposed on the basis of Union legislation are met and prevent breeding birds and pullets aged under 18 weeks from having access to open air areas, verandas shall be considered as open air areas and, in such cases, shall have a wire mesh barrier to keep other birds out;
  - (g) open air areas for poultry shall permit fowl to have easy access to adequate numbers of drinking troughs;
  - (h) open air areas for poultry shall be covered mainly with vegetation;
  - (i) under conditions where feed availability from the range area is limited, for example, due to long term snow cover or arid weather conditions, supplementary feeding of roughage shall be included as part of poultry diets;
  - (j) where poultry are kept indoors due to restrictions or obligations imposed on the basis of Union legislation, they shall have permanent access to sufficient quantities of roughage and suitable material in order to meet their ethological needs;
  - (k) 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; when weather conditions do not permit such access, they shall have access to water which enables them to dip their head therein so as to clean plumage;
  - (l) 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;
  - (m) the total usable surface area for fattening poultry in poultry houses of any production unit shall not exceed 1 600 m<sup>2</sup>;
  - (n) not more than 3 000 laying hens shall be allowed in a single compartment of a poultry house.

#### 1.9.5. For rabbits

##### 1.9.5.1. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at least 70 % of the feed shall come from the farm itself or, if this is not feasible or such feed is not available, shall be produced in cooperation with other organic or in-conversion production units and feed operators using feed and feed material from the same region;

- (b) rabbits shall have access to pasturage for grazing whenever conditions allow;
- (c) rearing systems shall be based on maximum use of grazing pasturage by reference to the availability of pastures in the different periods of the year;
- (d) fibrous feed such as straw or hay shall be provided when grass is not sufficient. Forage shall comprise at least 60 % of the diet.

#### 1.9.5.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) housing shall be provided with a comfortable, clean and dry laying or 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 pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production;
- (b) rabbits shall be kept in groups.
- (c) rabbit farms shall use robust breeds adapted to outdoor conditions;
- (d) rabbits shall have access to:
  - (i) covered shelter including dark hiding places;
  - (ii) an outdoor run with vegetation, preferably pasture;
  - (iii) a raised platform on which they can sit, either inside or out;
  - (iv) nesting material for all nursing does.

#### 1.9.6. For bees

##### 1.9.6.1. Origin of animals

For beekeeping, preference shall be given to the use of *Apis mellifera* and their local ecotypes.

##### 1.9.6.2. Nutrition

With regard to nutrition, the following rules shall apply:

- (a) at the end of the production season hives shall be left with sufficient reserves of honey and pollen for the bees to survive the winter;
- (b) bee colonies may only be fed where the survival of the colony is endangered due to climatic conditions. In such case, bee colonies shall be fed with organic honey, organic sugar syrups, or organic sugar.

##### 1.9.6.3. Health care

With regard to health care, the following rules shall apply:

- (a) for the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides used in traps, and appropriate products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be permitted;
- (b) physical treatments for disinfection of apiaries such as steam or direct flame shall be permitted;

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- (c) the practice of destroying the male brood shall only be permitted for the purpose of isolating 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, 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, including antibiotics, other than products and substances authorised pursuant to Articles 9 and 24 for use in organic production, for the duration of that treatment, the treated colonies shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of 12 months laid down in point 1.2.2 shall apply to those colonies.

#### 1.9.6.4. Animal welfare

With regard to beekeeping, the following additional general rules shall apply:

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

#### 1.9.6.5. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) apiaries shall be placed in areas which ensure the availability of nectar and pollen sources consisting essentially of organically produced crops or, where 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 apiculture 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 or spontaneous vegetation or crops treated with low environmental impact methods equivalent to those provided for in Articles 28 and 30 of Regulation (EU) No 1305/2013 which cannot affect the qualification of beekeeping production as being organic. That requirement does not apply where flowering is not taking place, or the bee colonies 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;
- (e) the beeswax for new foundations shall come from organic production units;
- (f) only natural products such as propolis, wax and plant oils may be used in the hives;
- (g) synthetic chemical repellents shall not be used during honey extraction operations;
- (h) brood combs shall not be used for honey extraction;
- (i) 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.

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

1. General requirements
  - 1.1. Operations shall be situated in locations that are not subject to contamination with products or substances not authorised for use in organic production, or with pollutants that would compromise the organic nature of the products.
  - 1.2. Organic and non-organic production units shall be adequately separated in accordance with the minimum separation distances set by Member States, where applicable. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, and the upstream and the downstream location of the organic production unit. Algae and aquaculture 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 such activities.
  - 1.3. An environmental assessment that is appropriate to the production unit shall be required for any new operators 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>(4)</sup>. If the production unit has already been subject to an equivalent assessment, that assessment may be used for this purpose.
  - 1.4. Mangrove destruction shall not be permitted.
  - 1.5. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and algae harvesting.
  - 1.6. The plan shall be updated annually and shall detail the environmental effects of the operation and the environmental monitoring to be undertaken, and shall list the 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.
  - 1.7. Defensive and preventive measures taken against predators in accordance with Directive 92/43/EEC and national rules shall be recorded in the sustainable management plan.
  - 1.8. Where applicable, coordination shall take place with the neighbouring operators in drawing up the management plan.
  - 1.9. Aquaculture and algae 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 from renewable sources.
  - 1.10. Preparation of unprocessed products

If preparation operations, other than processing, are carried out on algae or aquaculture animals, the general requirements laid down in points 1.2, 1.3, 1.4, 1.5 and 2.2.3 of Part IV shall apply *mutatis mutandis* to such operations.

2. Requirements for algae

In addition to the general production rules laid down in Articles 9, 10, 11 and 15, and where relevant in Section 1 of this Part, the rules laid down in this Section shall apply to the organic collection and production of algae. Those rules shall apply *mutatis mutandis* to the production of phytoplankton.

## 2.1. Conversion

2.1.1. The conversion period for a production unit for algae collection shall be six months.

2.1.2. The conversion period for a production unit for algae cultivation shall be a period of six months or one full production cycle, whichever is the longer.

## 2.2. Production rules for algae

2.2.1. The collection of wild algae and parts thereof is considered as organic production provided that:

- (a) the growing areas are suitable from a health point of view and are of high ecological status as defined by Directive 2000/60/EC, or are of equivalent quality to:
  - the production zones classed as A and B in Regulation (EC) No 854/2004 of the European Parliament and of the Council<sup>(5)</sup>, until 13 December 2019, or
  - the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, from 14 December 2019;
- (b) the collection does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area.

2.2.2. The cultivation of algae shall take place in areas with environmental and health characteristics at least equivalent to those outlined in point 2.2.1(a) 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 the collection of juvenile algae to harvesting;
- (b) to ensure that a wide gene-pool is maintained, the collection of juvenile algae in the wild shall take place on a regular basis so as to maintain and increase the diversity of indoor culture stock;
- (c) fertilisers shall not be used, except in indoor facilities, and only if they have been authorised pursuant to Article 24 for use in organic production for this purpose.

## 2.3. Algae cultivation

2.3.1. Algae 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.

2.3.2. 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 pursuant to Article 24 for use in organic production may be used.

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

- 2.3.4. Ropes and other equipment used for growing algae shall be re-used or recycled where possible.
- 2.4. Sustainable collection of wild algae
  - 2.4.1. A once-off biomass estimate shall be undertaken at the outset of algae collection.
  - 2.4.2. 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 collectors have supplied only wild algae produced in accordance with this Regulation.
  - 2.4.3. Collection shall be carried out in such a way that the amounts collected do not cause a significant impact on the state of the aquatic environment. Measures such as collection technique, minimum sizes, ages, reproductive cycles or size of remaining algae shall be taken to ensure that algae can regenerate and to ensure that by-catches are prevented.
  - 2.4.4. If algae are collected from a shared or common collection area, documentary evidence produced by the relevant authority designated by the Member State concerned shall be available showing that the total collection complies with this Regulation.
- 3. Requirements for aquaculture animals

In addition to the general production rules laid down in Article 9, 10, 11 and 15, and where relevant in Section 1 of this Part, the rules laid down in this Section shall apply to the organic production of species of fish, crustaceans, echinoderms and molluscs. Those rules also shall apply *mutatis mutandis* to the production of zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

### 3.1. General requirements

#### 3.1.1. Conversion

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.

#### 3.1.2. Origin of aquaculture animals

3.1.2.1. With regard to the origin of the aquaculture animals, the following rules shall apply:

- (a) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and from organic production units;
- (b) locally grown species shall be used, and breeding shall aim to produce strains which are better adapted to production conditions, ensuring good animal health and welfare and good utilisation of feed resources. Documentary evidence of their origin and

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- treatment shall be provided for the competent authority, or, where appropriate, the control authority or control body;
- (c) species shall be chosen which are robust and can be produced without causing significant damage to wild stocks;
  - (d) for breeding purposes, wild-caught or non-organic aquaculture animals may be brought into a holding only in duly justified cases where no organic breed is available or where new genetic stock for breeding purposes is brought into the production unit after an authorisation has been granted by the competent authority with a view to improving the suitability of genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding. For animals that are on the IUCN Red List of endangered species, the authorisation to use wild-caught specimens may only be granted in the context of conservation programmes recognised by the relevant public authority in charge of the conservation effort;
  - (e) for on-growing purposes, the collection of wild aquaculture juveniles shall be specifically restricted to the following cases:
    - (i) natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures;
    - (ii) restocking of wild fry or crustacean larvae of species that are not on the IUCN Red List of endangered species in extensive aquaculture farming inside wetlands, such as brackish water ponds, tidal areas and coastal lagoons, provided that:
      - the restocking is in line with management measures approved by the relevant authorities to ensure the sustainable exploitation of the species concerned, and
      - the animals are fed exclusively with feed naturally available in the environment.

By way of derogation from point (a), Member States may authorise the introduction for on-growing purposes on an organic production unit of a maximum of 50 % of non-organic juveniles of species that were not developed as organic in the Union by 1 January 2021, provided that at least the latter two thirds of the duration of the production cycle are managed under organic management. Such derogation may be granted for a maximum period of two years and shall not be renewable.

For aquaculture holdings situated outside the Union, such derogation may only be granted by control authorities or control bodies that have been recognised in accordance with Article 46(1) for species that were not developed as organic in either the territory of the country in which the holding is located or the Union. Such derogation may be granted for a maximum period of two years and shall not be renewable.

3.1.2.2. With regard to breeding, the following rules shall apply:

- (a) hormones and hormone-derivates shall not be used;
- (b) the artificial production of monosex strains, except by hand-sorting, the induction of polyploidy, artificial hybridisation and cloning shall not be used;
- (c) appropriate strains shall be chosen.

### 3.1.3. Nutrition

#### 3.1.3.1. With regard to feed for fish, crustaceans and echinoderms, the following rules shall apply:

- (a) animals shall be fed with feed that meets the animals' nutritional requirements at the various stages of its development;
- (b) feeding regimes shall be designed with the following priorities:
  - (i) animal health and welfare;
  - (ii) high product quality, including the nutritional composition of the product, which shall ensure high quality of the final edible product;
  - (iii) low environmental impact;
- (c) the plant fraction of feed shall be organic and the feed fraction derived from aquatic animals shall originate from organic aquaculture or from fisheries that have been certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013;
- (d) non-organic feed materials of plant, animal, algal or yeast origin, feed materials of mineral or microbial origin, feed additives, and processing aids shall only be used if they have been authorised under this Regulation for use in organic production;
- (e) growth promoters and synthetic amino-acids shall not be used.

#### 3.1.3.2. With regard to bivalve molluscs and other species which are not fed by man, but instead feed on natural plankton, the following rules shall apply:

- (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) the growing areas shall be suitable from a health point of view and shall either be of high ecological status as defined by Directive 2000/60/EC or of good environmental status as defined by Directive 2008/56/EC or of equivalent quality to:
  - the production zones classed as A in Regulation (EC) No 854/2004, until 13 December 2019, or
  - the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, from 14 December 2019.

#### 3.1.3.3. Specific rules on feed for carnivorous aquaculture animals

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

- (a) organic feed of aquaculture origin;
- (b) fish meal and fish oil from organic aquaculture trimmings sourced from fish, crustaceans or molluscs;
- (c) fish meal and fish oil and feed material of fish origin derived from trimmings of fish, crustaceans or molluscs already caught for human consumption in sustainable fisheries;

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- (d) fish meal and fish oil and feed material of fish origin derived from whole fish, crustaceans or molluscs caught in sustainable fisheries and not used for human consumption;
- (e) organic feed materials of plant or animal origin; plant material shall not exceed 60 % of total ingredients.

#### 3.1.3.4. Specific rules on feed for certain aquaculture animals

In the grow-out phase, fish in inland waters, penaeid shrimps and freshwater prawns and tropical freshwater fish shall be fed as follows:

- (a) they shall be fed with feed naturally available in ponds and lakes;
- (b) where natural feed referred to in point (a) is not available in sufficient quantities, organic feed of plant origin, preferably grown on the farm itself, or algae may be used. Operators shall keep documentary evidence of the need to use additional feed;
- (c) where natural feed is supplemented in accordance with point (b):
  - (i) the feed ration of penaeid shrimps and freshwater prawns (*Macrobrachium* spp.) may consist of a maximum of 25 % fishmeal and 10 % fish oil derived from sustainable fisheries;
  - (ii) the feed ration of siamese catfish (*Pangasius* spp.) may consist of a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries.

#### 3.1.4. Health care

##### 3.1.4.1. Disease prevention

With regard to disease prevention, the following rules shall apply:

- (a) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, taking into account, inter alia, the species' requirements for good water quality, flow and exchange rate, the 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) immunological veterinary medicines may be used;
- (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 or, in the case of bivalve shellfish, not less than once every two years;
- (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 pursuant to Article 24 for use in organic production may be used;
- (g) with regard to fallowing, the following rules shall apply:

- (i) the competent authority, or, where appropriate, control authority or control body, shall determine whether fallowing is necessary and shall determine 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, to minimise disease risks, and to avoid attracting insects or rodents;
- (i) ultraviolet light and ozone may only be used in hatcheries and nurseries;
- (j) for biological control of ectoparasites, preference shall be given to the use of cleaner fish and to the use of freshwater, marine water and sodium chloride solutions.

#### 3.1.4.2. Veterinary treatments

With regard to veterinary treatments, the following rules shall apply:

- (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, under strict conditions and under the responsibility of a veterinarian, where the use of phytotherapeutic, homeopathic and other products is inappropriate. Where appropriate, 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 referred to in 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 homeopathic 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 shall be 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 shall apply. Where the indicated limits for allopathic treatments are exceeded, the aquaculture animals concerned shall not be marketed as organic products;
- (e) the use of parasite treatments, other than through 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 (d), including treatments under compulsory control and

eradication schemes, shall be twice the withdrawal period referred to in Article 11 of Directive 2001/82/EC or, where this period is not specified, 48 hours;

- (g) any use of veterinary medicinal products shall be declared to the competent authority, or, where appropriate, to the control authority or control body, before the animals are marketed as organic products. Treated stock shall be clearly identifiable.

#### 3.1.5. Housing and husbandry practices

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

3.1.5.2. 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.

3.1.5.3. 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:

- (a) have sufficient space for their welfare and have the relevant stocking density laid down in the implementing acts referred to in Article 15(3);
- (b) are kept in water of good quality with, inter alia, an adequate flow and exchange rate, sufficient oxygen levels and keeping a low level of metabolites;
- (c) are kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location.

In considering the effects of 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 and taken into account.

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

In the case of carp and similar species:

- the bottom shall be natural earth,
- organic and mineral fertilisation of the ponds and lakes shall be carried out only with fertilisers and soil conditioners that have been authorised pursuant to Article 24 for use in organic production, with a maximum application of 20 kg nitrogen/ha,
- treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters shall be prohibited.

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

The specific characteristics for production systems and containment systems for species or group of species laid down in the implementing acts referred to in Article 15(3) shall be complied with.

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

- (a) flow-through systems shall allow the monitoring and control of the flow rate and water quality of both in-flowing and out-flowing water;
  - (b) at least 10 % of the perimeter ('land-water interface') area shall have natural vegetation.
- 3.1.5.6. Containment systems at sea shall meet the following conditions:
- (a) they shall 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) they shall have suitable cage design, construction and maintenance with regard to their exposure to the operating environment.
- 3.1.5.7. Containment systems shall be designed, located and operated to minimise the risk of escape incidents.
- 3.1.5.8. If fish or crustaceans escape, appropriate action shall be taken to reduce the impact on the local ecosystem, including recapture where appropriate. Records shall be kept.
- 3.1.5.9. 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 algae or animals (bivalves) which contribute to improving the quality of the effluent. Effluent monitoring shall be carried out at regular intervals where appropriate.
- 3.1.6. Animal welfare
- 3.1.6.1. All persons involved in keeping aquaculture animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of those animals.
- 3.1.6.2. The handling of aquaculture animals shall be minimised, and shall be undertaken with the greatest care. Proper equipment and protocols shall be used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in such a manner as to minimise physical damage and stress, and shall be handled under anaesthesia where appropriate. Grading operations shall be kept to a minimum and shall only be used where required to ensure fish welfare.
- 3.1.6.3. 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 the animals; this maximum shall not exceed 14 hours per day, except where necessary for reproductive purposes;
  - (b) abrupt changes in light intensity shall be avoided at the changeover time through the use of dimmable lights or background lighting.
- 3.1.6.4. Aeration shall be permitted to ensure animal welfare and health. Mechanical aerators shall be preferably powered by renewable energy sources.
- 3.1.6.5. Oxygen may only be used for uses linked to animal health and welfare requirements and for critical periods of production or transport, and only in the following cases:
- (a) exceptional cases of a change in temperature, a drop in atmospheric pressure or accidental water pollution;
  - (b) occasional stock management procedures, such as sampling and sorting;

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- (c) in order to assure the survival of the farm stock.
- 3.1.6.6. Appropriate measures shall be taken to keep the duration of the transport of aquaculture animals to a minimum.
- 3.1.6.7. Any suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.
- 3.1.6.8. Eyestalk ablation, including all similar practices such as ligation, incision and pinching, is prohibited.
- 3.1.6.9. Slaughter techniques shall render fish immediately unconscious and insensible to pain. Handling prior to slaughter shall be performed in a way that avoids injuries while keeping suffering and stress at a minimum. Differences in harvesting sizes, species, and production sites shall be taken into account when considering optimal slaughtering methods.

### 3.2. Detailed rules for molluscs

#### 3.2.1. Origin of seed

With regard to the origin of seed, the following rules shall apply:

- (a) wild seed from outside the boundaries of the production unit may be used in the case of bivalve shellfish, provided that there is no significant damage to the environment, provided that it is permitted by local legislation and provided that the wild seed 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;
- (b) for the cupped oyster (*Crassostrea gigas*), preference shall be given to stock which is selectively bred to reduce spawning in the wild;
- (c) records shall be kept of how, where and when wild seed was collected to allow traceability back to the collection area;
- (d) wild seed may only be collected after the competent authority has granted authorisation to do so.

#### 3.2.2. Housing and husbandry practices

With regard to housing and husbandry practices, the following rules shall apply:

- (a) production may be carried out in the same area of water as organic finfish and algae production, in a polyculture system that shall 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, where 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. Cultivation

With regard to cultivation, the following rules shall apply:

- (a) cultivation on mussel ropes and other methods listed in the implementing acts referred to in Article 15(3) may be used in organic production;
- (b) the bottom cultivation of molluscs is only permitted where no significant environmental impact is caused at the collection and growing sites. A survey and report supporting the evidence of minimal environmental impact shall be added as a separate chapter to the sustainable management plan, and shall be provided by the operator to the competent authority, or, where appropriate, to the control authority or control body, before starting operations.

#### 3.2.4. Management

With regard to management, the following rules shall apply:

- (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.

#### 3.2.5. Specific cultivation rules for oysters

Cultivation in bags on trestles shall be permitted. Those 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 the implementing acts referred to in Article 15(3).

### **Part IV: Processed food production rules**

In addition to the general production rules laid down in Articles 9, 11 and 16, the rules laid down in this Part shall apply to the organic production of processed food.

1. General requirements for the production of processed food
  - 1.1. Food additives, processing aids and other substances and ingredients used for processing food and any processing practice applied, such as smoking, shall comply with the principles of good manufacturing practice<sup>(6)</sup>.
  - 1.2. Operators producing processed food 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 ensure that the produced processed products comply with this Regulation at all times.
  - 1.4. Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28, shall in particular,:
    - (a) take precautionary measures;
    - (b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations;

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- (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
- 1.5. The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. Where organic, in-conversion and non-organic products, in any combination, are prepared or stored in the preparation unit concerned, the operator shall:
- (a) inform the competent authority, or, where appropriate, the control authority or control body, accordingly;
  - (b) carry out the operations continuously until the production run has been completed, separately in place or time from similar operations performed on any other kind of product (organic, in-conversion or non-organic);
  - (c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other;
  - (d) keep available an updated register of all operations and quantities processed;
  - (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges between organic, in-conversion and non-organic products;
  - (f) carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment.
- 1.6. 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 organic food, or that otherwise may be misleading as to the true nature of products intended to be marketed as organic food, shall not be used.
2. Detailed requirements for the production of processed food
- 2.1. The following conditions shall apply to the composition of processed organic food:
- (a) the product shall be produced mainly from agricultural ingredients or products intended for use as food listed in Annex I; for the purpose of determining whether a product has been produced mainly from those products, added water and salt shall not be taken into account;
  - (b) an organic ingredient shall not be present together with the same ingredient in non-organic form;
  - (c) an in-conversion ingredient shall not be present together with the same ingredient in organic or non-organic form.
- 2.2. Use of certain products and substances in processing of food
- 2.2.1. Only food additives, processing aids and non-organic agricultural ingredients authorised pursuant to Article 24 or Article 25 for use in organic production, and the products and substances referred to in point 2.2.2 may be used in the processing of food, with the exception of products and substances of the wine sector, for which point 2 of Part VI shall apply, and with the exception of yeast, for which point 1.3 of Part VII shall apply.
- 2.2.2. In the processing of food, the following products and substances may be used:

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- (a) preparations of micro-organisms and food enzymes normally used in food processing, provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production;
  - (b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation;
  - (c) colours for stamping meat and eggshells in accordance with Article 17 of Regulation (EC) No 1333/2008;
  - (d) natural colours and natural coating substances for the traditional decorative colouring of the shell of boiled eggs produced with the intention of placing them on the market at a given period of the year;
  - (e) drinking water and organic or non-organic salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;
  - (f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:
    - (i) their use in food for normal consumption is ‘directly legally required’, in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or
    - (ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:
      - in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council<sup>(7)</sup> their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or
      - in products regulated by Commission Directive 2006/125/EC<sup>(8)</sup>, their use is authorised by that Directive.
- 2.2.3. Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose.
- 2.2.4. For the purpose of the calculation referred to in Article 30(5), the following rules shall apply:
- (a) certain food additives authorised pursuant to Article 24 for use in organic production shall be calculated as agricultural ingredients;
  - (b) preparations and substances referred to in points (a), (c), (d), (e) and (f) of point 2.2.2 shall not be calculated as agricultural ingredients;
  - (c) yeast and yeast products shall be calculated as agricultural ingredients.

### **Part V: Processed feed production rules**

In addition to the general production rules laid down in Articles 9, 11 and 17, the rules laid down in this Part shall apply to the organic production of processed feed.

1. General requirements for the production of processed feed
  - 1.1. Feed additives, processing aids and other substances and ingredients used for processing feed, and any processing practice used, such as smoking, shall comply with the principles of good manufacturing practice.
  - 1.2. Operators that produce processed feed shall establish and update appropriate procedures based on a systematic identification of the critical processing steps.
  - 1.3. The application of the procedures referred to in point 1.2 shall ensure that the produced processed products comply with this Regulation at all times.
  - 1.4. Operators shall comply with and implement the procedures referred to in point 1.2, and, without prejudice to Article 28, shall in particular:
    - (a) take precautionary measures;
    - (b) implement suitable cleaning measures, monitor their effectiveness and keep records of those operations;
    - (c) guarantee that non-organic products are not placed on the market with an indication referring to organic production.
  - 1.5. The preparation of processed organic, in-conversion and non-organic products shall be kept separate from each other in time or space. Where organic, in-conversion and non-organic products, in any combination, are prepared or stored in the preparation unit concerned, the operator shall:
    - (a) inform the control authority or control body accordingly;
    - (b) carry out the operations continuously until the production run has been completed, separately in place or time from similar operations performed on any other kind of product (organic, in-conversion or non-organic);
    - (c) store organic, in-conversion and non-organic products, before and after the operations, separate by place or time from each other;
    - (d) keep available an updated register of all operations and quantities processed;
    - (e) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges between organic, in-conversion and non-organic products;
    - (f) carry out operations on organic or in-conversion products only after suitable cleaning of the production equipment.
2. Detailed requirements for the production of processed feed
  - 2.1. 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.
  - 2.2. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.

- 2.3. Only non-organic feed material of plant, algal, animal or yeast origin, feed material of mineral origin, and feed additives and processing aids authorised pursuant to Article 24 for use in organic production may be used in the processing of feed.
- 2.4. Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose.

## **Part VI: Wine**

1. Scope
  - 1.1. In addition to the general production rules laid down in Articles 9, 10, 11, 16 and 18, the rules laid down in this Part shall apply to the organic production of the products of the wine sector as referred to in point (l) of Article 1(2) of Regulation (EU) No 1308/2013.
  - 1.2. Commission Regulations (EC) No 606/2009<sup>(9)</sup> and (EC) No 607/2009<sup>(10)</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 pursuant to Article 24 for use in organic production may be used for the making of products of the wine sector, including during the oenological practices, processes and treatments, 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 the latter Regulation.
3. Oenological practices and restrictions
  - 3.1. Without prejudice to Sections 1 and 2 of this Part and to specific prohibitions and restrictions provided for in points 3.2, 3.3 and 3.4, only oenological practices, processes and treatments, including the restrictions provided for in Article 80 and Article 83(2) of Regulation (EU) No 1308/2013, in Article 3, Articles 5 to 9 and Articles 11 to 14 of Regulation (EC) No 606/2009, and in the Annexes to those Regulations used before 1 August 2010 shall be permitted.
  - 3.2. The use of the following oenological practices, processes and treatments shall be prohibited:
    - (a) partial concentration through cooling in accordance with point (c) of Section B.1 of Part I of Annex VIII to Regulation (EU) No 1308/2013;
    - (b) elimination of sulphur dioxide by physical processes in accordance with point 8 of Annex I A to Regulation (EC) No 606/2009;
    - (c) electro dialysis treatment to ensure the tartaric stabilisation of the wine in accordance with point 36 of Annex I A to Regulation (EC) No 606/2009;
    - (d) partial dealcoholisation of wine in accordance with 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 in accordance with 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) heat treatments in accordance with point 2 of Annex I A to Regulation (EC) No 606/2009, provided that the temperature does not exceed 75 °C;
  - (b) centrifuging and filtration with or without an inert filtering agent in accordance with point 3 of Annex I A to Regulation (EC) No 606/2009, provided that the size of the pores is not smaller than 0,2 micrometres.
- 3.4. Any amendment introduced after 1 August 2010 concerning the oenological practices, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009 may apply to the organic production of wine only after those measures have been included as permitted in this Section and, if required, after an evaluation in accordance with Article 24 of this Regulation.

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

In addition to the general production rules laid down in Articles 9, 11, 16, 17 and 19, the rules laid down in this Part shall apply to the organic production of yeast used as food or feed.

1. General requirements
  - 1.1. For the production of organic yeast, only organically produced substrates shall be used. However, until 31 December 2023, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in weight of dry matter) is allowed for the production of organic yeast where operators are unable to obtain yeast extract or autolysate from organic production.
  - 1.2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
  - 1.3. The following products and substances may be used in the production, confection and formulation of organic yeast:
    - (a) processing aids authorised pursuant to Article 24 for use in organic production;
    - (b) products and substances referred to in points (a), (b) and (e) of point 2.2.2 of Part IV.
  - 1.4. Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in processing shall be used for that purpose.

- (1) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 ([OJ L 3](#), 5.1.2005, p. 1).
- (2) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing ([OJ L 303](#), 18.11.2009, p. 1).
- (3) 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).
- (4) 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).
- (5) 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).
- (6) Good manufacturing practices (GMPs) as defined in Article 3(a) of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food ([OJ L 384](#), 29.12.2006, p. 75).
- (7) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 ([OJ L 181](#), 29.6.2013, p. 35).
- (8) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children ([OJ L 339](#), 6.12.2006, p. 16).
- (9) 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).
- (10) 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).