Version 25.6.2008

Working Document

Draft

Commission Regulation

Amending Commission Regulation X/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control

Chapter I
Introductory provisions

Article I

Subject matter and scope

This Regulation lays down specific rules for products originating from aquaculture and seaweed excluding microalgae.

Article 2

Definitions

Article 3

Suitability of aquatic medium and environmental sustainability

With reference to Articles 13 and 15 of Regulation 834/2007 and having regard to Community water legislation, including the Marine Strategy Directive 2008/56 and legislation on contaminants in food, Member State authorities may nominate areas which they judge to be unsuitable for organic aquaculture or seaweed production from an environmental point of view.

A sustainable management system must be established, detailing the environmental effects of the operation and listing measured to be takes to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle.

Aquaculture and seaweed business operators should use renewable energy sources and re-cycles materials where possible and should draw up a waste reduction plan to be put in operation at the commencement of operations.

Chapter II

Seaweeds

Article 4

Conversion

The conversion period for a seaweed harvesting site shall be 12 months. Where it can be demonstrated that the minimum control requirements in Article 63-37 of Regulation X/2008 have been satisfied for the previous 12-month period, and that there is no source of pollution, a reduced conversion period of six months shall apply.

For farmed seaweed, the conversion period shall be the longer of 12 months or a production cycle.

Article 5

Sustainable harvesting

In the inter-tidal zone seaweed shall be harvested by hand. Below the mean low tide mark of spring tides, harvesting by mechanical means is permitted using methods, tools and equipment which protect the natural resource and ensure biodiversity is preserved.

Harvesting shall only be carried out by trained collectors. There shall be written contracts between, the seaweed business operator and the harvesters.

Harvesting or gathering the product shall not exceed the sustainable yield of the ecosystem, or threaten the existence of plant or animal species.

Minimum measures shall be taken to ensure that plants can regenerate, such as harvest technique, minimum plant sizes, ages, reproductive cycles or size of remaining plant.

If seaweed is harvested from a shared or common harvest area, evidence must be available that the total harvest complies with these rules.

With respect to Article 5 b) and c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

Article 6

Seaweed Culture

With respect to the natural aquatic nature of seaweeds, Article 4 of Regulation X /2008 (prohibition of hydroponic production) shall not apply to seaweed.

Seaweed juveniles are grown in land-based hatcheries whereas on-growing to market size shall take place in the sea or in contained systems near the shore.

Heating or cooling of water shall only be permitted in hatcheries and only to within 5°C of deviation temperature. Artificial light shall only be permitted in hatcheries. The use of carbon dioxide is not permitted in organic seaweed culture.

Where external nutrient sources are used in indoor facilities, nutrient levels in the effluent water shall be the same, or lower, than the inflowing water.

Collection of wild spawning stock, or wild juvenile seaweed must comply with Article 6 on wild harvesting of seaweed.

Seaweed culture in the sea shall utilise nutrients naturally occurring in the environment, or from the culture of organic fish.

Culture density or operational intensity shall maintain the integrity of the aquatic environment, and not exceed its carrying capacity.

Fouling organisms must be removed by physical means and chemical anti-foulants are not permitted.

Cultivation in open water shall be carried out in a fashion which minimises the visual impact on the surrounding area.

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

Article 7

Post-harvest handling and processing

Flushing of freshly harvested seaweed shall use seawater where the final produce is fresh seaweed. If the final product is dehydrated seaweed, potable water may also be used for flushing.

Dehydrated seaweed shall be made using procedures not altering the product. In particular, the use of direct flames shall be prohibited. If ropes or other equipment are used (e.g. for sun-drying), they must be free of anti-fouling treatment.

Article 8

Controls for seaweed

The control requirements mentioned in Articles 63 – 67 of Regulation X shall apply to seaweed farming as well as to wild collection. In particular, there shall be one annual physical inspection of the onshore facility as well as at least one production site (bed) and one harvester per year.

Article 9

Controls for collection of wild seaweeds

The seaweed business operator shall draw up a full description and a map of shore and sea collection areas and land areas where post collection activities take place and include information on the following items:

a) list of species to be harvested;
b) history of harvesting activity for each species in named beds;
c) harvest estimate (volumes) per season;
d) sources of possible pollution for harvest beds;
e) sustainable annual yield for each bed .

Chapter III

Part A
All organic aquaculture species

Article 10

Aquaculture Production

These specifications in this chapter apply to all cultivated species of fish, molluscs and crustaceans. Technical rules are specified in Annex for main species or group of species.

Article 11

Origin of organic animals

Preference should be given to indigenous species and strains and young stock shall originate from organic brood stock and organic hatcheries or nurseries.
Nevertheless, given the current state of technical knowledge and the organization of organic aquaculture is still at an early stage, when organic animals, particularly molluscs, are not available in sufficient numbers, wild caught or non-organic animals may be brought into a holding for breeding, or for supplementing genetic stock. According to species, the whole or at least two thirds of the lifecycle, shall be managed under organic management. Details are provided for the main species in the Annexes.

2. It is necessary to choose breeds and strains which are well-adapted to the conditions of their environment while preserving and managing genetic diversity.

3. Species shall be chosen which can be bred with minimum interference to the wild stocks.

4. Collection of wild aquatic young stock for organic production is not permitted, with the following exceptions:

a) natural influx of fish or shrimp larvae and juveniles when filling ponds;

b) mussels seed from settlement beds which are unlikely to survive winter weather or are surplus to requirements;

c) natural settlement of shellfish larvae on the farm's collectors.

Article 12

Conversion and simultaneous production of organic and non-organic livestock

1. An organic aquaculture management unit shall be run according to organic principles in its entirety. The following exceptions shall apply:

a) The conversion period shall correspond to the lifecycle of each species;

b) hatcheries are allowed to rear both organic and non organic larvae and juveniles provided there is clear separation between both.

c) by five years from the coming into force of this Regulation, where not all production units or sites of an aquaculture holding, including hatcheries, are organic, the non-organic production must involve different species from the organic production.

Article 13

General husbandry rules

1. The environment of the animals must be designed in such a way that, in accordance with their needs, the animals shall:

a) have sufficient space to achieve physical integrity and keep their specific behaviour,

b) have sufficient oxygen level, and

c) enjoy natural temperature and light in accordance with the requirements of their species. Details are provided for the main species in the Annexes.

2. Organic productions shall adapt densities according to species and to the concerned environment.

3. The design and construction of aquatic containment system shall allow water exchange, flow rates and physiochemical parameters that safeguard the animals' welfare and provide for their ethological and behavioral needs.

4. Containment systems shall be designed, located and operated to minimize the risk and impact of escaping livestock.

5. The stocking density shall provide for the comfort and well being of the animals which, in particular, shall depend on the species, the age of the animals and their behavioral needs. Therefore maximum densities are defined in the Annexes for the main species.

6. The stocking density or operational intensity shall maintain the integrity of the aquatic environment, and not exceed its carrying capacity.

Part B

Fish and Crustaceans

Article 14

Containment systems - specific rules

1. Containment systems in which animals spend their entire lives indoors are not eligible for organic certification at present despite the obvious environmental advantages in relation to prevention of escapes. This point may be reviewed if research and practice indicate that they can be eligible for organic production in the future.

2. Onshore rearing units shall meet the following conditions:

a) it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;

b) at least five percent of the farm area shall be an undisturbed natural reserve area;

3. Open-water containment systems shall:

a) be located where water flow, depth and water body exchange rates are adequate to minimize the impact on the seabed and the surrounding water body;

b) demonstrate the suitability of net-pen design, construction and maintenance to the exposure of the relevant operating environment.

4. Antifoulants are not permitted.

5. Indoor production systems may be used for the hatchery stage.

6. Artificial heating or cooling of water shall only be permitted in hatcheries.

Article 15

Management of animals

1. Spawning shall be carried out with minimal interference to the breeding stock. Animals which so require shall be anaesthetized before manual stripping using an approved product before manual stripping.

2. Artificial light shall only be permitted in hatcheries, and used to influence reproduction and to improve survival and welfare of young stock. The following restrictions shall apply:

a) the use of artificial light to prolong natural day-length shall not exceed a maximum that respects the natural behaviour, geographical conditions and general health of the animals;

b) The use of artificial light shall be limited to prolonging natural light up to a maximum day length of 16 hours;

c) Abrupt changes in light intensity shall be avoided by the use of dimmable lights or background lighting.

3. When aquatic animals are grown from stocking to harvest without grading or reductions in density, the maximum densities specified in the Annexes shall apply.

4. Aeration shall not be used to raise the density above the permitted level. The use of liquid oxygen is prohibited.

5. The duration, stocking density and water quality management during transportation shall avoid unnecessary stress.

6 .Slaughter techniques shall render fish immediately unconscious and insensible to pain, a condition that must persist until death. *(*Fish welfare issues including approved stunning methods to take account of welfare of farmed fish opinions due from the European Food Safety Authority in July 2008).

Article 16

General rules on feeds

1. For species or production systems for which the aquatic environment does not supply enough natural food to the farmed animals, organic aquaculture feeds shall be formulated and feeding regimes designed with the following priorities:
a) animal health;
b) product quality;
c) low environmental impact.
Feed formulation must tend, within the limits of available knowledge, towards compliance with the specific needs of the animals and shall be specified in Annex for each species and, if appropriate, detailed by size or age of the animals.

2. All ingredients of agricultural origin shall be organic. This criterion does not apply for fishmeal and fish-oil which which shall originate from sustainable fisheries. [The culture for organic feed of microalgae, microcrustacea, rotifers, worms or other feed organisms shall comply with all the relevant sections of this Regulation].

Article 17

Specific rules on feeds

1. Fishmeal and oil shall by preference be made from trimmings of fish already caught for human consumption in sustainable fisheries. Preference should be given to fish meal which is

produced in a LT (low temperature) process. The maximum phosphorous content shall not exceed 1.2% of the dry matter of the feed. The nitrogen content shall not exceed 9% of the dry matter of the feed. Should feeds from trimmings not meet these criteria then fishmeal and oil may be used from sustainable fisheries.

2. Sustainable fisheries (move to definitions?) shall be subject to an effective management system that respects local, national and international laws and standards and incorporated institutional and operational frameworks that require fishing of the resource to be responsible and sustainable.
[The Commission plans to come forward with a proposal for a new Public/Private Partnership in early 2009 to stimulate the creation of a sector-driven European standard for sustainable fisheries which shall be the future basis of determining sustainability of sources of fishmeal and fish oil for organic feed].

3. Natural sources of carotenoid pigments [such as Phaffia rhodozyma yeast] listed in Annex V of Regulation X/2008 may be used for pigmentation of salmonid fish.

4. Only natural antioxidants based on tocopherols, [garlic acid, ascorbic acid or other natural plant extracts] shall be permitted to preserve the feed.

Part C

Molluscs

Article 18

Bivalve shellfish

Production of filter feeding organisms shall require a carrying capacity study demonstrating that the local ecosystem will not be significantly affected by the farm. Organic shellfish farming may be carried out in the same waters as organic finfish and seaweed farming as part of an agreed system of organic polyculture.

The shellfish business operator shall keep records of the results of periodic checks carried out under Annex II.B of Regulation (EC) 854/2004[1] and shall comply fully with competent authority decisions under Annex II.C of the same Regulation following monitoring concerning microbiological quality, contaminants and possible closures due to toxin-producing plankton in production and relaying areas.

Organic shellfish production shall take place within protected areas delimited by post, buoys or other clear marking system and shall, as appropriate, be restrained by nets, cages or other man made means and shall be clearly separated from conventional cultivation operations and wild shellfish stocks by a distance of no less than 500 metres.

[1] OJ L 226, 25.6.2004, p 83

Bouys and other structures above the surface, except for navigational markers shall be of uniform, subdued and neutral colour. All equipment at sea or onshore is to be stored in a tidy and unobtrusive manner.

Seed from non-organic oyster, scallop, and clam hatcheries can be used until 31.12.2012 but thereafter seed material must be sourced from organic hatcheries.

Providing there is no lasting damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the farm can be used in the case of mussels and scallops. Records must be kept of how, where and when wild seed was collected to allow traceability back to the collection area. Partially grown seed, which has been grown organically, can also be used under the same conditions.

Production must focus on size and density of shellfish so as to provide optimum conditions for the species with regard to water current and feed supply. Sorting, thinning and density adjustments shall be made according to the biomass.

Article 19

Mussels

Cultivation on ropes supported by long-lines or rafts in areas with good turnover of water shall be eligible for organic certification. Bouchot poles may also be used for mussel collection and on-growing.

In certain situations, providing environmental impact is minimised at the collection and growing sites, cultivation of mussels on licensed plots of sub-tidal ground shall also be eligible for organic certification. The evidence of minimal environmental impact must be supported by a survey and report on the dredged areas by an independent monitoring body.

Article 20

Oysters

(To be developed)

Part D

Disease preventions and transport

Article 21

General rules on disease prevention

1. Production techniques must be designed to keep the aquatic animals in perfect health via essentially preventative action. Prevention first involves maintaining a good balance between the stock and their environment.

2. Organic farms shall have a veterinary management plan detailing biosecurity and disease prevention practices including a written agreement for health counseling with a veterinarian who shall visit the farm at a frequency of not less than once every nine months.
5. Where appropriate, holding systems, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the buildup of disease carrying organisms.

6. A period of fallowing during which the facility used for animal production is emptied, disinfected and left empty before being used again is required after each production cycle in open water containment systems and is recommended in other branches of aquaculture.

7. Uneaten fishfeed (where appropriate), faeces and mortalities should be removed promptly to maximize water quality, minimize disease risks, and to avoid attracting insects or rodents.

[8. Vaccination shall be permitted where a known disease risk occurs.]

Article 22

Veterinary treatments

1 Preference shall be given to veterinary treatments based on:

a) substances of the plant, animal or mineral kingdom in a homoeopathic dilution
b) plants and their extracts, and
c) substances such as: [trace elements, metals or natural immunostimulants, authorised probiotics.]

2. Limitations to the use of allopathic treatments are detailed in the Annexes for each production system.

Article 20

Transport of fish and Crustaceans

1. Live fish and crustaceans animals must be carried in suitable tanks with water whose characteristics meet the physiological needs of the fish in terms of temperature and dissolved oxygen.

2. These tanks must be sealed in such a way as to prevent the substitution of their contents, and provided with a suitable label.

3. However, the tanks may be used beforehand or subsequently for the collection and transport of fish not originating from organic farming. Comprehensive precautions shall then be taken concerning cleaning, disinfection and rinsing of these tanks.

4. Comprehensive precautions shall be taken to reduce the conditions of stress. During transport, the density must not exceed X kg/m ^{3}.

Article 24

Exceptional production rules

By exception to Article 14.6 natural borehole water may be used to cool onshore rearing units in peak summer conditions to prevent mortalities.

With the exception of hatcheries, or where a known disease risk occurs, water shall not be treated with ultraviolet light or ozone for microbial control.

By exception to Article 15.2.b), to enable the development of organic cod farming the limit of 16 hours of light daily shall not apply to on-growing of this species until 2015.

Introduction of exogenous oxygen for aeration of aquaculture units (except hatchery systems) is allowed by exception to Article 15.4 under the following conditions:
1. Temporary use of mechanical systems (aerators,) preferably powered by renewable energy sources, due to temperature rise, drop in atmospheric pressure, accidental pollution, or for occasional stock management procedures such as sampling and sorting, fasting periods, or in order to assure the survival of the farm stock. Such temporary use shall also be permitted where a minimum oxygen threshold is to be met, adapted to species, in order to maintain animal welfare. All such use is to be recorded in the farm log

[Technical Annexes for main species

(Unless specifically mentioned the minimum duration of the life cycle in organic production is two thirds of total)

Annex 1: Organic production of salmonids in fresh water

<u>Species concerned</u>: Brown trout (Salmo trutta) – Rainbow trout (Oncorrhynchus mykiss) – American brook trout – Charr – Grayling – American lake trout (or grey trout) - Huchen

Minimum separation distance organic from conventional production unit/s	In a river 3,000 metres and the organic production unit must be upstream of conventional units. In a lake 1,000 metres.
Production system	Ongrowing farm systems must be fed from open systems The flow rate must be at least 7 litres/second/tonne of fish stock and must ensure the comfort of the animals and the elimination of farming effluent.
Maximum stocking density (kg fish per cubic metre of	30 kg/m^3

water)	
Allopathic treatments during on-growing	With the exception of [vaccinations and] compulsory eradication schemes, where fish receive more than **two** courses of treatments per year with chemically-synthesized allopathic veterinary medicinal products or antibiotics and more than **two** treatments per year with antiparasitics, the livestock concerned or produce derived from them, may not be sold as organic products. None permitted within three-months of harvest

Annex 2: Technical annex for the organic production of salmonids in sea water

<u>Species concerned</u>: Salmon (Salmo salar), Brown trout (Salmo trutta) – Rainbow trout (Oncorrhynchus mykiss)

Minimum separation distance organic from conventional production unit/s	2 nautical miles
Maximum stocking density (kg fish per cubic metre of water)	15 kg/m^3 in net pens
Allopathic treatments during on-growing	With the exception of [vaccinations and] compulsory eradication schemes, where fish receive more than **two** courses of treatments per year with chemically-synthesized allopathic veterinary medicinal products or antibiotics and more than **two** treatments per year with antiparasitics, the livestock concerned or produce derived from them, may not be sold as organic products. None permitted within three-months of harvest

Annex 3: Technical annex for the organic production of cod, sea bass, sea bream, meagre, and turbot

Minimum separation distance organic from conventional production unit/s	2 nautical miles
Production system	In open water containment systems (net pens/cages) with minimum sea current speed 2 metres/second. The depth must not be less than 20 metres giving a minimum distance between the bottom of the net and the sea floor of 10 metres

Maximum stocking density (kg fish per cubic metre of water)	offshore: 10 kg/m^3 [onshore: 20 kg/m^3]
Allopathic treatments during on-growing	With the exception of [vaccinations and] compulsory eradication schemes, where fish receive more than **one** course of treatments per year with chemically-synthesized allopathic veterinary medicinal products or antibiotics (possibly supplemented by **one** treatment per year with antiparasitics) the livestock concerned or produce derived from them, may not be sold as organic products. None permitted within three-months of harvest

Annex 4: Technical annex for the organic production of penaeid shrimps and freshwater prawns (*Macrobrachium sp.*)

Establishment of production unit/s	Location to be in sterile clay areas to minimise environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Maximum 2% mangrove destruction permitted. This ratio can be extended to 10 % if an existing conventional farm is converted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a farmed shrimp.
broodstock origin	[Minimum [50%] of the broodstock should be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm. The goal is to counteract genetic depletion.]
Eyestalk ablation	[Single eyestalk ablation ('epedonculation') of female *Penaeid* shrimp to be permitted on 90% of breeding stock until 2015, so long as no alternative is proven. The remaining 10% to be spawned without ablation as part of breeding programme.]
Allopathic treatment	Maximum one allopathic treatment shall be allowed in the hatchery for each larval cycle and for curative purposes only. Hatchery operator to justify each treatment by supplying relevant data. No treatment is to be allowed at the farm during grow-out.
Minimum duration of the organic life-cycle	Whole life cycle.
Maximum stocking densities and production limits	[Seeding: maximum 22 post larvae/m^2 Maximum instantaneous biomass (to be defined): 240 g/ m^2 Maximum annual production : 5 tonnes/ha]

Shell treatment	[Metabisulphite treatment shall be allowed until 2010 given the current absence of a treatment to prevent blackening of shells. One single treatment to be permitted at the farm on a specific platform with a residual water treatment and monitoring system. Maximum residuals permitted in the edible parts are 75ppm for raw products and 50ppm for cooked products.]

Annex 5: Technical annex for the organic production of Sturgeon in fresh water.

Species concerned: ***Acipenser family***

Minimum separation distance organic from conventional production unit/s	In a river 1,000 metres and the organic production unit must be upstream of conventional units. In a lake 1,000 metres.
production system	Water flow in each rearing unit shall be sufficient to ensure animal welfare, with a minimum turn over rate of 2 hours. Effluent water to be of equivalent quality to incoming water
maximum farming density	[35 kg/m^3]
minimum duration of the organic life-cycle	From juvenile to harvest

Annex 6: Technical annex for the organic production of sea bass, sea bream, meagre, mullets (*Liza, Mugil*) and eel in earth ponds of tidal areas

Containment system	Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas
Production system	[The average time for renewal of the water is set at 5 renewals per hour at most. At least 50% of the dikes must have plant cover Wetland based depuration ponds recommended]
maximum farming density	4 kg/m^3

Annex 7: Technical annex for the organic production of lake fish

Species concerned: C*arp (Cyrpinus carpio) and other associated species [in the context of lake polyculture]*

Site location	The organic production pond is to be located upstream of any non organic aquaculture zone.
Production system	Lakes and land-based ponds, with an average minimum depth of 0.7 m of water, in which any drained and dry periods, must be total (total dry-out, with the exception of fishery trenches). The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.

	Organic and mineral fertilisation of the ponds and lakes must be carried out in compliance with Regulation No 834/2007 (list?) Treatments involving synthetic chemicals for the control hydrophytes and plant coverage present on the water system on the production site are prohibited. Areas of natural vegetation 50m wide must be maintained around lakes and ponds as a buffer zone for external land areas not involved in the farming operation in accordance with the rules of organic aquaculture. ["Polyculture" (the simultaneous farming of different species of fish) is permitted on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.] Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas. Use of borehole water is prohibited.
Feed	Additional feed can by added only on an exceptional basis and over limited periods to supplement natural production
Farming yield	The total production of species is limited to 500 kg of fish produced per year and per hectare of pond (average area of water).

End of square brackets]