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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 6.1.2009

Draft

**COMMISSION REGULATION (EC) No .../..**

**of [...]**

**amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture and seaweed**

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**COMMISSION REGULATION (EC) No .../..**

**of [...]**

**amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture and seaweed**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91<sup>1</sup>, and in particular Articles 11, 13(3), 15(2), 16(1) and (3)(a) and (c), 17(2), 18(5), the second subparagraph of Article 19(3), Articles 22(1), 28(6) and 38(a), (b), (c), and Article 40 thereof,

Whereas:

- (1) Regulation (EC) No 834/2007 and in particular Title III thereof lays down basic requirements with regard to aquaculture and seaweed production. Detailed rules for the implementation of these requirements should be laid down by amending Commission Regulation (EC) No 889/2008<sup>2</sup>, which lays down detailed rules for the implementation of Regulation (EC) No 834/2007.
- (2) The Communication from the Commission to the Council and the European Parliament on a strategy for the sustainable development of European aquaculture<sup>3</sup> sets out a vision for the development of this sector over a ten year period to give a stable industry in rural and coastal areas providing alternatives to the fishing industry in terms of products and employment. The Communication pointed to the potential for organic aquaculture production and the requirement for norms and criteria to be developed.
- (3) To ensure common understanding the definitions as laid down in Article 2 of Regulation (EC) No 889/2008 should be supplemented and corrected in order to avoid ambiguities and to guarantee the uniform application of the organic aquaculture and seaweed production rules.
- (4) The aquatic growing area for organic seaweed and aquatic animals is of utmost importance both for growing safe and high quality products with minimal impact on

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<sup>1</sup> OJ L 189, 20.7.2007, p. 1.

<sup>2</sup> OJ L 250, 18.9.2008, p.1.

<sup>3</sup> COM(2002) 511 of 19.9.2002.

the aquatic environment. Community legislation on quality of waters and contaminants in food, including Directive (EC) 2000/60 of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy<sup>4</sup>, Directive (EC) 2008/56 of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)<sup>5</sup>, and Commission Regulation (EC) 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs<sup>6</sup>, ensures high food quality. It is therefore appropriate to draw up a sustainable management plan for seaweed and aquaculture production specifying measures, such as environmental assessment, and waste reduction.

- (5) The measures provided for in this Regulation should be without prejudice to Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment<sup>7</sup> and Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora<sup>8</sup>.
- (6) The cultivation of seaweed can have a beneficial effect on water quality and can facilitate polyculture. Care needs to be taken not to over-harvest wild seaweed beds to permit their regeneration.
- (7) The specific soluble medium of water requires organic and non-organic aquaculture production units to be adequately separated; appropriate separation distances should be laid down.
- (8) Given the early stage of organic aquaculture production organic broodstock is not available in sufficient quantities. Provision should be made for the introduction of non-organic broodstock and juveniles under certain conditions.
- (9) Organic aquaculture production should ensure that species-specific needs of animals are met. In this regard husbandry practices, management systems and containment systems should satisfy the welfare needs of animals. Provisions on the appropriate construction of cages and net pens at sea as well as for rearing systems on land should be made. To minimise pests and parasites and for the reason of high animal welfare and health, maximum stocking densities should be laid down. Taking account of the broad variation of species with particular needs, specific provisions should be laid down.
- (10) Recent technical development has led to increasing use of closed recirculation systems for aquaculture production, such systems depend on external input and high energy but permit reduction of waste discharges and prevention of escapes. Due to the principle that organic production should be as close as possible to nature the use of such systems should not be allowed for organic production until further knowledge is available. Exceptional use should be possible only for the specific production situation of hatcheries and nurseries.

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<sup>4</sup> OJ L 327, 22.7.2000, p.1.

<sup>5</sup> OJ L 164, 25.6.2008, p. 19.

<sup>6</sup> OJ L 364, 20.12.2006, p. 5.

<sup>7</sup> OJ L 175, 5.7.1985, p. 40.

<sup>8</sup> OJ L 206, 22.7.1992 p. 7.

- (11) The use of hormones and hormone derivatives for the induction of reproduction and other purposes is against the organic principles and therefore should be prohibited.
- (12) Feed for aquatic animals should meet the nutritional needs and is also required to meet the health requirement that feed coming from a species is not fed to the same species as laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies<sup>9</sup>. It is therefore appropriate to lay down specific provisions for herbivorous and non-herbivorous aquatic animals.
- (13) The raw materials for feeding organic non-herbivorous fish and crustaceans should preferably be derived from sustainable exploitation of fisheries as referred to in Article 5(o) of Regulation 834/2007 and defined in Article 3(e) of Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy<sup>10</sup> or organic feed derived from organic aquaculture sources. Given the early stage of organic aquaculture and sustainable fisheries shortages of organic feed or feed from sustainable fisheries may occur, provisions should be made for the use non-organic feed.
- (14) For the purpose of organic aquaculture and seaweed production, the use of certain non-organic feed materials, feed additives and processing aids is allowed under well-defined conditions. New materials in question should be authorised according to Article 16(1) of Regulation (EC) No 889/2008. Based on the recommendation of an ad-hoc expert group<sup>11</sup> on "Fish feed and cleaning materials in organic aquaculture" which concluded that such substances already listed in Annex V and Annex VI to Regulation (EC) No 889/2008 and authorised for organic livestock production should be allowed also for organic aquaculture and concluding that certain substances are essential for particular fish species, such substances should be added to Annex VI to that Regulation.
- (15) The cultivation of filter feeding bivalve molluscs can have a beneficial effect on coastal water quality via the removal of nutrients and their use can also facilitate polyculture. As supplementary feeding by man is not required the environmental impact is consequently lower than other branches of aquaculture. Specific rules for molluscs should be laid down.
- (16) Animal health management should be primarily based on the prevention of disease. The measures provided for in this Regulation should be without prejudice to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals<sup>12</sup>. Certain substances for cleaning, antifouling treatment and disinfection of production equipment and facilities should be allowed under defined conditions. In the presence of live animals the use of disinfection substances requires particular care and measures to ensure that the application is not harmful. Such substances should be authorised according to Article 16(1) of Regulation (EC)

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<sup>9</sup> OJ L 147, 31.5.2001, p. 1.

<sup>10</sup> OJ L 358, 31.12.2002, p. 59.

<sup>11</sup> Recommendations from the ad-hoc expert group on "Fish feed and cleaning materials in organic seaweed and aquaculture production" , 20.11.2008, [www.organic-farming.europa.eu](http://www.organic-farming.europa.eu)

<sup>12</sup> OJ L 328, 24.11.2006, p 14.

No 889/2008. Based on the recommendation of an ad-hoc expert group such substances should be listed in the Annex.

- (17) Specific rules for veterinary treatment should be laid down ranking the different types of treatments and limiting the frequency of use in the case of allopathic treatments.
- (18) Precaution should be taken during the handling and transport of live fish as to meet their physiological needs.
- (19) The conversion to the organic production method requires the adaptation of all means to the organic method for a given period. Depending on the previous production system specific conversion period should be laid down.
- (20) In helping to develop the organic fish feed market, the use of non-organic feed of plant origin should be allowed for a certain period.
- (21) Provisions for specific control requirements which take account of the specificities of aquaculture should be laid down.
- (22) To facilitate the conversion of holdings already producing organically under national or private standards to the new Community rules certain transitional measures should be laid down.
- (23) Regulation (EC) No 889/2008 should therefore be amended accordingly.
- (24) The measures provided for in this Regulation are in accordance with the opinion of the regulatory Committee on organic production,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 889/2008 is amended as follows:

- (1) In Article 1, paragraph 2 is replaced by the following:

"2. This Regulation shall not apply to:

- a) livestock species other than those referred to in Article 7; and
- b) to aquatic animals other than those referred to in Article 25a.

However, Title II, Title III and Title IV shall apply *mutatis mutandis* to such products until detailed production rules for those products are laid down on the basis of Regulation (EC) No 834/2007."

- (2) Article 2 is amended as follows:

- (a) points (f) and (g) are replaced by the following:

"(f) "production unit" means all assets to be used for a production sector such as production premises, land parcels, pasturages, open air areas, livestock

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buildings, fish ponds, containment systems for seaweed or aquaculture, shore or seabed concessions, the premises for the storage of crops, crop products, seaweed products, animal products, raw materials and any other input relevant for this specific production sector;

- (g) "hydroponic production" means the method of growing plants, other than seaweed, with growing their roots in a mineral nutrient solution only or in an inert medium, such as perlite, gravel, or mineral wool to which a nutrient solution is added;"
- (b) after point (i) the following points are added:
- “(j) 'carrying capacity' means the amount of a given aquaculture production or seaweed harvesting that can be accommodated within the environmental capacity of a defined area;
- (k) 'closed recirculation aquaculture facility' means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the full recirculation of water;
- (l) 'energy from renewable sources' means renewable non-fossil energy sources: wind, solar, geothermal, wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;
- (m) 'hatchery' means a place of breeding, hatching and rearing through the early life stages of animals, finfish and shellfish in particular;
- (n) 'nursery' means a place where an intermediate farming system, between the hatchery and grow-out stages is applied The nursery stage is always completed within the first third of the production cycle;
- (o) 'pollution' in the framework of aquaculture and seaweed production means the introduction into the marine environment of the items listed in Article 3, paragraph (8) of Directive 2008/56/EC. In the case of freshwaters it results from the introduction of pollutants listed in Annex VIII of Directive 2000/60/EC;
- (p) 'polyculture' in the framework of aquaculture and seaweed production, means the rearing of two or more non-competitive species in the same culture unit;
- (q) 'production cycle' in the framework of aquaculture and seaweed production, means the lifespan of an aquatic animal or seaweed from the earliest life stage to harvesting;
- (r) 'locally grown species' in the framework of aquaculture and seaweed production, means those which are neither alien nor locally absent species under Council Regulation (EC) No 708/2007; Those species listed in Annex IV of Regulation (EC) No 708/2007 may be considered as locally grown species.
- (3) In Title II, the following Chapter 1a is inserted:

## “CHAPTER 1a

### Seaweed

#### *Article 6a*

##### **Scope**

This Chapter lays down detailed production rules for the collection and farming seaweed. It applies *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed in aquaculture.

#### *Article 6b*

##### **Suitability of aquatic medium and sustainable management plan**

1. Member State authorities may designate areas which they consider to be unsuitable for organic aquaculture or seaweed harvesting from an environmental point of view.
2. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for organic production, or pollutants that would compromise the organic nature of the products.
3. An environmental assessment shall be required for all new operations applying for organic production 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 body or control authority. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC\*. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
4. The operator shall provide a sustainable management plan for aquaculture and seaweed harvesting.

The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and re-cycle materials where possible and shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. The use of residual heat shall be limited to energy from renewable sources.

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

### *Article 6c*

#### **Sustainable harvesting of wild seaweed**

1. Written contracts shall be required between the seaweed business operator and the harvesters.
2. Harvesting shall not exceed the sustainable yield of the ecosystem and measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.
4. With respect to Article 73b (2) (b) and c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

### *Article 6d*

#### **Seaweed Cultivation**

1. Seaweed culture at sea shall utilise nutrients naturally occurring in the environment, or from organic aquaculture production, preferably located nearby as part of a polyculture system.
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 and as listed in Annex I may be used.
3. Culture density or operational intensity shall be recorded and shall maintain the integrity of the aquatic environment, and not exceed its carrying capacity.
4. Ropes and other equipment used for growing seaweed shall be re-used or recycled where possible.
5. The minimum separation distance for organic and non-organic seaweed cultivation at sea shall be at least 100 metres.

### *Article 6e*

#### **Cleaning of production equipment and facilities**

1. Bio-fouling organisms shall be removed by physical means or by hand and returned to the sea at a distance from the farm.

2. Where cleaning measures under paragraph 1 are not satisfactory only chemical antifoulants, which are listed in Annex VII, Section 2 may be used.

\* OJ L 175, 5.7.1985, p. 40"

- (4) In Title II, the following Chapter 2a is inserted:

## **“CHAPTER 2a**

### **Aquaculture production**

#### **SECTION 1**

#### **GENERAL RULES**

##### *Article 25a*

##### **Scope**

This Chapter lays down detailed production rules for species of fish, crustaceans, echinoderms and molluscs as covered by Annex XIIIa.

It applies *mutatis mutandis* to zooplankton, micro-crustaceans, rotifers, worms and other aquatic feed animals.

##### *Article 25b*

##### **Suitability of aquatic medium and environmental sustainability**

1. The provisions of Article 6b shall apply to this Chapter.
2. Defensive and preventive measures taken against predators under Council Directive 92/43/EEC\* and national rules shall be recorded in the sustainable management plan.
3. Where more than one operation is based in an area, verifiable coordination shall take place between operators in drawing up their management plans.
4. For aquaculture in fishponds, tanks or raceways, effluent monitoring shall be carried out at regular intervals and farms shall be equipped with either natural-filter beds, settlement ponds, or biological filters to collect waste nutrients or use seaweeds and/or animals (bivalves and algae) which contribute to improving the quality of the effluent.
5. The competent authority may permit the use of mechanical filters and therefore shall lay down specific criteria in advance.

### **Separation distance for different species**

In accordance with Article 11 of Regulation (EC) No 834/2007, the minimum separation distance between units with organic and non-organic production involving different species, whether in the same holding or a different holding, shall be at least 500 metres.

### **Simultaneous production of organic and non-organic aquatic animals of the same species**

1. The competent authority may permit hatcheries and nurseries to rear both organic and non-organic juveniles of the same species provided there is clear separation between them and a separate water distribution system to reduce the risk of contamination by products and substances not authorised for organic production is set up.
2. Organic and non-organic aquaculture units which grow the same species, in accordance with Article 11 of Regulation (EC) No 834/2007, in the same or a different holding shall have a minimum separation distance between the units as prescribed in the relevant Section of Annex XIIIa or if not so prescribed a distance of one kilometre on land and one nautical mile at sea. The competent authority may stipulate differentiation criteria such as different phasing or different handling systems to operators and inform other Member States and the Commission.
3. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

## **SECTION 2**

### **ORIGIN OF AQUACULTURE ANIMALS**

#### **Origin of organic animals**

1. Locally grown species shall be used and breeding shall aim to give strains which are more adapted to farming conditions, good health and good utilisation of feed resources. Documentary evidence of their origin, treatment and health certification shall be provided for the control body or control authority.
2. Species shall be chosen which can be farmed without causing significant damage to wild stocks.

### **Origin and management of non-organic animals**

1. For breeding purposes or for improving genetic stock and when organic animals are not available in sufficient numbers, wild caught or non-organic animals may be brought into a holding. At least the latter two thirds of the duration of the production cycle shall be managed under organic management.
2. In the case of non-organic juveniles the percentage introduced to the farm shall decrease by a minimum of ten percent per year from 2010. These provisions will be reviewed by 2013.
3. For on-growing purposes the collection of wild aquatic juveniles is specifically restricted to the following cases:
  - (a) natural influx of fish or crustacean larvae and juveniles when filling ponds, containment systems and enclosures;
  - (b) European glass eel, providing an approved eel management plan is in place for the location and artificial reproduction of eel remains unsolved.

## **SECTION 3**

### **HUSBANDRY PRACTICES**

#### **General husbandry rules**

1. The husbandry environment of the animals shall be designed in such a way that, in accordance with their species specific needs, the animals shall:
  - (a) have sufficient space for their wellbeing;
  - (b) be kept in water of good quality with sufficient oxygen levels, and
  - (c) be kept in temperature and light conditions in accordance with the requirements of the species and having regard to the geographic location;
  - (d) in the case of freshwater fish the bottom type shall be as close as possible to natural conditions for example sand and gravel;
  - (e) in the case of carp the bottom shall be natural earth.
2. Stocking density is set out in Annex XIIIa by species or group of species.
3. The design and construction of aquatic containment systems shall provide flow rates and physiochemical parameters that safeguard the animals' health and welfare and provide for their behavioural needs.

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4. Containment systems shall be designed, located and operated to minimize the risk of animals escaping.
5. If fish or crustaceans escape, appropriate action must be taken to reduce the impact on the local ecosystem, including recapture, where appropriate. Documentary evidence shall be maintained.

*Article 25h*

**Specific rules for containment systems**

1. Closed recirculation aquaculture facilities are prohibited, with the exception of hatcheries and nurseries or for production of species used for organic feed organisms.
2. Rearing units on land shall meet the following conditions:
  - (a) for flow-through systems it shall be possible to monitor and control the flow rate and water quality of both in-flowing and out-flowing water;
  - (b) at least five percent of the farm area shall have undisturbed natural vegetation.
3. Containment systems at sea 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) shall have suitable cage design, construction and maintenance to the exposure of the operating environment.
4. Artificial heating or cooling of water shall be permitted in hatcheries and nurseries. Natural borehole water may be used to heat or cool water at all stages of production.

*Article 25i*

**Management of animals**

1. Handling of animals shall be minimised, undertaken with the greatest care and proper equipment and protocols used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in a manner to minimize physical damage and stress. Grading operations shall be kept to a minimum.
2. The following restrictions shall apply to the use of artificial light:
  - (a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general

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health of farmed animals, this maximum shall not exceed 16 hours per day, except for reproductive purposes;

- (b) Abrupt changes in light intensity shall be avoided at the changeover time by the use of dimmable lights or background lighting.
3. The non-routine use of aeration shall be permitted on the following conditions:
- (a) temporary use of mechanical aerators,
  - (b) temperature rise, drop in atmospheric pressure or accidental pollution,
  - (c) occasional stock management procedures such as sampling and sorting, and;
  - (d) fasting periods, or in order to assure the survival of the farm stock.

All such use is to be recorded in the aquaculture production record.

4. The use of liquid oxygen is only permitted for uses linked to animal health requirements and critical periods of production and transport. Documentary evidence shall be maintained.
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. Differences in harvesting sizes, species, and production sites must be taken into account when considering optimal slaughtering methods.
7. The ice slurry method of slaughter shall be permitted for seabass and seabream and closely related species in the Mediterranean Sea and areas of similar temperature and also for tropical invertebrates. For fish this shall be reviewed by 2013 with reference to scientific advice and evaluation of optimal stunning and slaughter conditions for these species. Stunning by carbon dioxide shall also be permitted for tropical invertebrates.

## SECTION 4

### BREEDING

#### *Article 25j*

#### **Prohibition of hormones**

The use of hormones and hormone derivatives is prohibited.

## SECTION 5

### FEED FOR FISH, CRUSTACEANS AND ECHINODERMES

#### *Article 25k*

##### **General rules on feeds**

Feeding regimes shall be designed with the following priorities:

- (a) animal health;
- (b) high product quality, including the nutritional composition;
- (c) low environmental impact.

#### *Article 25l*

##### **Specific rules on feeds for non-herbivorous animals**

1. Non-herbivorous aquatic animals shall be fed with the following priorities:
  - (a) organic aquatic feed products;
  - (b) fish meal and fish oil from organic aquaculture trimmings;
  - (c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries.
2. Where feed as mentioned in paragraph 1 is not available, fishmeal, fish oil and ingredients from sustainable fisheries as listed in Annex V may be used.
3. If feed mentioned under paragraphs 1 and 2 is not available in sufficient quantities, fishmeal and fish oil from non-organic aquaculture trimmings, or trimmings of fish caught for human consumption may be used for a transitional period until 31 December 2014, by which time this shall be reviewed. Such feed material shall not exceed 30% of the daily ration.
4. The feed of non-herbivorous species should comprise at least 10% and not more than 60% plant proteins from organic production. Complete substitution of fishmeal and fish-oil in carnivorous species is not permitted.
5. Astaxanthin derived primarily from organic sources, such as organic crustacean shells shall be used in the feed ration for salmon and trout to satisfy their physiological needs. If organic sources are not available in sufficient quantities natural sources of astaxanthin may be used.

**Specific rules on feeds for herbivorous animals**

1. Herbivorous species as referred to in Annex XIIIa, Section 6 shall be fed with natural feed.
2. If the natural feed resources are insufficient, organic feed of plant origin preferably grown on the farm itself or seaweed may be used.

*Article 25n*

**Products and substances referred to in Article 15(1)(d)(iii) of Regulation (EC) No 834/2007**

1. Non-organic feed materials of plant origin may be used in organic aquaculture, subject to the restrictions as laid down in Article 43a and only if listed in Annex V.
2. Feed additives, certain products used in animal nutrition and processing aids may be used if listed in Annex VI and the restrictions laid down therein are complied with.

**SECTION 6**

**SPECIFIC RULES FOR MOLLUSCS**

*Article 25o*

**Growing area**

1. Production of bivalve molluscs shall avoid damage to areas of high nature or biodiversity interest, particularly Natura 2000 areas, as defined in Council Directive 79/409/EEC\*\* and Directive 92/43/EEC. A special chapter shall be required in the environmental assessment covering best adaptation to the surrounding environment and mitigation of possible negative effects. These findings shall be incorporated into the sustainable management plan to be established under Article 25b.
2. Bivalve mollusc farming may be carried out in the same area of water as organic finfish and seaweed farming in a polyculture system to be documented in the sustainable management plan. Bivalve molluscs may also be grown together with gastropod molluscs, such as periwinkles, in polyculture.
3. Organic bivalve mollusc production shall take place within areas delimited by posts, floats or other clear markers and shall, as appropriate, be restrained by net bags, cages or other man made means.

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4. 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.

### *Article 25p*

#### **Sourcing of juveniles**

1. Seed from non-organic bivalve-shellfish hatcheries can be used until 31 December 2013 by which date consideration will be given to the need to continue such use.
2. Providing there is no lasting damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit can be used in the case of bivalve shellfish provided it comes from:
  - (a) settlement beds which are unlikely to survive winter weather or are surplus to requirements, or
  - (b) natural settlement of shellfish juveniles on collectors.

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

### *Article 25q*

#### **Management**

1. Production shall use a stocking density not in excess of two-thirds that used for non-organic shellfish in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass.
2. Biofouling organisms shall be removed by physical means or by hand and where appropriate returned to the sea away from shellfish farms. Shellfish may be treated once during the production cycle with a lime solution to control competing fouling organisms.

### *Article 25r*

#### **Specific cultivation rules for mussels and clams**

1. Cultivation on mussel ropes and other methods listed in the Annex XIIIa, Section 8 may be eligible for organic production.
2. Bottom cultivation of mussels and clams is permitted providing environmental impact is minimised at the collection and growing sites. The evidence of minimal environmental impact shall be supported by a survey and report on the exploited area to be provided by the operator to the control body or control authority. The report shall be added as a separate chapter to the sustainable management plan.

### **Specific cultivation rules for oysters**

1. Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the criteria listed in the Annex XIIIa, Section 8.
2. Bottom cultivation may also be eligible for organic production. Evidence of minimal environmental activity shall be supported in such cases by the special chapter of the environmental assessment which is required under Article 25o(1).
3. Preference shall be given to juvenile oysters produced by organic hatcheries, which in the case of the cupped oyster, *Crassostrea gigas*, shall be selectively bred to reduce spawning in the wild.

## **SECTION 7**

### **DISEASE PREVENTION AND VETERINARY TREATMENT**

#### **General rules on disease prevention**

1. The sustainable management plan outlined in Article 6b shall contain a section covering animal health and disease prevention entitled the animal health management plan.
2. The animal health management plan shall detail biosecurity and disease prevention practices including a written agreement for health counselling with a veterinarian who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish.
3. Holding systems, equipment and utensils shall be properly cleaned and disinfected. Only products listed in Annex VII, Section 2.1 to 2.2 may be used.
4. With regard to fallowing;
  - (a) The competent authority shall determine an appropriate fallowing period which shall be applied and documented after each production cycle in open water containment systems at sea. Fallowing is also recommended for other production methods using tanks, fishponds, and cages;
  - (b) it shall not be mandatory for bivalve mollusc cultivation;

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- (c) during fallowing the cage or other structure used for aquatic animal production is emptied, disinfected and left empty before being used again.
- 5. Uneaten fish-feed, faeces and dead animals shall be removed promptly to maximize water quality, minimize disease risks, and to avoid attracting insects or rodents.
- 6. Ultraviolet light and ozone may be used.
- 7. For biological control of ectoparasites preference shall be given to the use of cleaner fish.

*Article 25u*

**Veterinary treatments**

- 1. When despite preventive measures to ensure animal health, according to Article 15 (1) (f) (i), of Regulation 834/2007, a health problem arises, veterinary treatments may be used in the following order of preference:
  - (a) substances from plants, animals or minerals in a homoeopathic dilution;
  - (b) plants and their extracts not having anaesthetic effects, and
  - (c) substances such as: trace elements, metals, natural immunostimulants or authorised probiotics.
- 2. The use of allopathic treatments is limited to two courses of treatment per year, with the exception of vaccinations and compulsory eradication schemes. However, in the cases of fish with a production cycle of less than 18 months and shrimps and prawns and other species with a production cycle of less than a year a limit of one allopathic treatment applies.
- 3. The use of parasite treatments shall be limited to twice per year or once per year where the production cycle is less than 18 months. Only substances as listed in Annex VII, Section 2.3 and under the restrictions therein are allowed.
- 4. The withdrawal period for allopathic veterinary treatments and parasite treatments according to paragraph 3 shall be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours.
- 5. Whenever veterinary medicinal products are used, such use is to be declared to the control body or the control authority before the animals are marketed as organic. Treated stock shall be clearly identifiable.

\* OJ L 206, 22.7.1992 p. 7

\*\* OJ L 103, 25.4.1979, p.1"

- (5) In Chapter 3 of Title II, the following Article 29a is inserted after Article 29:

**Specific provisions for seaweed**

1. If the final product is fresh seaweed, flushing of freshly harvested seaweed shall use seawater.

If the final product is dehydrated seaweed, potable water may also be used for flushing. Salt may be used for removal of moisture.

2. The use of direct flames which come in direct contact with the seaweed shall be prohibited for drying. If ropes or other equipment are used in the drying process they shall be free of anti-fouling treatments except where a product is listed in Annex VII for this use.”

- (6) In Chapter 4 of Title II, the following Article 32a is inserted:

*“Article 32a*

**Transport of fish**

1. Live fish shall be transported in suitable tanks with clean water which meets their physiological needs in terms of temperature and dissolved oxygen.
2. Before transport of organic fish and fish products, tanks which have been used for the collection and transport of non-organic products shall be thoroughly cleaned, disinfected and rinsed.
3. Precautions shall be taken to reduce stress. During transport, the density shall not exceed a level which is detrimental to the species.
4. Documentary evidence shall be maintained for paragraphs 1 to 3.”

- (7) In Article 35, paragraphs 2 and 3 are replaced by the following:

- "2. In case of organic plant, seaweed, livestock and aquaculture production units, storage of input products other than those authorised under this Regulation is prohibited in the production unit.
3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in Art. 14(1)(e)(ii) of Regulation (EC) No 834/2007, that they are stored in a supervised location and that they are entered in the livestock record as referred to in Article 76 of this Regulation, or as appropriate, in the aquaculture production records as referred to in Article 79b of this Regulation."

- (8) In Chapter 5 of Title II, the following Article 36a is inserted:

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*“Article 36a*

**Seaweed**

1. The conversion period for a seaweed harvesting site shall be six months.
2. The conversion period for a seaweed cultivation unit shall be the longer of six months or one full production cycle.”

(9) In Chapter 5 of Title II, the following Article 38a is inserted after Article 38:

*“Article 38a*

**Aquaculture**

1. All of an organic aquaculture production unit shall be run according to the provisions of organic production.  
  
The conversion period shall correspond to the type of facility.
2. The following conversion periods shall apply for facilities:
  - (a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;
  - (b) for facilities capable of being drained, or fallowed, a conversion period of 12 months;
  - (c) for facilities capable of being drained, cleaned and disinfected a conversion period of six months;
  - (d) for open water facilities including those farming bivalve molluscs, a three month conversion period.
3. The competent authority may decide to recognize retroactively as being part of the conversion period any previously documented period in which the facilities were not treated or exposed to products not authorized for organic production.”

(10) The heading of Article 43 is replaced by the following:

**"Use of non-organic feed of plant and animal origin for livestock";**

(11) The following Article 43a is inserted:

*“Article 43a*

**Use of non-organic feed of plant origin for aquatic animals**

Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply, the use of non-organic feed of plant origin is allowed for herbivorous aquatic

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species for a limited period where operators are unable to obtain feed exclusively from organic production under the following conditions:

- (a) the maximum percentage calculated as percentage of dry matter of feed of plant origin and authorised for a calendar year shall be 10 % during the period from 1 January 2010 to 31 December 2010 and 5% in during the period from 1 January 2011 to 31 December 2012. The maximum percentage in the daily ration shall be 25% calculated as a percentage of the dry matter;
  - (b) the operator shall keep documentary evidence of the need for using this provision.
- (12) In Title IV, the following Chapter 2a is inserted:

### **“Chapter 2a**

#### **Specific control requirements for seaweed**

##### *Article 73a*

##### **Control arrangements**

When the control system applying specifically to seaweed is first implemented, the full description of the site referred to in Article 63 (1) (a) shall include:

- (a) a full description of the installations on land and at sea;
- (b) the environmental assessment as outlined in Article 6b(3);
- (c) the sustainable management plan as outlined in Article 6b(4);
- (d) for wild seaweed a full description and a map of shore and sea collection areas and land areas where post collection activities take place shall be drawn up.

##### *Article 73b*

##### **Seaweed Production Records**

1. Seaweed production records shall be compiled in the form of a register by the operator and kept available for the control authorities or control bodies at all times at the premises of the holding. It shall provide at least the following information:
  - (a) list of species , date and quantity harvested;
  - (b) date of application, type and amount of fertiliser used.
2. For collection of wild seaweeds the register shall also contain:

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- (a) history of harvesting activity for each species in named beds;
  - (b) harvest estimate (volumes) per season;
  - (c) sources of possible pollution for harvest beds;
  - (d) sustainable annual yield for each bed.”
- (13) In Title IV, the following Chapter 3a is inserted:

**“Chapter 3a**

**Specific control requirements for aquaculture**

*Article 79a*

**Control arrangements**

When the control system applying specifically to aquaculture is first implemented, the full description of the unit referred to in Article 63 (1) (a) shall include:

- (a) a full description of the installations on land and at sea;
- (b) the environmental assessment as outlined in Article 6b (3);
- (c) the sustainable management plan as outlined in Article 6b(4);
- (d) in the case of molluscs a summary of the special chapter of the environmental assessment required by Article 25o(1).

*Article 79b*

**Aquaculture Production Records**

The following information shall be provided by the operator in the form of a register which shall be kept up to date and made available for the control authorities or control bodies at all times at the premises of the holding

- (a) the origin, date of arrival and conversion period of animals arriving at the holding;
- (b) the number of lots, the age, weight and destination of animals leaving the holding;
- (c) records of mortalities of aquaculture species and of escapes of fish;
- (d) for fish the type and quantity of feed and in the case of carp and related species documentary evidence of the need to use additional feed;

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- (e) veterinary treatments giving details of the purpose, date of application, method of application, type of product and withdrawal period;
- (f) disease prevention measures giving details of fallowing, cleaning and water treatment.

*Article 79c*

**Specific control visits for bivalve molluscs**

For bivalve mollusc production inspection visits shall take place before and during maximum biomass production.

*Article 79d*

**Several production units run by the same operator**

When an operator manages several production units as provided for in Articles 25c and 25d, the units which produce non-organic animals shall also be subject to the control system as laid down in Chapter 1 and this Chapter."

- (14) The heading of Chapter 4 of Title IV is replaced by the following:

**"Control requirements for units for preparation of plant, seaweed, livestock and aquaculture products and foodstuffs composed thereof"**

- (15) The heading of Chapter 5 of Title IV is replaced by the following:

**"Control requirements for imports of organic products from third countries"**

- (16) In paragraph 2 of Article 93, the following points are added::

- “(e) the number of organic aquaculture and seaweed units,
- (f) the volume of organic aquaculture and seaweed production.”

- (17) In Article 95, the following paragraphs are added:

- “11. When at the date of application of this Regulation for aquaculture and seaweed, the remaining batches still under production according to national rules or Member State recognised or accepted private standards, will be allowed to be placed on the market using the corresponding label. Producers will have to declare within one month the facilities, fishponds, cages or seaweed lots which are concerned to the control body or the control authority in charge of their operation.
- 12. For existing organic aquaculture units a period of three years shall be permitted to comply with the requirement of Article 25h (2) (b).
- 13. For carp and associated species in Annex XIIIa, Section 6, produced in fishponds under nationally accepted rules, provided the conditions of paragraph

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one are met, organic status can be kept for a period of three years while adapting to these rules provided there is no undue pollution of the waters with substances not allowed in organic production.

14. Single eyestalk ablation ('epedonculatation') of female Penaeid shrimp is permitted on a maximum of 75% of breeding stock until 2013. A minimum of 25% are to be spawned without ablation as part of a breeding programme."

(18) The Annexes are amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the seventh day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

*For the Commission*

[...]

*Member of the Commission*

**ANNEX**

The Annexes to Regulation (EC) No 889/2008 are amended as follows:

- (1) The heading of Annex I is replaced by the following:  
"Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2)"
- (2) Annex V is amended as follows:
  - (a) The heading is replaced by the following:  
"Feed materials referred to in Article 22(1), (2) and (3) and Article 25l(2)"
  - (b) in Section 2.2, the fourth indent is replaced by the following:  
"– Hydrolysate and proteolysates obtained by an enzyme action, whether or not in soluble form, solely provided to aquatic animals and young livestock."
- (3) Annex VI is amended as follows:
  - (a) The heading is replaced by the following:  
"Feed additives and certain substances used in animal nutrition referred to in Article 22(4) and Article 25n(2)"
  - (b) After point (b) of Section 1.1 the following point is inserted:  
"(c) colorants, including pigments  
– Astaxanthin"
  - (c) Section 1.3 is amended as follows:
    - (i) point (b) is replaced by the following:  
"(b) Antioxidant substances  
E 306– Tocopherol-rich extracts of natural origin used as an antioxidant  
– Natural antioxidant substances (use restricted to feed for aquaculture)"
    - (ii) after point (d) the following point is added:  
"(e) emulsifying and stabilising agents:  
Lecithin of organic sources (use restricted to feed for aquaculture)"
- (4) Annex VII is replaced by the following:

**"Annex VII**

Products for cleaning and disinfection

1. Products for cleaning and disinfection of buildings and installations for livestock production referred to in Article 23(4):
  - Potassium and sodium soap
  - Water and steam
  - Milk of lime
  - Lime
  - Quicklime
  - Sodium hypochlorite (e.g. as liquid bleach)
  - Caustic soda
  - Caustic potash
  - Hydrogen peroxide
  - Natural essences of plants
  - Citric, peracetic acid, formic, lactic, oxalic and acetic acid
  - Alcohol
  - Nitric acid (dairy equipment)
  - Phosphoric acid (dairy equipment)
  - Formaldehyde
  - Cleaning and disinfection products for teats and milking facilities
  - Sodium carbonate
2. Products for cleaning (including antifouling) and disinfection for aquaculture and seaweed production referred to in Articles 6e, 25t, 25u and 29a.
  - 2.1 Substances for cleaning and disinfection of equipment and facilities, in the absence of aquatic animals:
    - ozone
    - sodium chloride
    - sodium hypochlorite

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- calcium hypochlorite
- lime (CaO, calcium oxide)
- caustic soda
- alcohol
- hydrogen peroxide
- organic acids (e.g. acetic acid, lactic acid, citric acid)
- humic acid
- peroxyacetic acids
- formaldehyde
- glutaraldehyde
- quaternary ammonium compounds
- iodophores
- copper sulphate
- potassium permanganate
- peracetic and peroctanoic acids
- tea seed cake made of natural camelia seed (use restricted to shrimp production)

### 2.2 Limited list of substances for use in the presence of aquatic animals:

- ozone
- limestone (calcium carbonate) for pH control
- dolomite for pH correction (use restricted to shrimp production)

### 2.3 Limited list of substances for use in the presence of aquatic animals for parasite treatments, subject to health counselling plan

- sodium chloride
- hydrogen peroxide
- quaternary ammonium compounds
- iodophores
- copper sulphate

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- peracetic and peroctanoic acids
- formaldehyde
- glutaraldehyde"

(5) In Annex VIII, Section A, the table is amended as follows:

(a) After the 4<sup>th</sup> line the following line is inserted:

B	E 223	Sodium metabisulphite or		x	Crustaceans (2)
	E 224	Potassium metabisulphite			

(b) After the 14<sup>th</sup> line the following line is inserted:

B	E 330	Citric acid		x	Crustaceans (2)
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(6) Annex XII is replaced by the following:

**"Model of documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article 68 of this Regulation"**

Documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007	
1. Document Number:	
2. Name and address of operator: main activity (producer, processor, importer, etc):	3. Name, address and code number of control body/authority:
4. Product groups/Activity: - Plant and plant products: - Seaweed and seaweed products: - Livestock and livestock products: - Aquatic animals and aquaculture products: - Processed products:	5. defined as: organic production, in-conversion products; and also non-organic production where parallel production/processing pursuant to Article 11 of Regulation (EC) No 834/2007 occurs
6. Validity period:	7. Date of control(s):

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Plant products from .....to.....	
Plant products from .....to.....	
Livestock products from .....to.....	
Aquaculture products from .....to.....	
Processed products from.....to.....	
<p>8. This document has been issued on the basis of Article 29(1) of Regulation (EC) No 834/2007 and of Regulation (EC) No 889/2008. The declared operator has submitted his activities under control, and meets the requirements laid down in the named Regulations.</p> <p>Date, place:</p> <p>Signature on behalf of the issuing control body/authority:</p>	

"

(7) The following Annex XIIIa is inserted after Annex XIII:

"Annex XIIIa

Section 1

Organic production of salmonids in fresh water:

Brown trout (*Salmo trutta*) – Rainbow trout (*Oncorhynchus mykiss*) – American brook trout (*Salvelinus fontinalis*) – Salmon (*Salmo salar*) – Charr (*Salvelinus alpinus*)– Grayling (*Thymallus thymallus*)– American lake trout (or grey trout) (*Salvelinus namaycush*) – Huchen (*Hucho hucho*)

Minimum separation distance organic from non-organic production units growing the same species	In a river: 2,000 metres, in a lake: 1,000 metres.
Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 65% oxygen saturation for stock and must ensure their comfort and the elimination of farming effluent.
Maximum stocking density (kg fish per cubic metre of water)	Brown trout and other salmonid species not listed below 15 kg/m <sup>3</sup> Salmon [20] kg/m <sup>3</sup> Rainbow trout [25] kg/m <sup>3</sup>

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	Arctic charr [50] kg/m <sup>3</sup>
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Section 2

Organic production of salmonids in sea water:

Salmon (*Salmo salar*), Brown trout (*Salmo trutta*) – Rainbow trout (*Oncorhynchus mykiss*)

Minimum separation distance organic from non-organic production units growing the same species	2 nautical miles
Maximum stocking density (kg fish per cubic metre of water)	10 kg/m <sup>3</sup> in net pens

Section 3

Organic production of cod (*Gadus morhua*) and other Gadidae, sea bass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), meagre (*Argyrosomus regius*), turbot (*Psetta maxima* [= *Scophthalmus maximus*]), red porgy (*Pagrus pagrus* [= *Sparus pagrus*]) and other Sparidae, and spinefeet (*Siganus* spp)

Production system	In open water containment systems (net pens/cages) with minimum sea current speed to provide optimum fish welfare.
Maximum stocking density (kg fish per cubic metre of water)	Offshore: 10 kg/m <sup>3</sup> On land: [15]kg/m <sup>3</sup>  The competent authority may authorise a higher density should local conditions warrant it, such measures shall be notified to other Member States and the Commission

Section 4

Organic production of sea bass, sea bream, meagre, mullets (*Liza*, *Mugil*) and eel (*Anguilla* spp) 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 required
maximum farming density	4 kg/m <sup>3</sup>

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Section 5

Organic production of Sturgeon in fresh water

Species concerned: Acipenser family

Minimum separation distance organic from non-organic production units growing the same species	In a river 2,000 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	[20] kg/m <sup>3</sup>

Section 6

Organic production of fish in inland waters

Species concerned: Carp (*Cyprinus carpio*) and other associated species in the context of polyculture, including tench, crucian carp, perch, pike, catfish, coregonids.

Production system	<p>In fishponds which shall periodically be fully drained and in lakes. Lakes must be devoted exclusively to organic production, including the growing of crops on dry areas.</p> <p>The fishery capture area must be equipped with a clean water inlet and of a size to provide optimal comfort for the fish. The fish must be stored in clean water after harvest.</p> <p>Organic and mineral fertilisation of the ponds and lakes shall be carried out in compliance with Annex I of Regulation 889/2008 with a maximum application of [70kg] Nitrogen/ha.</p> <p>Treatments involving synthetic chemicals for the control of hydrophytes and plant coverage present in production waters are prohibited.</p> <p>Areas of natural vegetation shall be maintained around inland water units as a buffer zone for external land areas not involved in the farming operation in accordance with the rules of organic aquaculture.</p> <p>"Polyculture" shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.</p>
[Farming yield	The total production of species is limited to [500kg] of fish per hectare per year.]

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Section 7

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. Mangrove destruction is not permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a farmed shrimp.
Broodstock origin	A minimum of half the broodstock shall be domesticated after three years operating. The remainder is to be pathogen free wild broodstock originating from sustainable fisheries. A compulsory screening to be implemented on the first and second generation prior to introducing to the farm.
Eyestalk ablation	Is prohibited.
Maximum on farm stocking densities and production limits	Seeding: maximum 22 post larvae/m <sup>2</sup> Maximum instantaneous biomass (to be defined): 240 g/ m <sup>2</sup> Maximum annual production : [5] tonnes/ha

Section 8

Molluscs and echinoderms

Production systems	<p>Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets and other containment systems.</p> <p>Stocking density not in excess of two-thirds of that of non-organic shellfish in the region concerned. This parameter shall apply to the density per container and not just to reducing the density of the container/containments system.</p> <p>For mussel cultivation on rafts the number of drop-ropes shall not exceed one per cubic meter of surface area. The maximum drop-rope length shall not exceed 20 metres. Splitting of drop-ropes shall not take place during the production cycle.</p>
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