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 [1], 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.

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

2.4.2. 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 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 costal 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;

(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 homoeopathic dilution;

(ii) plants and their extracts not having anaesthetic effects; and

(iii) substances such as trace elements, metals, natural immunostimulants or authorised probiotics;

(d) the use of allopathic treatments 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.