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COMMISSION REGULATION (EC) No 889/2008

of 5 September 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

(OJ L 250, 18.9.2008, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 1254/2008 of 15 December 2008	L 337	80	16.12.2008
►M2	Commission Regulation (EC) No 710/2009 of 5 August 2009	L 204	15	6.8.2009
►M3	Commission Regulation (EU) No 271/2010 of 24 March 2010	L 84	19	31.3.2010
►M4	Commission Implementing Regulation (EU) No 344/2011 of 8 April 2011	L 96	15	9.4.2011
►M5	Commission Implementing Regulation (EU) No 426/2011 of 2 May 2011	L 113	1	3.5.2011
►M6	Commission Implementing Regulation (EU) No 126/2012 of 14 February 2012	L 41	5	15.2.2012
►M7	Commission Implementing Regulation (EU) No 203/2012 of 8 March 2012	L 71	42	9.3.2012
►M8	Commission Implementing Regulation (EU) No 505/2012 of 14 June 2012	L 154	12	15.6.2012
►M9	Commission Implementing Regulation (EU) No 392/2013 of 29 April 2013	L 118	5	30.4.2013
►M10	Commission Regulation (EU) No 519/2013 of 21 February 2013	L 158	74	10.6.2013
►M11	Commission Implementing Regulation (EU) No 1030/2013 of 24 October 2013	L 283	15	25.10.2013
►M12	Commission Implementing Regulation (EU) No 1364/2013 of 17 December 2013	L 343	29	19.12.2013
►M13	Commission Implementing Regulation (EU) No 354/2014 of 8 April 2014	L 106	7	9.4.2014
►M14	Commission Implementing Regulation (EU) No 836/2014 of 31 July 2014	L 230	10	1.8.2014
►M15	Commission Implementing Regulation (EU) No 1358/2014 of 18 December 2014	L 365	97	19.12.2014
►M16	Commission Implementing Regulation (EU) 2016/673 of 29 April 2016	L 116	8	30.4.2016

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TITLE I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down specific rules on organic production, labelling and control in respect of products referred to in Article 1(2) of Regulation (EC) No 834/2007.

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2. This Regulation shall not apply to:

(a) livestock species other than those referred to in Article 7; and

(b) to aquaculture 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.

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Article 2

Definitions

In addition to the definitions laid down in Article 2 of Regulation (EC) No 834/2007, the following definitions shall apply for the purposes of this Regulation:

(a) 'non-organic': means not coming from or not related to a production in accordance to Regulation (EC) No 834/2007 and this Regulation;

(b) 'veterinary medicinal products': means products as defined in Article 1(2) of Directive 2001/82/EC of the European Parliament and of the Council [1] concerning the Community code relating to veterinary medicinal products;

(c) 'importer': means the natural or legal person within the community who presents a consignment for release for free circulation into the Community, either in person, or through a representative;

(d) 'first consignee' means the natural or legal person to whom the imported consignment is delivered and who will receive it for further preparation and/or marketing;

(e) 'holding' means all the production units operated under a single management for the purpose of producing agricultural products;

▼M2

(f) 'production unit' means all assets to be used for a production sector such as production premises, land parcels, pasturages, open air areas, livestock buildings, fish ponds, containment systems for seaweed or aquaculture animals, 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;

[1] OJ L 311, 28.11.2001, p. 1.

▼B

(g) ‘hydroponic production’ means the method of growing plants with 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;

(h) ‘veterinary treatment’ means all courses of a curative or preventive treatment against one occurrence of a specific disease;

(i) ‘in-conversion feedingstuffs’ means feedingstuffs produced during the conversion period to organic production, with the exclusion of those harvested in the 12 months following the beginning of the conversion as referred to in Article 17(1)(a) of Regulation (EC) No 834/2007;

▼M2

(j) ‘closed recirculation aquaculture facility’ means a facility where aquaculture takes place within an enclosed environment on land or on a vessel involving the recirculation of water, and depending on permanent external energy input to stabilize the environment for the aquaculture animals;

(k) ‘energy from renewable sources’ means renewable non-fossil energy sources: wind, solar, geothermal, wave, tidal, hydropower, landfill gas, sewage treatment plant gas and biogases;

(l) ‘hatchery’ means a place of breeding, hatching and rearing through the early life stages of aquaculture animals, finfish and shellfish in particular;

(m) ‘nursery’ means a place where an intermediate farming system, between the hatchery and grow-out stages is applied. The nursery stage is completed within the first third of the production cycle with the exception of species undergoing a smoltification process;

(n) ‘pollution’ in the framework of aquaculture and seaweed production means the direct or indirect introduction into the aquatic environment of substances or energy as defined in Directive 2008/56/EC of the European Parliament and of the Council ([1]) and in Directive 2000/60/EC of the European Parliament and of the Council ([2]), in the waters where they respectively apply;

(o) ‘polyculture’ in the framework of aquaculture and seaweed production, means the rearing of two or more species usually from different trophic levels in the same culture unit;

(p) ‘production cycle’ in the framework of aquaculture and seaweed production, means the lifespan of an aquaculture animal or seaweed from the earliest life stage to harvesting;

(q) ‘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 ([3]). Those species listed in Annex IV of Regulation (EC) No 708/2007 may be considered as locally grown species.

([1]) OJ L 164, 25.6.2008, p. 19.
([2]) OJ L 327, 22.12.2000, p. 1.
([3]) OJ L 168, 28.6.2007, p. 1.

▼M2

(r) ‘stocking density’ in the framework of aquaculture, means the live weight of animals per cubic metre of water at any time during the grow-out phase and in the case of flatfish and shrimp the weight per square metre of surface;

▼M9

(s) ‘control file’ means all the information and documents transmitted, for the purposes of the control system, to the competent authorities of the Member State or to control authorities and control bodies by an operator subject to the control system as referred to in Article 28 of Regulation (EC) No 834/2007, including all the relevant information and documents relating to that operator or the activities of that operator held by competent authorities, control authorities and control bodies, with the exception of information or documents that have no bearing on the operation of the control system.

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TITLE II

RULES ON PRODUCTION, PROCESSING, PACKAGING, TRANSPORT AND STORAGE OF ORGANIC PRODUCTS

CHAPTER 1

Plant Production

Article 3

Soil management and fertilisation

1. Where the nutritional needs of plants cannot be met by measures provided for in Article 12(1)(a), (b) and (c) of Regulation (EC) No 834/2007, only fertilisers and soil conditioners referred to in Annex I to this Regulation may be used in organic production and only to the extent necessary. Operators shall keep documentary evidence of the need to use the product.

2. The total amount of livestock manure, as defined in Council Directive 91/676/EEC ([1]) concerning the protection of waters against pollution caused by nitrates from agricultural sources, applied on the holding may not exceed 170 kg of nitrogen per year/hectare of agricultural area used. This limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrements, including poultry manure, composted farmyard manure and liquid animal excrements.

3. Organic-production holdings may establish written cooperation agreements exclusively with other holdings and enterprises which comply with the organic production rules, with the intention of spreading surplus manure from organic production. The maximum limit as referred to in paragraph 2, shall be calculated on the basis of all of the organic-production units involved in such cooperation.

([1]) OJ L 375, 31.12.1991, p. 1.

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4. Appropriate preparations of micro-organisms may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops.

5. For compost activation appropriate plant-based preparations or preparations of micro-organisms may be used.

Article 4

Prohibition of hydroponic production

Hydroponic production is prohibited.

Article 5

Pest, disease and weed management

1. Where plants cannot be adequately protected from pests and diseases by measures provided for in Article 12 (1)(a), (b), (c) and (g) of Regulation (EC) No 834/2007, only products referred to in Annex II to this Regulation may be used in organic production. Operators shall keep documentary evidence of the need to use the product.

2. For products used in traps and dispensers, except pheromone dispensers, the traps and/or dispensers, shall prevent the substances from being released into the environment and prevent contact between the substances and the crops being cultivated. The traps shall be collected after use and disposed off safely.

Article 6

Specific rules on mushroom production

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

(a) farmyard manure and animal excrements:

(i) either from holdings producing according to the organic production method;

(ii) or referred to in Annex I, only when the product referred to in point (i) is not available; and when they do not exceed 25 % of the weight of total components of the substrate, excluding the covering material and any added water, before composting;

(b) products of agricultural origin, other than those referred to in point (a), from holdings producing according to organic production method;

(c) peat not chemically treated;

(d) wood, not treated with chemical products after felling;

(e) mineral products referred to in Annex I, water and soil.

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CHAPTER 1a

Seaweed production

Article 6a

Scope

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

Article 6b

Suitability of aquatic medium and sustainable management plan

1. 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.

2. Organic and non-organic production units shall be separated adequately. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Member State authorities may designate locations or areas which they consider to be unsuitable for organic aquaculture or seaweed harvesting and may also set up minimum separation distances between organic and non-organic production units.

Where minimum separation distances are set Member States shall provide this information to operators, other Member States and the Commission.

3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control body or control authority. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC ([1]). 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 proportionate to the production unit 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.

([1]) OJ L 175, 5.7.1985, p. 40.

▼M2

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and re-cycle materials 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. Where possible, the use of residual heat shall be limited to energy from renewable sources.

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

Article 6c

Sustainable harvesting of wild seaweed

1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with Regulation (EC) No 834/2007.

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

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 only utilise nutrients naturally occurring in the environment, or from organic aquaculture animal 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 by ensuring that the maximum quantity of seaweed which can be supported without negative effects on the environment is not exceeded.

▼M2

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

Article 6e

Antifouling measures and cleaning of production equipment and facilities

1. 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.

2. Cleaning of equipment and facilities shall be carried out by physical or mechanical measures. Where this is not satisfactory only substances as listed in Annex VII, Section 2 may be used.

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CHAPTER 2

Livestock production

Article 7

Scope

This Chapter lays down detailed production rules for the following species: bovine including *bubalus* and bison, equidae, porcine, ovine, caprine, poultry (species as mentioned in Annex III) and bees.

Section 1

Origin of animals

Article 8

Origin of organic animals

1. In the choice of breeds or strains, account shall be taken of the capacity of animals to adapt to local conditions, their vitality and their resistance to disease. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production, such as porcine stress syndrome, PSE Syndrome (pale-soft-exudative), sudden death, spontaneous abortion and difficult births requiring caesarean operations. Preference is to be given to indigenous breeds and strains.

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

Article 9

Origin of non-organic animals

1. In accordance with Article 14(1)(a)(ii) of Regulation (EC) No 834/2007, non-organic animals may be brought onto a holding for breeding purposes, only when organic animals are not available in sufficient number and subject to the conditions provided for in paragraphs 2 to 5 of this Article.

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2. Non-organic young mammals, when a herd or flock is constituted for the first time, shall be reared in accordance with the organic production rules immediately after they are weaned. Moreover, the following restrictions shall apply at the date on which the animals enter the herd:

(a) buffalo, calves and foals shall be less than six months old;

(b) lambs and kids shall be less than 60 days old;

(c) piglets shall weigh less than 35 kg.

3. Non-organic adult male and nulliparous female mammals, for the renewal of a herd or flock, shall be reared subsequently in accordance with the organic production rules. Moreover, the number of female mammals is subject to the following restrictions per year:

(a) up to a maximum of 10 % of adult equine or bovine, including *bubalus* and bison species, livestock and 20 % of the adult porcine, ovine and caprine livestock, as female animals;

(b) for units with less than 10 equine or bovine animals, or with less than five porcine, ovine or caprine animals any renewal as mentioned above shall be limited to a maximum of one animal per year.

This provision of this paragraph will be reviewed in 2012 with a view to phase it out.

4. The percentages referred to in paragraph 3 may be increased up to 40 %, subject to prior authorisation by the competent authority, in the following special cases:

(a) when a major extension to the farm is undertaken;

(b) when a breed is changed;

(c) when a new livestock specialisation is initiated;

(d) when breeds are in danger of being lost to farming as laid down in Annex IV to Commission Regulation (EC) No 1974/2006 ([1]) and in that case animals of those breeds must not necessarily be nulliparous.

5. For the renovation of apiaries, 10 % per year of the queen bees and swarms may be replaced by non-organic queen bees and swarms in the organic production unit provided that the queen bees and swarms are placed in hives with combs or comb foundations coming from organic production units.

Section 2

Livestock housing and husbandry practices

Article 10

Rules pertaining to housing conditions

1. Insulation, heating and ventilation of the building shall ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which are not harmful to the animals. The building shall permit plentiful natural ventilation and light to enter.

([1]) OJ L 368, 23.12.2006, p. 15.

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2. Housing for livestock shall not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors.

3. The stocking density in buildings shall provide for the comfort, the well being and the species-specific needs of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The density shall ensure the animals' welfare by providing them with sufficient space to stand naturally, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.

4. The minimum surface for indoor and outdoor areas, and other characteristics of housing for different species and categories of animals, are laid down in Annex III.

Article 11

Specific housing conditions and husbandry practices for mammals

1. Livestock housing shall have smooth, but not slippery floors. At least half of the indoor surface area as specified in Annex III shall be solid, that is, not of slatted or of grid construction.

2. The housing shall be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product listed in Annex I.

3. Notwithstanding Article 3(3) of Council Directive 91/629/EEC ([1]) the housing of calves in individual boxes shall be forbidden after the age of one week.

4. Notwithstanding Article 3(8) of Council Directive 91/630/EEC ([2]) sows shall be kept in groups, except in the last stages of pregnancy and during the suckling period.

5. Piglets shall not be kept on flat decks or in piglet cages.

6. Exercise areas shall permit dunging and rooting by porcine animals. For the purposes of rooting different substrates can be used.

([1]) OJ L 340, 11.12.1991, p. 28.
([2]) OJ L 340, 11.12.1991, p. 33.

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Article 12

Specific housing conditions and husbandry practices for poultry

1. Poultry shall not be kept in cages.

2. Water fowl shall have access to a stream, pond, lake or a pool whenever the weather and hygienic conditions permit in order to respect their species-specific needs and animal welfare requirements.

3. Buildings for all poultry shall meet the following conditions:

(a) at least one third of the floor area shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;

(b) in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens shall be available for the collection of bird droppings;

(c) they shall have perches of a size and number commensurate with the size of the group and of the birds as laid down in Annex III;

(d) they shall have exit/entry pop-holes of a size adequate for the birds, and these pop-holes shall have a combined length of at least 4 m per 100 m^2 area of the house available to the birds;

(e) each poultry house shall not contain more than:

(i) 4 800 chickens,

(ii) 3 000 laying hens,

(iii) 5 200 guinea fowl,

(iv) 4 000 female Muscovy or Peking ducks or 3 200 male Muscovy or Peking ducks or other ducks,

(v) 2 500 capons, geese or turkeys;

(f) the total usable area of poultry houses for meat production on any single unit, shall not exceed 1 600 m^2;

(g) poultry houses shall be constructed in a manner allowing all birds easy access to open air area.

4. Natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours.

5. To prevent the use of intensive rearing methods, poultry shall either be reared until they reach a minimum age or else shall come from slow-growing poultry strains. Where slow-growing poultry strains are not used by the operator the following minimum age at slaughter shall be:

(a) 81 days for chickens,

(b) 150 days for capons,

(c) 49 days for Peking ducks,

(d) 70 days for female Muscovy ducks,

(e) 84 days for male Muscovy ducks,

(f) 92 days for Mallard ducks,

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(g) 94 days for guinea fowl,

(h) 140 days for male turkeys and roasting geese and

(i) 100 days for female turkeys.

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

Article 13

Specific requirements and housing conditions in beekeeping

1. The siting of the apiaries shall be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops and/or spontaneous vegetation and/or crops treated with low environmental impact methods equivalent to those as described in Article 36 of Council Regulation (EC) No 1698/2005 ([1]) or in Article 22 of Council Regulation 1257/1999 ([2]) which cannot affect the qualification of beekeeping production as being organic. The above mentioned requirements do not apply where flowering is not taking place, or the hives are dormant.

2. The Member States may designate regions or areas where beekeeping complying with organic production rules is not practicable.

3. The hives shall be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products.

4. The bees wax for new foundations shall come from organic production units.

5. Without prejudice to Article 25, only natural products such as propolis, wax and plant oils can be used in the hives.

6. The use of chemical synthetic repellents is prohibited during honey extractions operations.

7. The use of brood combs is prohibited for honey extraction.

Article 14

Access to open air areas

1. Open air areas may be partially covered.

2. In accordance with Article 14(1)(b)(iii) of Regulation (EC) No 834/2007 herbivores shall have access to pasturage for grazing whenever conditions allow.

3. In cases where herbivores have access to pasturage during the grazing period and where the winter-housing system gives freedom of movement to the animals, the obligation to provide open air areas during the winter months may be waived.

4. Notwithstanding paragraph 2, bulls over one year old shall have access to pasturage or an open air area.

([1]) OJ L 277, 21.10.2005, p. 1.
([2]) OJ L 160, 26.6.1999, p. 80.

▼B

5. Poultry shall have access to an open air area for at least one third of their life.

6. Open air areas for poultry shall be mainly covered with vegetation and be provided with protective facilities and permit fowl to have easy access to adequate numbers of drinking and feeding troughs.

7. Where poultry are kept indoors due to restrictions or obligations imposed on the basis of Community legislation, they shall permanently have access to sufficient quantities of roughage and suitable material in order to meet their ethological needs.

Article 15

Stocking density

1. The total stocking density shall be such as not to exceed the limit of 170 kg of nitrogen per year and hectare of agricultural area as referred to in Article 3(2).

2. To determine the appropriate density of livestock referred to above, the competent authority shall set out the livestock units equivalent to the above limit, taking as a guideline, the figures laid down in Annex IV or the relevant national provisions adopted pursuant to Directive 91/676/EEC.

Article 16

Prohibition of landless livestock production

Landless livestock production, by which the operator of the livestock does not manage agricultural land and/or has not established a written cooperation agreement with another operator according to Article 3(3), is prohibited.

Article 17

Simultaneous production of organic and non-organic livestock

1. Non organic livestock may be present on the holding provided they are reared on units where the buildings and parcels are separated clearly from the units producing in accordance with the organic production rules and a different species is involved.

2. Non-organic livestock may use organic pasturage for a limited period of time each year, provided that such animals come from a farming system as defined in paragraph 3(b) and that organic animals are not present at the same time on that pasture.

3. Organic animals may be grazed on common land, providing that:

(a) the land has not been treated with products not authorised for organic production for at least three years;

(b) any non-organic animals which use the land concerned are derived from a farming system equivalent to those as described in Article 36 of Regulation (EC) No 1698/2005 or in Article 22 of Regulation 1257/1999;

(c) any livestock products from organic animals, whilst using this land, shall not be regarded as being from organic-production, unless adequate segregation from non-organic animals can be proved.

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4. During the period of transhumance animals may graze on non-organic land when they are being moved on foot from one grazing area to another. The uptake of non-organic feed, in the form of grass and other vegetation on which the animals graze, during this period shall not exceed 10 % of the total feed ration per year. This figure shall be calculated as a percentage of the dry matter of feedingstuffs from agricultural origin.

5. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

Article 18

Management of animals

1. Operations such as attaching elastic bands to the tails of sheep, tail-docking, cutting of teeth, trimming of beaks and dehorning shall not be carried out routinely in organic farming. However, some of these operations may be authorised by the competent authority for reasons of safety or if they are intended to improve the health, welfare or hygiene of the livestock on a case-by-case basis.

Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out the operation only at the most appropriate age by qualified personnel.

2. Physical castration is allowed in order to maintain the quality of products and traditional production practices but only under the conditions set out in the second subparagraph of paragraph 1.

3. Mutilation such as clipping the wings of queen bees is prohibited.

4. Loading and unloading of animals shall be carried out without the use of any type of electrical stimulation to coerce the animals. The use of allopathic tranquillisers, prior to or during transport, is prohibited.

Section 3

Feed

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Article 19

Feed from own holding and other sources

1. In case of herbivores, except during the period each year when the animals are under transhumance subject to Article 17(4), at least 60 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in cooperation with other organic farms in the same region.

2. In case of pigs and poultry, at least 20 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in the same region in cooperation with other organic farms or feed business operators.

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3. In the case of bees, at the end of the production season hives shall be left with sufficient reserves of honey and pollen to survive the winter.

The feeding of bee colonies shall only be permitted where the survival of the hives is endangered due to climatic conditions. Feeding shall be with organic honey, organic sugar syrups, or organic sugar.

▼B

Article 20

Feed meeting animals' nutritional requirements

1. All young mammals shall be fed on maternal milk in preference to natural milk, for a minimum period of three months for bovines including *bubalus* and bison species and equidae, 45 days for sheep and goats and 40 days for pigs.

2. Rearing systems for herbivores are to be based on maximum use of grazing pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations of herbivores shall consist of roughage, fresh or dried fodder, or silage. A reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation is allowed.

3. Roughage, fresh or dried fodder, or silage shall be added to the daily ration for pigs and poultry.

4. The keeping of livestock in conditions, or on a diet, which may encourage anaemia, is prohibited.

5. Fattening practices shall be reversible at any stage of the rearing process. Force-feeding is forbidden.

Article 21

In-conversion feed

▼M1

1. Up to 30 % of the feed formula of rations on average may comprise in-conversion feedingstuffs. When the in-conversion feedingstuffs come from a unit of the holding itself, this percentage may be increased to 100 %.

▼M2

2. Up to 20 % of the total average amount of feedingstuffs fed to livestock may originate from the grazing or harvesting of permanent pastures, perennial forage parcels or protein crops, sown under organic management on lands in their first year of conversion, provided that they are part of the holding itself and have not been part of an organic production unit of that holding in the last five years. When both in-conversion feedingstuffs and feedingstuffs from parcels in their first year of conversion are being used, the total combined percentage of such feedingstuffs shall not exceed the maximum percentages fixed in paragraph 1.

▼B

3. The figures in paragraph 1 and 2 shall be calculated annually as a percentage of the dry matter of feedingstuffs of plant origin.

▼M8

Article 22

Use of certain products and substances in feed

For the purposes of Article 14(1)(d)(iv) of Regulation (EC) No 834/2007 only the following substances may be used in the processing of organic feed and feeding organic animals:

(a) non-organic feed materials of plant or animal origin, or other feed materials that are listed in Section 2 of Annex V, provided that:

(i) they are produced or prepared without chemical solvents; and

(ii) the restrictions laid down in Article 43 or Article 47(c) are complied with;

(b) non-organic spices, herbs, and molasses, provided that:

(i) their organic form is not available;

(ii) they are produced or prepared without chemical solvents; and

(iii) their use is limited to 1 % of the feed ration of a given species, calculated annually as a percentage of the dry matter of feed from agricultural origin;

(c) organic feed materials of animal origin;

(d) feed materials of mineral origin that are listed in Section 1 of Annex V;

(e) products from sustainable fisheries, provided that:

(i) they are produced or prepared without chemical solvents;

(ii) their use is restricted to non-herbivores; and

(iii) the use of fish protein hydrolysate is restricted solely to young animals;

(f) salt as sea salt, coarse rock salt;

(g) feed additives listed in Annex VI.

▼B

Section 4

Disease prevention and veterinary treatment

Article 23

Disease prevention

1. The use of chemically synthesised allopathic veterinary medicinal products or antibiotics for preventive treatment is prohibited, without prejudice to Article 24(3).

2. The use of substances to promote growth or production (including antibiotics, coccidiostatics and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), is prohibited.

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

▼B

4. Housing, pens, equipment and utensils shall be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Faeces, urine and uneaten or spilt feed shall be removed as often as necessary to minimise smell and to avoid attracting insects or rodents.

For the purpose of Article 14(1)(f) of Regulation (EC) No 834/2007, only products listed in Annex VII may be used for cleaning and disinfection of livestock buildings installations and utensils. Rodenticides (to be used only in traps), and the products listed in Annex II, can be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.

5. Buildings shall be emptied of livestock between each batch of poultry reared. The buildings and fittings shall be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs shall be left empty to allow vegetation to grow back. Member States shall establish the period for which runs must be empty. The operator shall keep documentary evidence of the application of this period. These requirements shall not apply where poultry is not reared in batches, is not kept in runs and is free to roam, throughout the day.

Article 24

Veterinary treatment

1. Where despite preventive measures to ensure animal health as laid down in Article 14(1)(e)(i) of Regulation (EC) No 834/2007 animals become sick or injured they shall be treated immediately, if necessary in isolation and in suitable housing.

▼M13

2. Phytotherapeutic and homeopathic products, trace elements and products listed in Section 1 of Annex V and in Section 3 of Annex VI shall be used in preference to chemically-synthesised allopathic veterinary treatment or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.

▼B

3. If the use of measures referred to in paragraph 1 and 2 is not effective in combating illness or injury, and if treatment is essential to avoid suffering or distress of the animal, chemically-synthesised allopathic veterinary medicinal products or antibiotics may be used under the responsibility of a veterinarian.

4. With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, may not be sold as organic products, and the livestock shall undergo the conversion periods laid down in Article 38(1).

Records of documented evidence of the occurrence of such circumstances shall be kept for the control body or control authority.

▼B

5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours.

Article 25

Specific rules on disease prevention and veterinary treatment in beekeeping

1. For the purposes of protecting frames, hives and combs, in particular from pests, only rodenticides (to be used only in traps), and appropriate products listed in Annex II, are permitted.

2. Physical treatments for disinfection of apiaries such as steam or direct flame are permitted.

3. The practice of destroying the male brood is permitted only to isolate the infestation of *Varroa destructor*.

4. If despite all preventive measures, the colonies become sick or infested, they shall be treated immediately and, if necessary, the colonies can be placed in isolation apiaries.

5. Veterinary medicinal products may be used in organic beekeeping in so far as the corresponding use is authorised in the Member State in accordance with the relevant Community provisions or national provisions in conformity with Community law.

6. Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with *Varroa destructor*.

7. If a treatment is applied with chemically synthesised allopathic products, during such a period, the colonies treated shall be placed in isolation apiaries and all the wax shall be replaced with wax coming from organic beekeeping. Subsequently, the conversion period of one year laid down in Article 38(3) will apply to those colonies.

8. The requirements laid down in paragraph 7 shall not apply to products listed in paragraph 6.

▼M2

CHAPTER 2a

Aquaculture animal 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.

▼M2

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

Article 25b

Suitability of aquatic medium and sustainable management plan

1. The provisions of Article 6b(1) to (5) shall apply to this Chapter.

2. Defensive and preventive measures taken against predators under Council Directive 92/43/EEC ([1]) and national rules shall be recorded in the sustainable management plan.

3. Verifiable coordination shall take place with the neighbouring operators in drawing up their management plans where applicable.

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

Article 25c

Simultaneous production of organic and non-organic aquaculture animals

1. The competent authority may permit hatcheries and nurseries to rear both organic and non-organic juveniles in the same holding provided there is clear physical separation between the units and a separate water distribution system exists.

2. In case of grow-out production, the competent authority may permit organic and non-organic aquaculture animal production units on the same holding provided Article 6b(2) of this Regulation is complied with and where different production phases and different handling periods of the aquaculture animals are involved.

3. Operators shall keep documentary evidence of the use of provisions referred to in this Article.

Section 2

Origin of aquaculture animals

Article 25d

Origin of organic aquaculture 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 and treatment shall be provided for the control body or control authority.

([1]) OJ L 206, 22.7.1992, p. 7.

▼M2

2. Species shall be chosen which can be farmed without causing significant damage to wild stocks.

Article 25e

Origin and management of non-organic aquaculture animals

1. For breeding purposes or for improving genetic stock and when organic aquaculture animals are not available, wild caught or non-organic aquaculture animals may be brought into a holding. Such animals shall be kept under organic management for at least three months before they may be used for breeding.

2. For on-growing purposes and when organic aquaculture juvenile animals are not available non-organic aquaculture juveniles 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.

▼M16

3. The maximum percentage of non-organic aquaculture juveniles introduced to the farm shall be 80 % by 31 December 2011, 50 % by 31 December 2014 and 0 % by 31 December 2016.

▼M15

4. For on-growing purposes the collection of wild aquaculture 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, provided that an approved eel management plan is in place for the location and artificial reproduction of eel remains unsolved;

(c) the collection of wild fry of species other than European eel for on-growing in traditional extensive aquaculture farming inside wetlands, such as brackish water ponds, tidal areas and costal lagoons, closed by levees and banks, provided that:

(i) the restocking is in line with management measures approved by the relevant authorities in charge of the management of the fish stocks in question to ensure the sustainable exploitation of the species concerned, and

(ii) the fish are fed exclusively with feed naturally available in the environment.

▼M2

Section 3

Aquaculture Husbandry practices

Article 25f

General aquaculture husbandry rules

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

(a) have sufficient space for their wellbeing;

▼M2

(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;

(e) in the case of carp the bottom shall be natural earth.

▼M15

2. Stocking density and husbandry practices are set out in Annex XIIIa by species or group of species. In considering the effects of stocking density and husbandry practices on the welfare of farmed 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.

▼M2

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.

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

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 25g

Specific rules for aquatic containment systems

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

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

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

(b) at least five percent of the perimeter ('land-water interface') area shall have natural vegetation.

3. 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 with regard to their exposure to the operating environment.

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

▼M2

Article 25h

Management of aquaculture animals

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

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

(a) for prolonging natural day-length it shall not exceed a maximum that respects the ethological needs, geographical conditions and general health of 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. Aeration is permitted to ensure animal welfare and health, under the condition that mechanical aerators are preferably powered by renewable energy sources.

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

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

(a) exceptional cases of temperature rise or drop in atmospheric pressure or accidental pollution,

(b) occasional stock management procedures such as sampling and sorting,

(c) in order to assure the survival of the farm stock.

Documentary evidence shall be maintained.

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

Section 4

Breeding

Article 25i

Prohibition of hormones

The use of hormones and hormone derivates is prohibited.

▼M2

Section 5

Feed for fish, crustaceans and echinodermes

Article 25j

General rules on feeds

Feeding regimes shall be designed with the following priorities:

(a) animal health;

(b) high product quality, including the nutritional composition which shall ensure high quality of the final edible product;

(c) low environmental impact.

Article 25k

Specific rules on feeds for carnivorous aquaculture animals

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

(a) organic feed products of aquaculture origin;

(b) fish meal and fish oil from organic aquaculture trimmings;

(c) fish meal and fish oil and ingredients of fish origin derived from trimmings of fish already caught for human consumption in sustainable fisheries;

▼M8

(d) organic feed materials of plant or animal origin;

▼M15

(e) feed products derived from whole fish caught in fisheries certified as sustainable under a scheme recognised by the competent authority in line with the principles laid down in Regulation (EU) No 1380/2013 of the European Parliament and of the Council ([1]).

———————

▼M2

3. The feed ration may comprise a maximum of 60 % organic plant products.

4. Astaxanthin derived primarily from organic sources, such as organic crustacean shells may be used in the feed ration for salmon and trout within the limit of their physiological needs. If organic sources are not available natural sources of astaxanthin (such as Phaffia yeast) may be used.

([1]) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22)

▼M15

5. Histidine produced through fermentation may be used in the feed ration for salmonid fish when the feed sources listed in paragraph 1 do not provide a sufficient amount of histidine to meet the dietary needs of the fish and prevent the formation of cataracts.

▼M2

Article 25l

Specific rules on feeds for certain aquaculture animals

1. Aquaculture animals as referred to in Annex XIIIa, Section 6, Section 7 and Section 9 shall be fed with feed naturally available in ponds and lakes.

2. Where natural feed resources are not available in sufficient quantities as referred to in paragraph 1, organic feed of plant origin, preferably grown on the farm itself or seaweed may be used. Operators shall keep documentary evidence of the need to use additional feed.

▼M15

3. Where natural feed is supplemented according to paragraph 2:

(a) the feed ration of siamese catfish (*Pangasius* spp.) as referred to in Section 9 of Annex XIIIa may comprise a maximum of 10 % fishmeal or fish oil derived from sustainable fisheries;

(b) the feed ration of shrimps as referred to in Section 7 of Annex XIIIa may comprise a maximum of 25 % fishmeal and 10 % fish oil derived from sustainable fisheries. In order to secure the quantitative dietary needs of shrimps, organic cholesterol may be used to supplement their diets; where organic cholesterol is not available, non-organic cholesterol derived from wool, shellfish or other sources may be used.

Article 25la

Specific rules on feeds for organic juveniles

In the larval rearing of organic juveniles, conventional phytoplankton and zooplankton may be used as feed.

▼M2

Article 25m

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

▼M8

1. Feed materials of mineral origin may be used in organic aquaculture only if listed in Section 1 of Annex V.

▼M2

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.

▼M2

Section 6

Specific rules for molluscs

Article 25n

Growing area

1. 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.

2. 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.

3. 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 25o

Sourcing of seed

1. Provided that there is no significant damage to the environment and if permitted by local legislation, wild seed from outside the boundaries of the production unit 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 seed on collectors.

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

▼M16

However, the maximum percentage of seed from non- organic bivalve shellfish hatcheries that may be introduced to the organic production units shall be 80 % by 31 December 2011, 50 % by 31 December 2014 and 0 % by 31 December 2016.

▼M2

2. For the cupped oyster, *Crassostrea gigas*, preference shall be given to stock which is selectively bred to reduce spawning in the wild.

Article 25p

Management

1. Production shall use a stocking density not in excess of that used for non-organic shellfish in the locality. Sorting, thinning and stocking density adjustments shall be made according to the biomass and to ensure animal welfare and high product quality.

▼M2

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 25q

Cultivation rules

1. Cultivation on mussel ropes and other methods listed in Annex XIIIa, Section 8 may be eligible for organic production.

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

Article 25r

Specific cultivation rules for oysters

Cultivation in bags on trestles is permitted. These or other structures in which the oysters are contained shall be set out so as to avoid the formation of a total barrier along the shoreline. Stock shall be positioned carefully on the beds in relation to tidal flow to optimise production. Production shall meet the criteria listed in the Annex XIIIa, Section 8.

Section 7

Disease prevention and veterinary treatment

Article 25s

General rules on disease prevention

1. The animal health management plan in conformity with Article 9 of Directive 2006/88/EC shall detail biosecurity and disease prevention practices including a written agreement for health counselling, proportionate to the production unit, with qualified aquaculture animal health services who shall visit the farm at a frequency of not less than once per year and not less than once every two years in the case of bivalve shellfish.

2. Holding systems, equipment and utensils shall be properly cleaned and disinfected. Only products listed in Annex VII, Sections 2.1 to 2.2 may be used.

3. With regard to fallowing:

(a) The competent authority shall determine whether fallowing is necessary and the appropriate duration which shall be applied and documented after each production cycle in open water containment systems at sea. Fallowing is also recommended for other production methods using tanks, fishponds, and cages;

▼M2

(b) it shall not be mandatory for bivalve mollusc cultivation;

(c) during fallowing the cage or other structure used for aquaculture animal production is emptied, disinfected and left empty before being used again.

4. 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, minimize disease risks, and to avoid attracting insects or rodents.

5. Ultraviolet light and ozone may be used only in hatcheries and nurseries.

▼M15

6. 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.

▼M2

Article 25t

Veterinary treatments

1. When despite preventive measures to ensure animal health, according to Article 15(1)(f)(i) of Regulation (EC) No 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 a production cycle of less than a year a limit of one allopathic treatment applies. If the mentioned limits for allopathic treatments are exceeded the concerned aquaculture animals can not be sold as organic products.

3. The use of parasite treatments, not including compulsory control schemes operated by Member States, shall be limited to twice per year or once per year where the production cycle is less than 18 months.

4. The withdrawal period for allopathic veterinary treatments and parasite treatments according to paragraph 3 including treatments under compulsory control and eradication schemes shall be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/-82/EC or in a case in which this period in not specified 48 hours.

▼M2

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.

▼B

CHAPTER 3

Processed products

Article 26

Rules for the production of processed feed and food

1. Additives, processing aids and other substances and ingredients used for processing food or feed and any processing practice applied, such as smoking, shall respect the principles of good manufacturing practice.

2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

3. The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.

4. Operators shall comply with and implement the procedures referred to in paragraph 2. In particular, operators shall:

(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products;

(b) implement suitable cleaning measures, monitor their effectiveness and record these operations;

(c) guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.

5. Further to the provisions laid down in paragraphs 2 and 4, when non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:

(a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;

(b) store organic products, before and after the operations, separate by place or time from non-organic products;

▼B

(c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;

(d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;

(e) carry out operations on organic products only after suitable cleaning of the production equipment.

Article 27

Use of certain products and substances in processing of food

1. ►M7 For the purposes of Article 19(2)(b) of Regulation (EC) No 834/2007, only the following substances can be used in the processing of organic food, with the exception of products of the wine sector, for which the provisions of Chapter 3a shall apply: ◄

(a) substances listed in Annex VIII to this Regulation;

(b) preparations of micro-organisms and enzymes normally used in food processing; ►M1 however, enzymes to be used as food additives have to be listed in Annex VIII, Section A; ◄

(c) substances, and products as defined in Articles 1(2)(b)(i) and 1(2)(c) of Council Directive 88/388/EEC ([1]) labelled as natural flavouring substances or natural flavouring preparations, according to Articles 9(1)(d) and (2) of that Directive;

(d) colours for stamping meat and eggshells in accordance with, respectively, Article 2(8) and Article 2(9) of European Parliament and Council Directive 94/36/EC ([2]);

(e) drinking water and salt (with sodium chloride or potassium chloride as basic components) generally used in food processing;

(f) minerals (trace elements included), vitamins, aminoacids, and micronutrients, only authorised as far their use is legally required in the foodstuffs in which they are incorporated.

([1]) OJ L 184, 15.7.1988, p. 61.
([2]) OJ L 237, 10.9.1994, p. 13.

▼B

2. For the purpose of the calculation referred to in Article 23(4)(a)(ii) of Regulation (EC) No 834/2007,

(a) food additives listed in Annex VIII and marked with an asterisk in the column of the additive code number, shall be calculated as ingredients of agricultural origin;

(b) preparations and substances referred to in paragraph (1)(b),(c),(d),(e) and (f) of this Article and substances not marked with an asterisk in the column of the additive code number shall not be calculated as ingredients of agricultural origin;

▼M1

(c) yeast and yeast products shall be calculated as ingredients of agricultural origin as of 31 December 2013.

▼B

3. The use of the following substances listed in Annex VIII shall be re-examined before 31 December 2010:

(a) Sodium nitrite and potassium nitrate in Section A with a view to withdrawing these additives;

(b) Sulphur dioxide and potassium metabisulphite in Section A;

(c) Hydrochloric acid in Section B for the processing of Gouda, Edam and Maasdammer cheeses, Boerenkaas, Friese, and Leidse Nagelkaas.

The re-examination referred to in point (a) shall take account of the efforts made by Member States to find safe alternatives to nitrites/nitrates and in establishing educational programmes in alternative processing methods and hygiene for organic meat processors/manufacturers.

▼M1

4. For the traditional decorative colouring of the shell of boiled eggs produced with the intention to place them on the market at a given period of the year, the competent authority may authorise for the period referred to above, the use of natural colours and natural coating substances. The authorisation may comprise synthetic forms of iron oxides and iron hydroxides until 31 December 2013. Authorisations shall be notified to the Commission and the Member States.

Article 27a

For the purpose of the application of Article 20(1) of Regulation (EC) No 834/2007, the following substances may be used in the production, confection and formulation of yeast:

(a) substances listed in Annex VIII, Section C to this Regulation;

(b) products and substances referred to in Article 27(1)(b) and (e) of this Regulation.

▼B

Article 28

Use of certain non-organic ingredients of agricultural origin in processing food

For the purpose of Article 19(2)(c) of Regulation (EC) No 834/2007, non-organic agricultural ingredients listed in Annex IX to this Regulation can be used in the processing of organic food.

Article 29

Authorisation of non-organic food ingredients of agricultural origin by Member State

1. Where an ingredient of agricultural origin is not included in Annex IX to this Regulation, that ingredient may only be used under the following conditions:

(a) the operator has notified to the competent authority of the Member State all the requisite evidence showing that the ingredient concerned is not produced in sufficient quantity in the Community in accordance with the organic production rules or cannot be imported from third countries;

(b) the competent authority of the Member State has provisionally authorised, the use for a maximum period of 12 months after having verified that the operator has undertaken the necessary contacts with suppliers in the Community to ensure himself of the unavailability of the ingredients concerned with the required quality requirements;

(c) no decision has been taken, in accordance with the provisions of paragraphs 3 or 4 that a granted authorisation with regard to the ingredient concerned shall be withdrawn.

The Member State may prolong the authorisation provided for in point (b) a maximum of three times for 12 months each.

2. Where an authorisation as referred to in paragraph 1 has been granted, the Member State shall immediately notify to the other Member States and to the Commission, the following information:

(a) the date of the authorisation and in case of a prolonged authorisation, the date of the first authorisation;

(b) the name, address, telephone, and where relevant, fax and e-mail of the holder of the authorisation; the name and address of the contact point of the authority which granted the authorisation;

(c) the name and, where necessary, the precise description and quality requirements of the ingredient of agricultural origin concerned;

(d) the type of products for the preparation of which the requested ingredient is necessary;

(e) the quantities that are required and the justification for those quantities;

(f) the reasons for, and expected period of, the shortage;

▼B

(g) the date on which the Member State sends this notification to the other Member States and the Commission. The Commission and/or Member States may make this information available to the public.

3. Where a Member State submits comments to the Commission and to the Member State which granted the authorisation, which show that supplies are available during the period of the shortage, the Member State shall consider withdrawal of the authorisation or reducing the envisaged period of validity, and shall inform the Commission and the other Member States of the measures it has taken or will take, within 15 working days from the date of receipt of the information.

4. At the request of a Member State or at the Commission's initiative, the matter shall be submitted for examination to the Committee set up in accordance with Article 37 of Regulation (EC) No 834/2007. It may be decided, in accordance with the procedure laid down in paragraph 2 of that Article, that a previously granted authorisation shall be withdrawn or its period of validity amended, or where appropriate, that the ingredient concerned shall be included in Annex IX to this Regulation.

5. In case of an extension as referred to in the second subparagraph of paragraph 1, the procedures of paragraphs 2 and 3 shall apply.

▼M2

Article 29a

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 and cleaning or disinfection substances except where a product is listed in Annex VII for this use.

▼M7

CHAPTER 3a

Specific rules for the making of wine

Article 29b

Scope

1. This Chapter lays down specific rules for the organic production of the products of the wine sector as referred to in Article 1(1)(l) of Council Regulation (EC) No 1234/2007 ([1]).

2. Commission Regulations (EC) No 606/2009 ([2]) and (EC) No 607/2009 ([3]) shall apply, save as explicitly provided otherwise in this Chapter.

([1]) OJ L 299, 16.11.2007, p. 1.
([2]) OJ L 193, 24.7.2009, p. 1.
([3]) OJ L 193, 24.7.2009, p. 60.

▼M7

Article 29c

Use of certain products and substances

1. For the purposes of Article 19(2)(a) of Regulation (EC) No 834/2007, products of the wine sector shall be produced from organic raw material.

2. For the purposes of Article 19(2)(b) of Regulation (EC) No 834/2007, only products and substances listed in Annex VIIIa to this Regulation can be used for the making of products of the wine sector, including during the processes and oenological practices, subject to the conditions and restrictions laid down in Regulation (EC) No 1234/2007 and Regulation (EC) No 606/2009 and in particular in Annex I A to that Regulation.

3. Products and substances listed in Annex VIIIa to this Regulation and marked with an asterisk, derived from organic raw material, shall be used if available.

Article 29d

Oenological practices and restrictions

1. Without prejudice to Article 29c and to specific prohibitions and restrictions provided for in paragraphs 2 to 5 of this Article, only oenological practices, processes and treatments, including the restrictions provided for in Article 120c and 120d of Regulation (EC) No 1234/2007 and in Articles 3, 5 to 9 and 11 to 14 of Regulation (EC) No 606/2009 and in their Annexes, used before 1 August 2010 are permitted.

2. The use of the following oenological practices, processes and treatments is prohibited:

(a) partial concentration through cooling according to point (c) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007;

(b) elimination of sulphur dioxide by physical processes according to point 8 of Annex I A to Regulation (EC) No 606/2009;

(c) electrodialysis treatment to ensure the tartaric stabilisation of the wine according to point 36 of Annex I A to Regulation (EC) No 606/2009;

(d) partial dealcoholisation of wine according to point 40 of Annex I A to Regulation (EC) No 606/2009;

(e) treatment with cation exchangers to ensure the tartaric stabilisation of the wine according to point 43 of Annex I A to Regulation (EC) No 606/2009.

▼M7

3. The use of the following oenological practices, processes and treatments is permitted under the following conditions:

(a) for heat treatments according to point 2 of Annex I A to Regulation (EC) No 606/2009, the temperature shall not exceed 70 °C;

(b) for centrifuging and filtration with or without an inert filtering agent according to point 3 of Annex I A to Regulation (EC) No 606/2009, the size of the pores shall be not smaller than 0,2 micrometer.

4. The use of the following oenological practices, processes and treatments shall be re-examined by the Commission before ►M16 1 August 2018 ◄ with a view to phase out or to further restrict those practices:

(a) heat treatments as referred to in point 2 of Annex I A to Regulation (EC) No 606/2009;

(b) use of ion exchange resins as referred to in point 20 of Annex I A to Regulation (EC) No 606/2009;

(c) reverse osmosis according to point (b) of Section B.1 of Annex XVa to Regulation (EC) No 1234/2007.

5. Any amendment introduced after 1 August 2010, as regards the oenological practice, processes and treatments provided for in Regulation (EC) No 1234/2007 or Regulation (EC) No 606/2009, may be applicable in the organic production of wine only after the adoption of the measures necessary for the implementation of the production rules provided for in Article 19(3) of Regulation (EC) No 834/2007 and, if required, an evaluation process according to Article 21 of that Regulation.

▼B

CHAPTER 4

Collection, packaging, transport and storage of products

Article 30

Collection of products and transport to preparation units

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

▼B

Article 31

Packaging and transport of products to other operators or units

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

(a) the name and address of the operator and, where different, of the owner or seller of the product;

(b) the name of the product or a description of the compound feedingstuff accompanied by a reference to the organic production method;

(c) the name and/or the code number of the control body or authority to which the operator is subject; and

(d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the control body or authority and which permits to link the lot with the accounts referred to in Article 66.

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

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

(a) transportation is direct between an operator and another operator who are both subject to the organic control system, and

(b) the products are accompanied by a document giving the information required under paragraph 1, and

(c) both the expediting and the receiving operators shall keep documentary records of such transport operations available for the control body or control authority of such transport operations.

Article 32

Special rules for transporting feed to other production/preparation units or storage premises

In addition to the provisions of Article 31, when transporting feed to other production or preparation units or storage premises, operators shall ensure that the following conditions are met:

(a) during transport, organically-produced feed, in-conversion feed, and non-organic feed shall be effectively physically separated;

▼B

(b) the vehicles and/or containers which have transported non-organic products are used to transport organic products provided that:

(i) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of organic products; operators shall record these operations,

(ii) all appropriate measures are implemented, depending on the risks evaluated in accordance with Article 88(3) and, where necessary, operators shall guarantee that non-organic products cannot be placed on the market with an indication referring to organic production,

(iii) the operator shall keep documentary records of such transport operations available for the control body or control authority;

(c) the transport of finished organic feed shall be separated physically or in time from the transport of other finished products;

(d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round shall be recorded.

▼M2

Article 32a

Transport of live 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 shall be thoroughly cleaned, disinfected and rinsed.

3. Precautions shall be taken to reduce stress. During transport, the density shall not reach a level which is detrimental to the species.

4. Documentary evidence shall be maintained for paragraphs 1 to 3.

▼B

Article 33

Reception of products from other units and other operators

On receipt of an organic product, the operator shall check the closing of the packaging or container where it is required and the presence of the indications provided to in Article 31.

The operator shall crosscheck the information on the label referred to in Article 31 with the information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in Article 66.

▼B

Article 34

Special rules for the reception of products from a third country

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

On receipt of an organic product, imported from a third country, the first consignee shall check the closing of the packaging or container and, in the case of products imported in accordance with Article 33 of Regulation (EC) No 834/2007, shall check that the certificate mentioned in that Article covers the type of product contained in the consignment. The result of this verification shall be explicitly mentioned in the documentary accounts referred to in Article 66 of this Regulation.

Article 35

Storage of products

1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.

▼M2

2. In case of organic plant, seaweed, livestock and aquaculture animal 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 Articles 14(1)(e)(ii) or 15(1)(f)(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.

▼B

4. In case where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:

(a) the organic products shall be kept separate from the other agricultural products and/or foodstuffs;

(b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;

▼B

(c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.

CHAPTER 5

Conversion rules

Article 36

Plant and plant products

1. For plants and plant products to be considered organic, the production rules as referred to in Articles 9, 10, 11 and 12 of Regulation (EC) No 834/2007 and Chapter 1 of this Regulation and where applicable the exceptional production rules in Chapter 6 of this Regulation must have been applied on the parcels during a conversion period of at least two years before sowing, or, in the case of grassland or perennial forage, at least two years before its use as feed from organic farming, or, in the case of perennial crops other than forage, at least three years before the first harvest of organic products.

2. The competent authority may decide to recognise retroactively as being part of the conversion period any previous period in which:

(a) the land parcels were subject of measures defined in a programme implemented pursuant to Regulations (EC) No 1257/99, (EC) No 1698/2005, or in another official programme, provided that the measures concerned ensure that products not authorised for organic production have not been used on those parcels, or

(b) the parcels were natural or agricultural areas which were not treated with products not authorised for organic production.

The period referred to in point (b) of the first subparagraph can be taken into consideration retroactively only where satisfactory proof has been furnished to the competent authority allowing it to satisfy itself that the conditions were met for a period of at least three years.

3. The competent authority may decide, in certain cases, where the land had been contaminated with products not authorised for organic production, to extend the conversion period beyond the period referred to in paragraph 1.

4. In the case of parcels which have already been converted to or were in the process of conversion to organic farming, and which are treated with a product not authorised for organic production, the Member State may shorten the conversion period referred to in paragraph 1 in the following two cases:

(a) parcels treated with a product not authorised for organic production as part of a compulsory disease or pest control measure imposed by the competent authority of the Member State;

▼B

(b) parcels treated with a product not authorised for organic production as part of scientific tests approved by the competent authority of the Member State.

In the cases provided for in points (a) and (b) of the first subparagraph, the length of the conversion period shall be fixed taking into account of the following factors:

(a) the process of degradation of the product concerned shall guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant;

(b) the harvest following the treatment may not be sold with reference to organic production methods.

The Member State concerned shall inform the other Member States and the Commission of its decision to require compulsory measures.

▼M2

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.

▼B

Article 37

Specific conversion rules for land associated with organic livestock production

1. The conversion rules as referred to in Article 36 of this Regulation shall apply to the whole area of the production unit on which animal feed is produced.

2. Notwithstanding the provisions in paragraph 1, the conversion period may be reduced to one year for pasturages and open air areas used by non-herbivore species. This period may be reduced to six months where the land concerned has not during the last year, received treatments with products not authorised for organic production.

▼B

Article 38

Livestock and livestock products

1. Where non-organic livestock has been brought onto a holding in accordance with Article 14(1)(a)(ii) of Regulation (EC) No 834/2007 and Article 9 and/or Article 42 of this Regulation and if livestock products are to be sold as organic products, the production rules as referred to in Articles 9, 10, 11 and 14 of Regulation (EC) No 834/2007 and in Chapter 2 of Title II and where applicable in Article 42 of this Regulation must have been applied for at least:

(a) 12 months in the case of equidae and bovines, including *bubalus* and bison species, for meat production, and in any case at least three quarters of their lifetime;

(b) six months in the case of small ruminants and pigs and animals for milk production;

(c) 10 weeks for poultry for meat production, brought in before they are three days old;

(d) six weeks in the case of poultry for egg production.

2. Where non-organic animals exist on a holding at the beginning of the conversion period in accordance with Article 14(1)(a)(iii) of Regulation (EC) No 834/2007 their products may be deemed organic if there is simultaneous conversion of the complete production unit, including livestock, pasturage and/or any land used for animal feed. The total combined conversion period for both existing animals and their offspring, pasturage and/or any land used for animal feed, may be reduced to 24 months, if the animals are mainly fed with products from the production unit.

3. Beekeeping products can be sold with references to the organic production method only when the organic production rules have been complied with for at least one year.

4. The conversion period for apiaries does not apply in the case of application of Article 9(5) of this Regulation.

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

▼M2

Article 38a

Aquaculture animal production

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

(a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;

(b) for facilities that have been drained, or fallowed, a conversion period of 12 months;

▼M2

(c) for facilities that have been 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.

2. 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.

▼B

CHAPTER 6

Exceptional production rules

Section 1

Exceptional production rules related to climatic, geographical or structural constraints in accordance with Article 22(2)(a) of Regulation (EC) No 834/2007

Article 39

Tethering of animals

Where the conditions laid down in Article 22(2)(a) of Regulation (EC) No 834/2007 apply, competent authorities may authorise cattle in small holdings to be tethered if it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have access to pastures during the grazing period according to Article 14(2), and at least twice a week access to open air areas when grazing is not possible.

Article 40

Parallel production

1. Where the conditions laid down in Article 22(2)(a) of Regulation (EC) No 834/2007 apply, a producer may run organic and non-organic production units in the same area:

(a) in the case of the production of perennial crops, which require a cultivation period of at least three years, where varieties cannot be easily differentiated, provided the following conditions are met:

(i) the production in question forms part of a conversion plan in respect of which the producer gives a firm undertaking and which provides for the beginning of the conversion of the last part of the area concerned to organic production in the shortest possible period which may not in any event exceed a maximum of five years;

▼B

(ii) appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned;

(iii) the control authority or control body is notified of the harvest of each of the products concerned at least 48 hours in advance;

(iv) upon completion of the harvest, the producer informs the control authority or control body of the exact quantities harvested on the units concerned and of the measures applied to separate the products;

(v) the conversion plan and the control measures referred to in Chapter 1 and 2 of Title IV have been approved by the competent authority; this approval shall be confirmed each year after the start of the conversion plan;

(b) in the case of areas intended for agricultural research or formal education agreed by the Member States' competent authorities and provided the conditions set out in point (a)(ii)(iii)(iv) and the relevant part of point (v) are met;

(c) in the case of production of seed, vegetative propagating material and transplants and provided the conditions set out in point (a)(ii)(iii)(iv) and the relevant part of point (v) are met;

(d) in the case of grassland exclusively used for grazing.

2. The competent authority may authorise holdings carrying out agricultural research or formal education to rear organic and non-organic livestock of the same species, where the following conditions are met:

(a) appropriate measures, notified in advance to the control authority or control body, have been taken in order to guarantee the permanent separation between livestock, livestock products, manure and feedingstuffs of each of the units;

(b) the producer informs the control authority or control body in advance of any delivery or selling of the livestock or livestock products;

(c) the operator informs the control authority or control body of the exact quantities produced in the units together with all characteristics permitting the identification of the products and confirms that the measures taken to separate the products have been applied.

Article 41

Management of beekeeping units for the purpose of pollination

Where the conditions laid down in Article 22(2)(a) of Regulation (EC) No 834/2007 apply, for the purpose of pollination actions an operator may run organic and non-organic beekeeping units on the same holding, provided that all the requirements of the organic production rules are fulfilled, with the exception of the provisions for the siting of the apiaries. In that case the product cannot be sold as organic.

▼B

The operator shall keep documentary evidence of the use of this provision.

Section 2

Exceptional production rules related to non-availability of organic farm inputs in accordance with Article 22(2)(b) of Regulation (EC) No 834/2007

Article 42

Use of non-organic animals

Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply, and with prior authorisation of the competent authority,

(a) when a flock is constituted for the first time, renewed or reconstituted and organically reared poultry are not available in sufficient numbers, non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old;

(b) non-organically reared pullets for egg production of not more than 18 weeks may be brought into an organic livestock unit until ►M14 31 December 2017 ◄, when organically reared pullets are not available and provided that the relevant provisions laid down in Section 3 and 4 of Chapter 2 are complied with.

▼M8

Article 43

Use of non-organic protein feed of plant and animal origin for livestock

Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply and where farmers are unable to obtain protein feed exclusively from organic production, the use of a limited proportion of non-organic protein feed is allowed for porcine and poultry species.

▼M14

The maximum percentage of non-organic protein feed authorised per period of 12 months for those species shall be 5 % for calendar years 2015, 2016 and 2017.

▼M8

The figures shall be calculated annually as a percentage of the dry matter of feed from agricultural origin.

The operator shall keep documentary evidence of the need for the use of this provision.

▼B

Article 44

Use of non-organic beeswax

In the case of new installations or during the conversion period, non-organic beeswax may be used only

(a) where beeswax from organic beekeeping is not available on the market;

(b) where it is proven free of contamination by substances not authorised for organic production; and

(c) provided that it comes from the cap.

Article 45

Use of seed or vegetative propagating material not obtained by the organic production method

1. Where the conditions laid down in Article 22(2)(b) of Regulation (EC) No 834/2007 apply,

(a) seed and vegetative propagating material from a production unit in conversion to organic farming may be used,

(b) where point (a) is not applicable, Member States may authorise the use of non-organic seed or vegetative propagating material if not available from organic production. However, for the use of non-organic seed and seed potatoes the following paragraphs (2) to (9) apply.

2. Non-organic seed and seed potatoes may be used, provided that the seed or seed potatoes are not treated with plant protection products, other than those authorised for treatment of seed in accordance with Article 5(1), unless chemical treatment is prescribed in accordance with Council Directive 2000/29/EC ([1]) for phytosanitary purposes by the competent authority of the Member State for all varieties of a given species in the area where the seed or seed potatoes are to be used.

3. Species for which it is established that organically produced seed or seed potatoes are available in sufficient quantities and for a significant number of varieties in all parts of the Community are set out in Annex X.

The species listed in Annex X may not be subject of authorisations pursuant to paragraph 1(b), unless these are justified by one of the purposes referred to in paragraph 5(d).

4. Member States may delegate the responsibility for granting the authorisation referred to in paragraph 1(b) to another public administration under their supervision or to the control authorities or control bodies referred to in Article 27 of Regulation (EC) No 834/2007.

([1]) OJ L 169, 10.7.2000, p. 1.

▼B

5. Authorisation to use seed or seed potatoes not obtained by the organic production method may only be granted in the following cases:

(a) where no variety of the species which the user wants to obtain is registered in the database referred to in Article 48;

(b) where no supplier, meaning an operator who markets seed or seed potatoes to other operators, is able to deliver the seed or seed potatoes before sowing or planting in situations where the user has ordered the seed or seed potatoes in reasonable time;

(c) where the variety which the user wants to obtain is not registered in the database referred to in Article 48, and the user is able to demonstrate that none of the registered alternatives of the same species are appropriate and that the authorisation therefore is significant for his production;

(d) where it is justified for use in research, test in small-scale field trials or for variety conservation purposes agreed by the competent authority of the Member State.

6. The authorisation shall be granted before the sowing of the crop.

7. The authorisation shall be granted only to individual users for one season at a time and the authority or body responsible for the authorisations shall register the quantities of seed or seed potatoes authorised.

8. By way of derogation from paragraph 7, the competent authority of the Member State may grant to all users a general authorisation:

(a) for a given species when and in so far as the condition laid down in paragraph 5(a) is fulfilled;

(b) for a given variety when and in so far as the conditions laid down in paragraph 5(c) are fulfilled.

The authorisations referred to in the first subparagraph shall be clearly indicated in the database referred to in Article 48.

9. Authorisation may only be granted during periods for which the database is updated in accordance with Article 49(3).

Section 3

Exceptional production rules related to specific management problems in organic livestock in accordance with Article 22(2)(d) of Regulation (EC) No 834/2007

Article 46

Specific management problems in organic livestock

The final fattening phase of adult bovines for meat production may take place indoors, provided that this indoors period does not exceed one fifth of their lifetime and in any case for a maximum period of three months.

▼M1

Section 3a

Exceptional production rules with regard to the use of specific products and substances in the processing in accordance with Article 22(2)(e) of Regulation (EC) No 834/2007

Article 46a

Addition of non-organic yeast extract

Where the conditions laid down in Article 22(2)(e) of Regulation (EC) No 834/2007 apply, the addition of up to 5 % non-organic yeast extract or autolysate to the substrate (calculated in dry matter) is allowed for the production of organic yeast, where operators are unable to obtain yeast extract or autolysate from organic production.

The availability of organic yeast extract or autolysate shall be re-examined by 31 December 2013 with a view to withdrawing this provision.

▼B

Section 4

Exceptional production rules related to catastrophic circumstances in accordance with Article 22(2)(f) of Regulation (EC) No 834/2007

Article 47

Catastrophic circumstances

The competent authority may authorise on a temporary basis:

▼M16

(a) in the case of high mortality of animals caused by health or catastrophic circumstances, the renewal or reconstitution of the herd or flock with non-organic animals, when organically reared animals are not available and provided that the respective conversion period are applied to the non-organic animals;

▼B

(b) in case of high mortality of bees caused by health or catastrophic circumstances, the reconstitution of the apiaries with non-organic bees, when organic apiaries are not available;

(c) the use of non-organic feedingstuffs for a limited period and in relation to a specific area by individual operators, when forage production is lost or when restrictions are imposed, in particular as a result of exceptional meteorological conditions, the outbreak of infectious diseases, the contamination with toxic substances, or as a consequence of fires;

(d) the feeding of bees with organic honey, organic sugar or organic sugar syrup in case of long lasting exceptional weather conditions or catastrophic circumstances, which hamper the nectar or honeydew production;

▼M7

(e) the use of sulphur dioxide up to the maximum content to be fixed in accordance with the Annex I B to Regulation (EC) No 606/2009 if the exceptional climatic conditions of a given harvest year deteriorate the sanitary status of organic grapes in a specific geographical area because of severe bacterial attacks or fungal attacks, which oblige the winemaker to use more sulphur dioxide than in previous years to obtain a comparable final product;

▼M16

(f) in the case of high mortality of aquaculture animals caused by circumstances listed in Article 57(1)(a) to (d) of Regulation (EU) No 508/2014 of the European Parliament and of the Council [1], the renewal or reconstitution of the aquaculture stock with non-organic aquaculture animals, when organically reared animals are not available and provided that at least the latter two thirds of the duration of the production cycle are managed under organic management.

▼M7

Upon approval by the competent authority, the individual operators shall keep documentary evidence of the use of the above exceptions. Member States shall inform each other and the Commission on the exceptions they have granted under points (c) and (e) of the first paragraph.

▼B

CHAPTER 7

Seed data base

Article 48

Database

1. Each Member State shall ensure that a computerised database is established for the listing of the varieties for which seed or seed potatoes obtained by the organic production method are available on its territory.

2. The database shall be managed either by the competent authority of the Member State or by an authority or body designated for this purpose by the Member State, hereinafter referred to as ‘manager of the database’. Member States may also designate an authority or a private body in another country.

3. Each Member State shall inform the Commission and the other Member States of the authority or private body designated to manage the database.

Article 49

Registration

1. Varieties for which seed or seed potatoes produced by the organic production method are available shall be registered in the database referred to in Article 48 at the request of the supplier.

[1] Regulation (EU) No 508/2014 of the European Parliament and of the Council of 15 May 2014 on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council (OJ L 149, 20.5.2014, p. 1).

▼B

2. Any variety which has not been registered in the database shall be considered as unavailable with regard to Article 45(5).

3. Each Member State shall decide in which period of the year the database has to be regularly updated for each species or group of species cultivated on its territory. The database shall hold information with regard to that decision.

Article 50

Conditions for registration

1. For registration, the supplier shall:

(a) demonstrate that he or the last operator, in cases where the supplier is only dealing with pre-packaged seed or seed potatoes, has been subject to the control system referred to in Article 27 of Regulation (EC) No 834/2007;

(b) demonstrate that the seed or seed potatoes to be placed on the market comply with the general requirements applicable to seed and seed potatoes;

(c) make available all the information required under Article 51 of this Regulation, and undertake to update this information at the request of the manager of the database or whenever such updating is necessary to ensure that the information remains reliable.

2. The manager of the database may, with the approval by the competent authority of the Member State, refuse a supplier's application for registration or delete a previously accepted registration if the supplier does not comply with the requirements set out in paragraph 1.

Article 51

Registered information

1. For each registered variety and for each supplier, the database referred to in Article 48 shall contain at least the following information:

(a) the scientific name of the species and the variety denomination;

(b) the name and contact details of the supplier or his representative;

(c) the area where the supplier can deliver the seed or seed potatoes to the user in the usual time needed for the delivery;

(d) the country or region in which the variety is tested and approved for the purpose of the common catalogues of varieties of agricultural plant species and vegetable species as defined in Council Directives 2002/53/EC on the common catalogue of varieties of agricultural plant species ([1]) and 2002/55/EC on the marketing of vegetable seed ([2]);

(e) the date from which the seed or seed potatoes will be available;

(f) the name and/or code number of the control authority or control body in charge of the control of the operator as referred to in Article 27 of Regulation (EC) No 834/2007.

([1]) OJ L 193, 20.7.2002, p. 1.
([2]) OJ L 193, 20.7.2002, p. 33.

▼B

2. The supplier shall immediately inform the manager of the database if any of the registered varieties are no longer available. The amendments shall be recorded in the database.

3. Besides the information specified in paragraph 1, the database shall contain a list of the species listed in Annex X.

Article 52

Access to information

1. The information in the database referred to in Article 48 shall be available through the Internet, free of cost, to the users of seed or seed potatoes and to the public. Member States may decide that any user who has notified its activity in accordance with Article 28(1)(a) of Regulation (EC) No 834/2007 may obtain, on request, an extract of data concerning one or several groups of species from the database manager.

2. The Member States shall ensure that all users referred to in paragraph 1 are informed, at least once a year, about the system and how to obtain the information in the database.

Article 53

Registration fee

Each registration may be subject to the levying of a fee, which shall represent the cost of inserting and maintaining the information in the database referred to in Article 48. The competent authority of the Member State shall approve the amount of the fee charged by the manager of the database.

Article 54

Annual report

1. The authorities or bodies designated to grant authorisations in accordance with Article 45 shall register all authorisations, and shall make this information available in a report to the competent authority of the Member State and to the manager of the database.

The report shall contain, for each species concerned by an authorisation according to Article 45(5), the following information:

(a) the scientific name of the species and the variety denomination;

(b) the justification for the authorisation indicated by a reference to Article 45(5)(a), (b), (c) or (d);

(c) the total number of authorisations;

(d) the total quantity of seed or seed potatoes involved;

(e) the chemical treatment for phytosanitary purposes, as referred to in Article 45(2).

2. For authorisations according to Article 45(8) the report shall contain the information referred to in point (a) of the second subparagraph of paragraph 1 of this Article and the period for which the authorisations were in force.

▼B

Article 55

Summary report

The competent authority of the Member State shall, before 31 March each year, collect the reports and send a summary report covering all authorisations of the Member State from the previous calendar year to the Commission and to the other Member States. The report shall cover the information specified in Article 54. The information shall be published in the database referred to in Article 48. The competent authority may delegate the task of collecting the reports to the manager of the database.

Article 56

Information upon request

Upon request from a Member State or the Commission, detailed information on authorisations granted in individual cases shall be made available to other Member States or to the Commission.

TITLE III

LABELLING

CHAPTER 1

▼M3

Organic production logo of the European Union

Article 57

Organic logo of the EU

In accordance with Article 25(3) of Regulation (EC) No 834/2007, the organic production logo of the European Union (hereinafter 'Organic logo of the EU') shall follow the model set out in Part A of Annex XI to this Regulation.

▼M4

For the purpose of labelling, the organic logo of the EU shall only be used if the product concerned is produced in accordance with the requirements of Regulation (EC) No 834/2007, of Commission Regulation (EC) No 1235/2008 ([1]) and of this Regulation, by operators who comply with the requirements of the control system referred to in Articles 27, 28, 29, 32 and 33 of Regulation (EC) No 834/2007.

▼B

Article 58

Conditions for the use of the code number and place of origin

1. The indication of the code number of the control authority or control body referred to in Article 24(1)(a) of Regulation (EC) 834/2007 shall,

(a) start with the acronym identifying the Member State or the third country, as referred to in the international standard for the two letter country codes under ISO 3166 (*Codes for the representation of names of countries and their subdivisions*);

([1]) OJ L 334, 12.12.2008, p. 25.

▼M3

(b) include a term which establishes a link with the organic production method, as referred to in Article 23(1) of Regulation (EC) No 834/2007 in accordance with Part B(2) of Annex XI to this Regulation;

(c) include a reference number to be decided by the Commission or by the competent authority of the Member States in accordance with Part B(3) of Annex XI to this Regulation; and

(d) be placed in the same visual field as the Organic logo of the EU, where the Organic logo of the EU is used in the labelling.

▼B

2. The indication of the place where the agricultural raw materials of which the products is composed have been farmed, as referred to in Article 24(1)(c) of Regulation (EC) 834/2007, shall be placed immediately below the code number referred to in paragraph 1.

CHAPTER 2

Specific labelling requirements for feed

▼M8

Article 59

Scope, use of trade marks and sales descriptions

This Chapter shall not apply to pet food and feed for fur animals.

The trade marks and sales descriptions bearing an indication referred to in Article 23(1) of Regulation (EC) No 834/2007 may be used only if all ingredients of plant or animal origin are from the organic production method and at least 95 % of the product's dry matter is comprised of such ingredients.

Article 60

Indications on processed feed

1. The terms referred to in Article 23(1) of Regulation (EC) No 834/2007 and the Organic logo of the EU may be used on processed feed provided that all the following requirements are complied with:

(a) the processed feed complies with the provisions of Regulation (EC) No 834/2007 and in particular with Article 14(1)(d)(iv) and (v) for livestock or with Article 15(1)(d) for aquaculture animals and Article 18 thereof;

(b) the processed feed complies with the provisions of this Regulation and in particular with Articles 22 and 26 thereof;

(c) all ingredients of plant or animal origin contained in the processed feed are from the organic production method;

(d) at least 95 % of the product's dry matter is comprised of organic agricultural products.

▼M8

2. Subject to the requirements laid down in points (a) and (b) of paragraph 1, the following statement is permitted in the case of products comprising variable quantities of feed materials from the organic production method and/or feed materials from products in conversion to organic farming and/or products as referred to in Article 22 of this Regulation:

'may be used in organic production in accordance with Regulations (EC) No 834/2007 and (EC) No 889/2008'.

▼B

Article 61

Conditions for the use of indications on processed feed

1. The indication provided for in Article 60 shall be:

(a) separate from the wording referred to in Article 5 of Council Directive 79/373/EEC ([1]) or in Article 5(1) of Council Directive 96/25/EC ([2]);

(b) presented in a colour, format or character font that does not draw more attention to it than to the description or name of the animal feedingstuff referred to in Article 5(1)(a) of Directive 79/373/EEC or in Article 5(1)(b) of Directive 96/25/EC respectively;

(c) accompanied, in the same field of vision, by an indication by weight of dry matter referring:

(i) to the percentage of feed material(s) from the organic production method;

(ii) to the percentage of feed material(s) from products in conversion to organic farming;

(iii) to the percentage of feed material(s) not covered by points (i) and (ii);

(iv) to the total percentage of animal feed of agricultural origin;

(d) accompanied by a list of names of feed materials from the organic production method;

(e) accompanied by a list of names of feed materials from products in conversion to organic production.

2. The indication provided for in Article 60 may be also accompanied by a reference to the requirement to use the feedingstuffs in accordance with Articles 21 and 22.

([1]) OJ L 86, 6.4.1979, p. 30.
([2]) OJ L 125, 23.5.1996, p. 35.

▼B

CHAPTER 3

Other specific labelling requirements

Article 62

In-conversion products of plant origin

In-conversion products of plant origin may bear the indication 'product under conversion to organic farming' provided that:

(a) a conversion period of at least 12 months before the harvest has been complied with;

(b) the indication shall appear in a colour, size and style of lettering which is not more prominent than the sales description of the product, the entire indication shall have the same size of letters;

(c) the product contains only one crop ingredient of agricultural origin;

(d) the indication is linked to the code number of the control body or control authority as referred to in Article 27(10) of Regulation 834/2007.

TITLE IV

CONTROLS

CHAPTER 1

Minimum control requirements

Article 63

Control arrangements and undertaking by the operator

1. When the control arrangements are first implemented, the operator shall draw up and subsequently maintain:

(a) a full description of the unit and/or premises and/or activity;

(b) all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules;

(c) the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised products or substances and the cleaning measures to be taken in storage places and throughout the operator's production chain;

▼M6

(d) the specific characteristics of the production method used, where the operator intends to request documentary evidence in accordance with Article 68(2).

▼B

Where appropriate, the description and measures provided for in the first subparagraph may be part of a quality system as set up by the operator.

▼B

2. The description and the measures referred to in paragraph 1 shall be contained in a declaration, signed by the responsible operator. In addition, this declaration shall include an undertaking by the operator:

(a) to perform the operations in accordance with the organic production rules;

(b) to accept, in the event of infringement or irregularities, the enforcement of the measures of the organic production rules;

(c) to undertake to inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production;

▼M9

(d) to accept, in cases where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies in accordance with the control system set up by Member State concerned, the exchange of information between those authorities or bodies;

(e) to accept, in cases where the operator and/or the subcontractors of that operator change their control authority or control body, the transmission of their control files to the subsequent control authority or control body;

(f) to accept, in cases where the operator withdraws from the control system, to inform without delay the relevant competent authority and control authority or control body;

(g) to accept, in cases where the operator withdraws from the control system, that the control file is kept for a period of at least five years;

(h) to accept to inform the relevant control authority or authorities or control body or bodies without delay of any irregularity or infringement affecting the organic status of their product or organic products received from other operators or subcontractors.

▼B

The declaration provided for in the first subparagraph shall be verified by the control body or control authority that issues a report identifying the possible deficiencies and non-compliances with the organic production rules. The operator shall countersign this report and take the necessary corrective measures.

3. For the application of Article 28(1) of Regulation (EC) No 834/2007 the operator shall notify the following information to the competent authority:

(a) Name and address of operator;

(b) Location of premises and, where appropriate, parcels (land register data) where operations are carried out;

(c) Nature of operations and products;

(d) Undertaking by the operator to carry out the operation in accordance with the provision laid down in Regulation (EC) No 834/2007 and this Regulation;

(e) In the case of an agricultural holding, the date on which the producer ceased to apply products not authorised for organic production on the parcels concerned;

(f) The name of the approved body to which the operator entrusted control of his undertaking, where the Member State has implemented the control system by approving such bodies.

▼B

Article 64

Modification of control arrangements

The operator responsible shall notify any change in the description or of the measures referred to in Article 63 and in the initial control arrangements set out in Articles 70, 74, 80, 82, 86 and 88 to the control authority or control body in due time.

Article 65

Control visits

1. The control authority or control body shall carry out at least once a year a physical inspection of all operators.

▼M9

2. The control authority or control body shall take and analyse samples for detecting of products not authorised for organic production, for checking production techniques not in conformity with the organic production rules or for detecting possible contamination by products not authorised for organic production. The number of samples to be taken and analysed by the control authority or control body every year shall correspond to at least 5 % of the number of operators under its control. The selection of the operators where samples have to be taken shall be based on the general evaluation of the risk of non-compliance with the organic production rules. This general evaluation shall take into account all stages of production, preparation and distribution.

The control authority or control body shall take and analyse samples in each case where the use of products or techniques not authorised for organic production is suspected. In such cases no minimum number of samples to be taken and analysed shall apply.

Samples may also be taken and analysed by the control authority or control body in any other case for detecting of products not authorised for organic production, for checking production techniques not in conformity with the organic production rules or for detecting possible contamination by products not authorised for organic production.

▼B

3. A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.

4. Moreover, the control authority or control body shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

Article 66

Documentary accounts

1. Stock and financial records shall be kept in the unit or premises and shall enable the operator to identify and the control authority or control body to verify:

(a) the supplier and, where different, the seller, or the exporter of the products;

▼B

(b) the nature and the quantities of organic products delivered to the unit and, where relevant, of all materials bought and the use of such materials, and, where relevant, the composition of the compound feedingstuffs;

(c) the nature and the quantities of organic products held in storage at the premises;

(d) the nature, the quantities and the consignees and, where different, the buyers, other than the final consumers, of any products which have left the unit or the first consignee's premises or storage facilities;

(e) in case of operators who do not store or physically handle such organic products, the nature and the quantities of organic products bought and sold, and the suppliers, and where different, the sellers or the exporters and the buyers, and where different, the consignees.

2. The documentary accounts shall also comprise the results of the verification at reception of organic products and any other information required by the control authority or control body for the purpose of proper control. The data in the accounts shall be documented with appropriate justification documents. The accounts shall demonstrate the balance between the input and the output.

3. Where an operator runs several production units in the same area, the units for non organic products, together with storage premises for input products must also be subject to the minimum control requirements.

Article 67

Access to facilities

1. The operator shall:

(a) give the control authority or control body, for control purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents;

(b) provide the control authority or control body with any information reasonably necessary for the purposes of the control;

(c) submit, when requested by the control authority or control body, the results of its own quality assurance programmes.

2. In addition to the requirements set out in paragraph 1, importers and first consignees shall submit the information on imported consignments referred to in Article 84.

▼M6

Article 68

Documentary evidence

1. For the purpose of the application of Article 29(1) of Regulation (EC) No 834/2007 the control authorities and control bodies shall use the model of the documentary evidence set out in Annex XII to this Regulation.

▼M9

In case of electronic certification as referred to in Article 29(3) of Regulation (EC) No 834/2007, the signature in box 8 of the documentary evidence shall not be required if the authenticity of the documentary evidence is otherwise shown by a tamper-proof electronic method.

▼M6

2. If an operator subject to the controls of the control authorities and control bodies as referred to in paragraph 1 so requests within a time period to be indicated by those control authorities and control bodies, the control authorities and control bodies shall provide complementary documentary evidence confirming the specific characteristics of the production method used by means of the model set out in Annex XIIa.

Applications for complementary documentary evidence shall contain in box 2 of the model set out in Annex XIIa the relevant entry listed in Annex XIIb.

▼B

Article 69

Vendor declaration

For the purpose of the application of Article 9(3) of Regulation (EC) No 834/2007 the vendor declaration that products supplied have not been produced from or by GMOs may follow the model set out in Annex XIII to this Regulation.

CHAPTER 2

Specific control requirements for plants and plant products from farm production or collection

Article 70

Control arrangements

1. The full description of the unit referred to in Article 63(1)(a) shall:

(a) be drawn up even where the operator limits his activity to the collection of wild plants;

(b) indicate the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place; and

(c) specify the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with the organic production rules.

2. In case of collection of wild plants, the practical measures referred to in Article 63(1)(b) shall include any guarantees given by third parties which the operator can provide to ensure that the provisions of Article 12(2) of Regulation (EC) No 834/2007 are complied with.

Article 71

Communications

Each year, before the date indicated by the control authority or control body, the operator shall notify the control authority or control body of its schedule of production of crop products, giving a breakdown by parcel.

▼B

Article 72

Plant production records

Plant production records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. In addition to Article 71 such records shall provide at least the following information:

(a) as regards the use of fertiliser: date of application, type and amount of fertiliser, parcels concerned;

(b) as regards the use of plant protection products: reason and date of treatment, type of product, method of treatment;

(c) as regards purchase of farm inputs: date, type and amount of purchased product;

(d) as regards harvest: date, type and amount of organic or in conversion crop production.

Article 73

Several production units run by the same operator

Where an operator runs several production units in the same area, the units producing non-organic crops, together with storage premises for farm input products shall also be subject to the general and the specific control requirements laid down in Chapter 1 and this Chapter of this Title.

▼M2

CHAPTER 2a

Specific control requirements for seaweed

Article 73a

Control arrangements for seaweed

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) where applicable;

(c) the sustainable management plan as outlined in Article 6b(4) where applicable;

(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;

▼M2

(b) date of application, type and amount of fertiliser used.

2. For collection of wild seaweeds the register shall also contain:

(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.

▼B

CHAPTER 3

Control requirements for livestock and livestock products produced by animal husbandry

Article 74

Control arrangements

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

(a) a full description of the livestock buildings, pasturage, open air areas, etc., and, where applicable, the premises for the storage, packaging and processing of livestock, livestock products, raw materials and inputs;

(b) a full description of the installations for the storage of livestock manure.

2. The practical measures referred to in Article 63(1)(b) shall include:

(a) a plan for spreading manure agreed with the control body or authority, together with a full description of the areas given over to crop production;

(b) where appropriate, as regards the spreading of manure, the written arrangements with other holdings as referred to in Article 3(3) complying with the provisions of the organic production rules;

(c) a management plan for the organic-production livestock unit.

Article 75

Identification of livestock

The livestock shall be identified permanently using techniques adapted to each species, individually in the case of large mammals and individually or by batch in the case of poultry and small mammals.

▼B

Article 76

Livestock records

Livestock records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. Such records shall provide a full description of the herd or flock management system comprising at least the following information:

(a) as regards animals arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record;

(b) as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination;

(c) details of any animals lost and reasons thereof;

(d) as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply;

(e) as regards disease prevention and treatment and veterinary care: date of treatment, details of the diagnosis, the posology; type of treatment product, the indication of the active pharmacological substances involved method of treatment and veterinary prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed labelled as organic.

Article 77

Control measures on veterinary medicinal products for livestock

Whenever veterinary medicinal products are used the information according to Article 76(e) is to be declared to the control authority or body before the livestock or livestock products are marketed as organically produced. Livestock treated shall be clearly identified, individually in the case of large animals; individually, or by batch, or by hive, in the case of poultry, small animals and bees.

Article 78

Specific control measures on beekeeping

1. A map on an appropriate scale listing the location of hives shall be provided to the control authority or control body by the beekeeper. Where no areas are identified in accordance with Article 13(2), the beekeeper shall provide the control authority or control body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation.

2. The following information shall be entered in the register of the apiary with regard to the use of feeding: type of product, dates, quantities and hives where it is used.

▼B

3. Whenever veterinary medicinal products are to be used, the type of product, including the indication of the active pharmacological substance, together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period shall be recorded clearly and declared to the control body or authority before the products are marketed as organically produced.

4. The zone where the apiary is situated shall be registered together with the identification of the hives. The control body or authority shall be informed of the moving of apiaries by a deadline agreed on with the control authority or body.

5. Particular care shall be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measures to comply with this requirement shall be recorded.

6. The removals of the supers and the honey extraction operations shall be entered in the register of the apiary.

Article 79

Several production units run by the same operator

Where an operator manages several production units, as provided for in Articles 17(1), 40 and 41, the units which produce non-organic livestock or non-organic livestock products shall also be subject to the control system as laid down in Chapter 1 and this Chapter of this Title.

▼M2

CHAPTER 3a

Specific control requirements for aquaculture animal production

Article 79a

Control arrangements for aquaculture animal production

When the control system applying specifically to aquaculture animal production 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) where applicable;

(c) the sustainable management plan as outlined in Article 6b(4) where applicable;

(d) in the case of molluscs a summary of the special chapter of the sustainable management plan as required by Article 25q(2).

Article 79b

Aquaculture animal 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

▼M2

(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 escapes of fish;

(d) for fish the type and quantity of feed and in the case of carp and related species a documentary record of the use additional feed;

(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, the units which produce non-organic aquaculture animals shall also be subject to the control system as laid down in Chapter 1and this Chapter.

▼B

CHAPTER 4

►M2 Control requirements for units for preparation of plant, seaweed, livestock and aquaculture animal products and foodstuffs composed thereof ◄

Article 80

Control arrangements

In the case of a unit involved in the preparation for its own account or for account of a third party, and including in particular units involved in packaging and/or re-packaging of such products or units involved in labelling and/or re-labelling of such products, the full description of the unit referred to in Article 63(1)(a) shall show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.

▼B

CHAPTER 5

►M2 *Control requirements for imports of organic products from third countries* ◄

Article 81

Scope

This Chapter applies to any operator involved, as importer and/or as first consignee, in the import and/or reception, for its own account or for account of another operator, of organic products.

Article 82

Control arrangements

1. In the case of the importer, the full description of the unit referred to in Article 63(1)(a) shall include the importer's premises and of his import activities, indicating the points of entry of the products into the Community and any other facilities the importer intends to use for the storage of the imported products pending their delivery to the first consignee.

In addition, the declaration referred to in Article 63(2) shall include an undertaking by the importer to ensure that any facilities that the importer will use for storage of products are submitted to control, to be carried out either by the control body or control authority or, when these storage facilities are situated in another Member State or region, by a control body or authority approved for control in that Member State or region.

2. In the case of the first consignee, the full description of the unit referred to in Article 63(1)(a) shall show the facilities used for the reception and storage.

3. Where the importer and the first consignee are the same legal person and operate in one single unit, the reports referred to in the second subparagraph of Article 63(2) may be formalised within one single report.

Article 83

Documentary accounts

The importer and the first consignee shall keep separate stock and financial records, unless where they are operating in one single unit.

On request of the control authority or control body, any details on the transport arrangements from the exporter in the third country to the first consignee and, from the first consignee's premises or storage facilities to the consignees within the Community shall be provided.

Article 84

Information on imported consignments

The importer shall, in due time, inform the control body or control authority of each consignment to be imported into the Community, providing:

(a) the name and address of the first consignee;

▼B

(b) any details the control body or authority may reasonably require,

(i) in case of products imported in accordance with Article 32 of Regulation (EC) No 834/2007, the documentary evidence referred to in that Article;

(ii) in case of products imported in accordance with Article 33 of Regulation (EC) No 834/2007, a copy of the certificate of inspection referred to in that Article.

On the request of the control body or control authority of the importer, the latter shall forward the information referred to in the first paragraph to the control body or control authority of the first consignee.

Article 85

Control visits

The control authority or control body shall check the documentary accounts referred to in Article 83 of this Regulation and the certificate referred to in Article 33(1)(d) of Regulation (EC) No 834/2007 or the documentary evidence referred to in Article 32(1)(c) of the latter Regulation.

Where the importer performs the import operations by different units or premises, he shall make available on request the reports referred to in the second subparagraph of Article 63(2) of this Regulation for each of these facilities.

CHAPTER 6

Control requirements for units involved in the production, preparation or import of organic products and which have contracted out to third parties in part or in total the actual operations concerned

Article 86

Control arrangements

With regard to the operations, which are contracted out to third parties, the full description of the unit referred to in Article 63(1)(a) shall include:

(a) a list of the subcontractors with a description of their activities and an indication of the control bodies or authorities to which they are subject;

(b) written agreement by the subcontractors that their holding will be subject to the control regime of Title V of Regulation (EC) No 834/2007;

(c) all the practical measures, including inter alia an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to, as appropriate, their suppliers, sellers, consignees and buyers.

▼B

CHAPTER 7

Control requirements for units preparing feed

Article 87

Scope

This Chapter applies to any unit involved in the preparation of products referred to in Article 1(2)(c) of Regulation (EC) No 834/2007 on its own account or on behalf of a third party.

Article 88

Control arrangements

1. The full description of the unit referred to in Article 63(1)(a) shall indicate:

(a) the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them;

(b) the facilities used for the storage of other products used to prepare feedingstuffs;

(c) the facilities used to store products for cleaning and disinfection;

(d) where necessary, the description of the compound feedingstuff that the operator intends to produce, in accordance with Article 5(1)(a) of Directive 79/373/EEC, and the livestock species or class for which the compound feedingstuff is intended;

(e) where necessary, the name of the feed materials that the operator intends to prepare.

2. The measures to be taken by operators, as referred to in Article 63(1)(b), to guarantee compliance with the organic production rules shall include the indications of measures referred to in Article 26.

3. The control authority or control body shall use these measures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up a control plan. This control plan shall provide for a minimum number of random samples depending on the potential risks.

Article 89

Documentary accounts

For the purposes of proper control of the operations, the documentary accounts referred to in Article 66 shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.

Article 90

Control visits

The control visit referred to in Article 65 shall comprise a full physical inspection of all premises. Moreover, the control authority or control body shall make targeted visits based on a general evaluation of the potential risks of non-compliance with the organic production rules.

▼B

The control body or authority shall pay particular attention to the critical control points pointed out for the operator, with a view to establishing whether the surveillance and checking operations are carried out correctly.

All the premises used by the operator for the conduct of his activities may be checked as frequently as the attendant risks warrant.

CHAPTER 8

Infringements and exchange of information

Article 91

Measures in case of suspicion of infringements and irregularities

1. Where an operator considers or suspects that a product which he has produced, prepared, imported or that he has received from another operator, is not in compliance with organic production rules, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He may only put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the control body or authority. The control authority or control body may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

2. Where a control authority or control body has a substantiated suspicion that an operator intends to place on the market a product not in compliance with the organic production rules but bearing a reference to the organic production method, this control authority or control body can require that the operator may provisionally not market the product with this reference for a time period to be set by that control authority or control body. Before taking such a decision, the control authority or control body shall allow the operator to comment. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the control authority or control body is sure that the product does not fulfil the requirements of organic production.

However, if the suspicion is not confirmed within the said time period, the decision referred to in the first subparagraph shall be cancelled not later than the expiry of that time period. The operator shall cooperate fully with the control body or authority in resolving the suspicion.

3. Member States shall take whatever measures and sanctions are required to prevent fraudulent use of the indications referred to in Title IV of Regulation (EC) No 834/2007 and Title III and/or Annex XI of this Regulation.

▼M9

Article 92

Exchange of information between control authorities, control bodies and competent authorities

1. Where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies, the control authorities or control bodies shall exchange the relevant information on the operations under their control.

2. Where operators and/or their subcontractors change their control authority or control body, the change shall be notified without delay to the competent authority by the control authorities or control bodies concerned.

The previous control authority or control body shall hand over the relevant elements of the control file of the operator concerned and the reports referred to in the second subparagraph of Article 63(2) to the subsequent control authority or control body.

The new control authority or control body shall ensure that non-conformities noted in the report of the previous control authority or control body have been or are being addressed by the operator.

3. Where the operator withdraws from the control system, the control authority or control body of that operator shall, without delay, inform the competent authority.

4. Where a control authority or control body finds irregularities or infringements affecting the organic status of products, it shall without delay inform the competent authority of the Member State which designated or approved it in accordance with Article 27 of Regulation (EC) No 834/2007.

That competent authority may require, on its own initiative, also any other information on irregularities or infringements.

In case of irregularities or infringements found with regard to products under the control of other control authorities or control bodies, it shall also inform those authorities or bodies without delay.

5. Member States shall take the appropriate measures and establish documented procedures to enable exchange of information between all control authorities they have designated and/or all control bodies they have approved in accordance with Article 27 of Regulation (EC) No 834/2007, including procedures for the exchange of information for the purpose of verifying documentary evidence referred to in Article 29(1) of that Regulation.

6. Member States shall take the appropriate measures and establish documented procedures in order to ensure that information on the results of inspections and visits as referred to in Article 65 of this Regulation is communicated to the paying agency in accordance with the needs of that paying agency as provided for in Article 33(1) of Commission Regulation (EU) No 65/2011 ([1]).

([1]) OJ L 25, 28.1.2011, p. 8.

▼M9

Article 92a

Exchange of information between different Member States and the Commission

1. Where a Member State finds irregularities or infringements relating to the application of this Regulation with regard to a product coming from another Member State and bearing indications as referred to in Title IV of Regulation (EC) No 834/2007 and in Title III and/or Annex XI to this Regulation, it shall notify the Member State which designated the control authority or approved the control body, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.

2. Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 33(2) or (3) of Regulation (EC) No 834/2007 with the requirements laid down in that Regulation or Regulation (EC) No 1235/2008, it shall notify the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.

3. Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 19 of Regulation (EC) No 1235/2008 with the requirements laid down in that Regulation and Regulation (EC) No 834/2007, it shall notify the Member State which issued the authorisation, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation. The notification shall be sent to the other Member States and to the Commission in case the irregularity or infringement is found with regard to products for which the Member State itself issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008.

4. The Member State which receives a notification relating to non-compliant products in accordance with paragraph 1 or 3 or the Member State which issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008 for a product for which an irregularity or infringement was found, shall investigate the origin of the irregularities or infringements. It shall take appropriate action immediately.

It shall inform the Member State which sent the notification, the other Member States and the Commission of the result of the investigation and of the action taken by replying to the original notification via the system referred to in Article 94(1). The reply shall be sent within 30 calendar days from the date of the original notification.

5. The Member State which sent the original notification may ask the replying Member State for additional information, if needed. In any case, after receiving a reply or additional information from a notified Member State, the Member State which sent the original notification shall make the necessary entries and updates in the system referred to in Article 94(1).

▼M9

Article 92b

Publication of information

Member States shall make available to the public, in an appropriate manner including publication on the internet, the updated lists referred to in Article 28(5) of Regulation (EC) No 834/2007 containing updated documentary evidence related to each operator, as provided for in Article 29(1) of that Regulation and using the model set out in Annex XII to this Regulation. The Member States shall duly observe the requirements of the protection of personal data as laid down in Directive 95/46/EC of the European Parliament and of the Council ([1]).

CHAPTER 9

Supervision by competent authorities

Article 92c

Supervisory activities relating to control bodies

1. The supervisory activities by competent authorities delegating control tasks to control bodies in accordance with Article 27(4)(b) of Regulation (EC) No 834/2007 shall focus on the evaluation of the operational performance of those control bodies, taking into account the results of the work of the national accreditation body as referred to in Article 2(11) of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([2]).

Those supervisory activities shall include an assessment of the internal procedures of the control bodies for the controls, the management and examination of control files in the light of the obligations established by Regulation (EC) No 834/2007 and the verification of handling of non-conformities and the handling of appeals and complaints.

2. The competent authorities shall require control bodies to submit documentation on their risk analysis procedure.

The risk analysis procedure shall be designed in such a way that:

(a) the result of the risk analysis provides the basis for determining the intensity of the unannounced or announced annual inspections and visits;

(b) additional random control visits carried out in accordance with Article 65(4) of at least 10 % of operators under contract in accordance with the risk category are performed;

(c) at least 10 % of all inspections and visits carried out in accordance with Article 65(1) and (4) are unannounced;

(d) the selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk.

([1]) OJ L 281, 23.11.1995, p. 31.
([2]) OJ L 218, 13.8.2008, p. 30.

▼M9

3. Competent authorities delegating control tasks to control bodies shall verify that the staff of the control bodies has sufficient knowledge, including knowledge of the risk elements affecting the organic status of products, qualifications, training and experience with respect to organic production in general and with the relevant Union rules in particular and that appropriate rules on rotation of inspectors are in force.

4. Competent authorities shall have documented procedures for the delegation of tasks to control bodies in accordance with Article 27(5) of Regulation (EC) No 834/2007 and for the supervision in accordance with this Article, detailing the information to be submitted by control bodies.

Article 92d

Catalogue of measures in case of irregularities and infringements

Competent authorities shall adopt and communicate to control bodies that have been delegated control tasks, a catalogue at least listing infringements and irregularities affecting the organic status of products and corresponding measures to be applied by control bodies in case of infringements or irregularities by operators under their control who are involved in organic production.

Competent authorities may include other relevant information in the catalogue on their own initiative.

Article 92e

Annual inspection of control bodies

Competent authorities shall organise an annual inspection of the control bodies that have been delegated control tasks in accordance with Article 27(4)(b) of Regulation (EC) No 834/2007. For the purposes of the annual inspection, the competent authority shall take into account the results of the work of the national accreditation body as referred to in Article 2(11) of Regulation (EC) No 765/2008. During the annual inspection, the competent authority shall, in particular, verify:

(a) the compliance with the control body's standard control procedure as submitted by the control body to the competent authority in accordance with Article 27(6)(a) of Regulation (EC) No 834/2007;

(b) that the control body has a sufficient number of suitable qualified and experienced staff in accordance with Article 27(5)(b) of Regulation (EC) No 834/2007 and that training concerning risks affecting the organic status of products has been implemented;

(c) that the control body has and follows documented procedures and templates for:

(i) the annual risk analysis in accordance with Article 27(3) of Regulation (EC) No 834/2007;

(ii) preparing a risk-based sampling strategy, conducting sampling and laboratory analysis;

▼M9

(iii) information exchange with other control bodies and with the competent authority;

(iv) initial and follow-up controls of operators under their control;

(v) the application and follow-up to the catalogue of measures to be applied in case of infringements or irregularities;

(vi) observing the requirements of the protection of personal data for the operators under its control as laid down by the Member States where that competent authority operates and in accordance with Directive 95/46/EC.

Article 92f

Organic data in the multi-annual national control plan and annual report

Member States shall ensure that their multi-annual national control plans referred to in Article 41 of Regulation (EC) No 882/2004 cover the supervision of controls performed on the organic production in accordance with this Regulation and to include the specific data on that supervision, hereinafter referred to as 'the organic data', in the annual report referred to in Article 44 of Regulation (EC) No 882/2004. The organic data shall cover the topics listed in Annex XIIIb to this Regulation.

The organic data shall be based on information on the controls performed by the control bodies and/or control authorities and on audits performed by the competent authority.

The data shall be presented according to the templates provided for in Annex XIIIc to this Regulation as from 2015 for the year 2014.

Member States may insert the organic data as an organic chapter of their national control plan and their annual report.

▼B

TITLE V

TRANSMISSION OF INFORMATION TO THE COMMISSION, TRANSITIONAL AND FINAL PROVISIONS

CHAPTER 1

Transmission of information to the Commission

Article 93

Statistical information

1. Member States shall provide the Commission with the annual statistical information on organic production referred to in Article 36 of Regulation (EC) No 834/2007 by using the computer system enabling electronic exchanges of documents and information made available by the Commission (Eurostat) before 1 July each year.

▼B

2. The statistical information referred to in paragraph 1 shall comprise, in particular the following data:

(a) the number of organic producers, processors, importers and exporters;

(b) the organic crop production and crop area under conversion and under organic production;

(c) the organic livestock numbers and the organic animal products;

(d) the data on organic industrial production by type of activities;

▼M2

(e) the number of organic aquaculture animal production units;

(f) the volume of organic aquaculture animal production;

(g) optionally, the number of organic seaweed units and the volume of organic seaweed production.

▼B

3. For the transmission of the statistical information referred to in paragraphs 1 and 2, Member States shall use the Single Entry point provided by the Commission (Eurostat).

4. The provisions relating to the characteristics of statistical data and metadata shall be defined within the context of the Community Statistical Programme on the basis of models or questionnaires made available via the system referred to in paragraph 1.

Article 94

Other information

1. Member States shall provide the Commission with the following information by using the computer system enabling electronic exchanges of documents and information made available by the Commission (DG Agriculture and rural development) for information other than statistical information:

(a) before 1 January 2009, the information referred to in Article 35(a) of Regulation (EC) No 834/2007 and afterwards each modification when that appears;

(b) by 31 March each year, the information referred to in Article 35(b) of Regulation (EC) No 834/2007, as regards control authorities and bodies approved on 31 December of the previous year;

(c) before 1 July each year, all other information required or needed in accordance with this Regulation;

▼M7

(d) within one month from their approval, the exceptions granted by the Member States under points (c) and (e) of the first paragraph of Article 47.

▼B

2. The data shall be communicated, entered and updated in the system referred to in paragraph 1 under the responsibility of the competent authority as referred to in Article 35 of Regulation (EC) No 834/2007, by the authority itself or by the body to which that function has been delegated.

▼B

3. The provisions relating to the characteristics of data and metadata shall be defined on the basis of models or questionnaires made available via the system referred to in paragraph 1.

CHAPTER 2

Transitional and final provisions

Article 95

Transitional measures

1. For a transitional period expiring on 31 December 2010, cattle may be tethered in buildings already existing before 24 August 2000, provided that regular exercise is provided and rearing takes place in line with animal welfare requirements with comfortably littered areas as well as individual management and provided that the competent authority has authorised this measure. The competent authority may continue authorising this measure upon request of individual operators for its application in a limited period ending before the 31 December 2013, under the additional condition that the controls visits referred to in Article 65(1) are carried out at least twice a year.

2. The competent authority may authorise, for a transitional period expiring on 31 December 2010, the exceptions concerning housing conditions and stocking density granted to livestock producing holdings on the basis of the derogation provided for in part B, paragraph 8.5.1 of Annex I to Regulation (EEC) No 2092/91. The operators benefiting from this extension shall present a plan to the control authority or control body, containing the description of arrangements which are intended to ensure compliance with the provisions of the organic production rules by the end of the transitional period. The competent authority may continue authorising this measure upon request of individual operators for its application in a limited period ending before the 31 December 2013, under the additional condition that the controls visits referred to in Article 65(1) are carried out at least twice a year.

3. For a transition period expiring 31 December 2010 the final fattening phase of sheep and pigs for meat production as laid down under point 8.3.4 of Annex I.B of Regulation (EEC) No 2092/91 may take place indoors under the condition that the controls visits referred to in Article 65(1) are carried out at least twice a year.

4. The castration of piglets may be carried out without the application of anaesthesia and/or analgesia during a transition period expiring on 31 December 2011.

5. Pending the inclusion of detailed processing rules for pet food, national rules or in the absence thereof, private standards accepted or recognised by the Member States shall apply.

▼M2

6. For the purpose of Article 12(1)(j) of Regulation (EC) No 834/2007 and pending the inclusion of specific substances according to Article 16(1)(f) of that Regulation, only products authorised by the competent authority may be used.

▼B

7. Authorisations of non-organic ingredients of agricultural origin granted by Member States under Regulation (EEC) No 207/93 may be deemed granted as under this Regulation. However, authorisations granted in accordance with Article 3(6) of the former Regulation shall expire on 31 December 2009.

8. For a transitional period expiring on the 1 July 2010, the operators may continue to use in the labelling the provisions as laid down in Regulation (EEC) No 2092/91 for:

(i) the system for calculation the percentage of organic ingredients of food;

(ii) the code number and/or the name of the control body or control authority.

▼M3

9. Stocks of products produced, packaged and labelled before 1 July 2010 in accordance with either Regulation (EEC) No 2092/91 or Regulation (EC) No 834/2007 may continue to be brought on the market bearing terms referring to organic production until stocks are exhausted.

10. Packaging material in accordance with either Regulation (EEC) No 2092/91 or Regulation (EC) No 834/2007 may continue to be used for products placed on the market bearing terms referring to organic production until 1 July 2012, where the product otherwise complies with the requirements of Regulation (EC) No 834/2007.

▼M7

10a. As regards products of the wine sector, the transitional period referred to in paragraph 8 shall expire on 31 July 2012.

Stocks of wines produced until 31 July 2012 in accordance with either Regulation (EEC) No 2092/91 or Regulation (EC) No 834/2007 may continue to be brought on the market until stocks are exhausted, and subject to the following labelling requirements:

(a) the Community organic production logo as referred to in Article 25(1) of Regulation (EC) No 834/2007, called from 1 July 2010 the ‘Organic logo of the EU’ may be used provided that the wine-making process complies with Chapter 3a of Title II of this Regulation;

(b) operators using ‘Organic logo of the EU’ shall keep recorded evidence, for a period of at least five years after they placed on the market that wine obtained from organic grapes, including of the corresponding quantities of wine in litres, per wine category and per year;

(c) where the evidence referred to in point (b) of this paragraph is not available, such wine may be labelled as ‘wine made from organic grapes’, provided that it complies with the requirements of this Regulation except those provided for in Chapter 3a of Title II thereof;

(d) wine labelled as ‘wine made from organic grapes’ cannot bear the ‘Organic logo of the EU’.

▼**M2**

11. The competent authority may authorise for a period expiring on ►**M11** 1 January 2015 ◄, those aquaculture animal and seaweed production units which are established and produce under nationally accepted organic rules before entry into force of this Regulation, to keep their organic status while adapting to the rules of this Regulation, provided there is no undue pollution of the waters with substances not allowed in organic production. Operators benefiting from this measure shall notify the facilities, fishponds, cages or seaweed lots which are concerned to the competent authority.

▼**B**

Article 96

Repeal

Regulations (EEC) No 207/93, (EC) No 223/2003 and (EC) No 1452/2003 are repealed.

References to the repealed Regulations and to Regulation (EEC) No 2092/91 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XIV.

Article 97

Entry into force and application

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

It shall apply as from 1 January 2009.

However, paragraph 2(a) of Article 27 and Article 58 shall apply as of 1 July 2010.

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

▼B

ANNEX I

▼M2

Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2)

▼B

Note:

A: authorised under Regulation (EEC) No 2092/91 and carried over by Article 16(3)(c) of Regulation (EC) No 834/2007

B: authorised under Regulation (EC) No 834/2007

▼M2

Authorisation	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
A	Farmyard manure	Products comprising a mixture of animal excrements and vegetable matter (animal bedding) Factory farming origin forbidden
A	Dried farmyard manure and dehydrated poultry manure	Factory farming origin forbidden
A	Composted animal excrements, including poultry manure and composted farmyard manure included	Factory farming origin forbidden
A	Liquid animal excrements	Use after controlled fermentation and/or appropriate dilution Factory farming origin forbidden
B	Composted or fermented mixture of household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production Only vegetable and animal household waste Only when produced in a closed and monitored collection system, accepted by the Member State Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable
A	Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
A	Mushroom culture wastes	The initial composition of the substrate shall be limited to products of this Annex
A	Dejecta of worms (vermicompost) and insects	
A	Guano	

▼B

Authorisation	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
A	Composted or fermented mixture of vegetable matter	Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
▼M13 B	Biogas digestate containing animal by-products co-digested with material of plant or animal origin as listed in this Annex	Animal by-products (including by-products of wild animals) of category 3 and digestive tract content of category 2 (categories 2 and 3 as defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council) [2] must not be from factory farming origin. The Processes have to be in accordance with Commission Regulation (EU) No 142/2011 [3]. Not to be applied to edible parts of the crop
B	Products or by-products of animal origin as below: Blood meal Hoof meal Horn meal Bone meal or degelatinised bone meal Fish meal Meat meal Feather, hair and ‘chiquette’ meal Wool Fur (1) Hair Dairy products Hydrolysed proteins (2)	(1) Maximum concentration in mg/kg of dry matter of chromium (VI): not detectable (2) Not to be applied to edible parts of the crop
▼B A	Products and by-products of plant origin for fertilisers	Examples: oilseed cake meal, cocoa husks, malt culms
A	Seaweeds and seaweed products	As far as directly obtained by: (i) physical processes including dehydration, freezing and grinding (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation
A	Sawdust and wood chips	Wood not chemically treated after felling
A	Composted bark	Wood not chemically treated after felling
A	Wood ash	From wood not chemically treated after felling

▼B

Authorisation	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
A	Soft ground rock phosphate	Product as specified in point 7 of Annex IA.2. to Regulation (EC) No 2003/2003 of the European Parliament and of the Council ([1]) relating to fertilisers, 7 Cadmium content less than or equal to 90 mg/kg of $P_2 0_5$
A	Aluminium-calcium phosphate	Product as specified in point 6 of Annex IA.2. of Regulation 2003/2003, Cadmium content less than or equal to 90 mg/kg of $P_2 0_5$ Use limited to basic soils (pH > 7,5)
A	Basic slag	Products as specified in point 1 of Annex IA.2. of Regulation 2003/2003
A	Crude potassium salt or kainit	Products as specified in point 1 of Annex IA.3. of Regulation 2003/2003
A	Potassium sulphate, possibly containing magnesium salt	Product obtained from crude potassium salt by a physical extraction process, containing possibly also magnesium salts
A	Stillage and stillage extract	Ammonium stillage excluded
A	Calcium carbonate (chalk, marl, ground limestone, Breton ameliorant, (maerl), phosphate chalk)	Only of natural origin
A	Magnesium and calcium carbonate	Only of natural origin e.g. magnesian chalk, ground magnesium, limestone
A	Magnesium sulphate (kieserite)	Only of natural origin
A	Calcium chloride solution	Foliar treatment of apple trees, after identification of deficit of calcium
A	Calcium sulphate (gypsum)	Products as specified in point 1 of Annex ID. of Regulation 2003/2003 Only of natural origin
A	Industrial lime from sugar production	By-product of sugar production from sugar beet
A	Industrial lime from vacuum salt production	By-product of the vacuum salt production from brine found in mountains
A	Elemental sulphur	Products as specified in Annex ID.3 of Regulation 2003/2003
A	Trace elements	Inorganic micronutrients listed in part E of Annex I to Regulation 2003/2003

▼B

Authorisation	Name Compound products or products containing only materials listed hereunder	Description, compositional requirements, conditions for use
A	Sodium chloride	Only mined salt
A	Stone meal and clays	
▼M13 B	Leonardite (Raw organic sediment rich in humic acids)	Only if obtained as a by-product of mining activities
B	Chitin (Polysaccharide obtained from the shell of crustaceans)	Only if obtained from sustainable fisheries, as defined in Article 3(e) of Council Regulation (EC) No 2371/2002 ([4]) or organic aquaculture
B	Organic rich sediment from fresh water bodies formed under exclusion of oxygen (e.g. sapropel)	Only organic sediments that are by-products of fresh water body management or extracted from former freshwater areas When applicable, extraction should be done in a way to cause minimal impact on the aquatic system Only sediments derived from sources free from contaminations of pesticides, persistent organic pollutants and petrol like substances Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): not detectable

▼B

([1]) OJ L 304, 21.11.2003, p. 1.

►M13 ([2]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

([3]) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1). ◄

►M13 ([4]) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy (OJ L 358, 31.12.2012, p. 59). ◄

▼M16

ANNEX II

Pesticides — Products referred to in Article 5(1)

All the substances listed in this Annex have to comply at least with the conditions for use as specified in the Annex to Commission Implementing Regulation (EU) No 540/2011 [1]. More restrictive conditions for use for organic production are specified in the second column of each table.

1. **Substances of plant or animal origin**

Name	Description, compositional requirement, conditions for use
Azadirachtin extracted from *Azadirachta indica* (Neem tree)	
Basic substances	Only those basic substances within the meaning of Article 23(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council [1] that are covered by the definition of 'foodstuff' in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [2] and have plant or animal origin. Substances not to be used as herbicides, but only for the control of pests and diseases.
Beeswax	Only as pruning agent/wound protectant.
Hydrolysed proteins excluding gelatine	
Laminarin	Kelp shall be either grown organically in accordance with Article 6d or harvested in a sustainable way in accordance with Article 6c.
Pheromones	Only in traps and dispensers.
Plant oils	All uses authorised, except herbicide.
Pyrethrins extracted from *Chrysanthemum cinerariaefolium*	
Pyrethroids (only deltamethrin or lambdacyhalothrin)	Only in traps with specific attractants; only against *Bactrocera oleae* and *Ceratitis capitata* Wied.
Quassia extracted from *Quassia amara*	Only as insecticide, repellent.
Repellents by smell of animal or plant origin/sheep fat	Only on non-edible parts of the crop and where crop material is not ingested by sheep or goats.

([1]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).
([2]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([1]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

▼M16

2. **Micro-organisms or substances produced by micro-organisms**

Name	Description, compositional requirement, conditions for use
Micro-organisms	Not from GMO origin.
Spinosad	

3. **Substances other than those mentioned in Sections 1 and 2**

Name	Description, compositional requirement, conditions or restrictions to use
Aluminium silicate (Kaolin)	
Calcium hydroxide	When used as fungicide, only in fruit trees, including nurseries, to control *Nectria galligena*.
Carbon dioxide	
Copper compounds in the form of: copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture, and tribasic copper sulphate	Up to 6 kg copper per ha per year. For perennial crops, by way of derogation from the first paragraph, Member States may provide that the 6 kg copper limit can be exceeded in a given year provided that the average quantity actually used over a 5-year period consisting of that year and of the 4 preceding years does not exceed 6 kg.
Ethylene	
Fatty acids	All uses authorised, except herbicide.
Ferric phosphate (iron (III) orthophosphate)	Preparations to be surface-spread between cultivated plants.
Kieselgur (diatomaceous earth)	
Lime sulphur (calcium polysulphide)	
Paraffin oil	
Potassium hydrogen carbonate (aka potassium bicarbonate)	
Quartz sand	
Sulphur	

▼B

ANNEX III

Minimum surface areas indoors and outdoors and other characteristics of housing in the different species and types of production referred to in Article 10(4)

1. **Bovines, equidae, ovine, caprine and porcine**

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M^2/head	M^2/head
Breeding and fattening bovine and equidae	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3
	over 350	5 with a minimum of 1 m^2/100 kg	3,7 with a minimum of 0,75 m^2/100 kg
Dairy cows		6	4,5
Bulls for breeding		10	30
Sheep and goats		1,5 sheep/goat	2,5
		0,35 lamb/kid	0,5
Farrowing sows with piglets up to 40 days		7,5 sow	2,5
Fattening pigs	up to 50	0,8	0,6
	up to 85	1,1	0,8
	up to 110	1,3	1
▼M2 Over 110 kg		1,5	1,2
▼B Piglets	over 40 days and up to 30 kg	0,6	0,4
Brood pigs		2,5 female	1,9
		6 male If pens are used for natural service: 10 m^2/boar	8,0

▼B

2. **Poultry**

	Indoors area (net area available to animals)			Outdoors area (m^2 of area available in rotation/head)
	No animals/m^2	cm perch/animal	nest	
Laying hens	6	18	7 laying hens per nest or in case of common nest 120 cm^2/bird	4, provided that the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry (in fixed housing)	10 with a maximum of 21 kg live-weight/m^2	20 (for guinea fowl only)		4 broilers and guinea fowl 4,5 ducks 10 turkey 15 geese In all the species mentioned above the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry in mobile housing	16 (1) in mobile poultry houses with a maximum of 30 kg live-weight/m^2			2,5, provided that the limit of 170 kg of N/ha/year is not exceeded

(1) Only in the case of mobile houses not exceeding 150 m^2 floor space.

▼B

ANNEX IV

Maximum number of animals per hectare referred to in Article 15 (2)

Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Equines over six months old	2
Calves for fattening	5
Other bovine animals less than one year old	5
Male bovine animals from one to less than two years old	3,3
Female bovine animals from one to less than two years old	3,3
Male bovine animals two years old or over	2
Breeding heifers	2,5
Heifers for fattening	2,5
Dairy cows	2
Cull dairy cows	2
Other cows	2,5
Female breeding rabbits	100
Ewes	13,3
Goats	13,3
Piglets	74
Breeding sows	6,5
Pigs for fattening	14
Other pigs	14
Table chickens	580
Laying hens	230

▼M8

ANNEX V

Feed materials as referred to in Article 22(d), Article 24(2) and Article 25m(1)

▼M13

1. FEED MATERIALS OF MINERAL ORIGIN

A	Calcareous marine shells	
A	Maerl	
A	Lithotamn	
A	Calcium gluconate	
A	Calcium carbonate	
A	Defluorinated monocalciumphosphate	
A	Defluorinated dicalciumphosphate	
A	Magnesium oxide (anhydrous magnesia)	
A	Magnesium sulphate	
A	Magnesium chloride	
A	Magnesium carbonate	
A	Calcium magnesium phosphate	
A	Magnesium phosphate	
A	Monosodium phosphate	
A	Calcium sodium phosphate	
A	Sodium chloride	
A	Sodium bicarbonate	
A	Sodium carbonate	
A	Sodium sulphate	
A	Potassium chloride	

▼M8

2. OTHER FEED MATERIALS

Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed:

A	Saccharomyces cerevisiae	
A	Saccharomyces carlsbergiensis	

▼M16

ANNEX VI

Feed additives used in animal nutrition referred to in Article 22(g), Article 24(2) and Article 25m(2)

Feed additives listed in this Annex must be authorised under Regulation (EC) No 1831/2003 of the European Parliament and of the Council [1].

1. TECHNOLOGICAL ADDITIVES

(a) *Preservatives*

ID numbers or Functional groups		Substance	Description, conditions for use
	E 200	Sorbic acid	
	E 236	Formic acid	
	E 237	Sodium formate	
	E 260	Acetic acid	
	E 270	Lactic acid	
	E 280	Propionic acid	
	E 330	Citric acid	

(b) *Antioxidants*

ID number or Functional groups		Substance	Description, conditions for use
	1b306(i)	Tocopherol extracts from vegetable oils	
	1b306(ii)	Tocopherol-rich extracts from vegetable oils (delta rich)	

(c) *Emulsifiers, stabilisers, thickeners and gelling agents*

ID numbers or Functional groups		Substance	Description, conditions for use
	E 322	Lecithins	Only when derived from organic raw material. Use restricted to aquaculture animal feed.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

▼**M16**

(d) *Binders and anti-caking agents*

ID number or Functional groups		Substance	Description, conditions for use
	E 535	Sodium ferrocyanide	Maximum dose rate of 20 mg/kg NaCl calculated as ferrocyanide anion.
	E 551b	Colloidal silica	
	E 551c	Kieselgur (diatomaceous earth, purified)	
	1m558i	Bentonite	
	E 559	Kaolinitic clays, free of asbestos	
	E 560	Natural mixtures of stearites and chlorite	
	E 561	Vermiculite	
	E 562	Sepiolite	
	E 566	Natrolite-Phonolite	
	1g568	Clinoptilolite of sedimentary origin	
	E 599	Perlite	

(e) *Silage additives*

ID number or Functional groups	Substance	Description, conditions for use
1k	Enzymes and micro-organisms	Use restricted to production of silage when weather conditions do not allow for adequate fermentation.

2. SENSORY ADDITIVES

ID number or Functional groups	Substance	Description, conditions for use
2b	Flavouring compounds	Only extracts from agricultural products.

▼**M16**

3. NUTRITIONAL ADDITIVES

(a) *Vitamins, pro-vitamins and chemically well-defined substances having similar effect*

ID number or Functional groups	Substance	Description, conditions for use
3a	Vitamins and provitamins	— Derived from agricultural products. — If derived synthetically, only those identical to vitamins derived from agricultural products may be used for monogastric animals and aquaculture animals. — If derived synthetically, only vitamins A, D and E identical to vitamins derived from agricultural products may be used for ruminants; the use is subject to prior authorisation of the Member States based on the assessment of the possibility for organic ruminants to obtain the necessary quantities of the said vitamins through their feed rations.

(b) *Compounds of trace elements*

ID numbers or Functional groups		Substance	Description, conditions for use
	E1 Iron	Ferric oxide Ferrous carbonate Ferrous sulphate, heptahydrate Ferrous sulphate, monohydrate	
	3b201	Potassium iodide	
	3b202	Calcium iodate, anhydrous	
	3b203	Coated granulated calcium iodate anhydrous	
	3b301	Cobalt(II) acetate tetrahydrate	
	3b302	Cobalt(II) carbonate	
	3b303	Cobalt(II) carbonate hydroxide (2:3) monohydrate	
	3b304	Coated granulated cobalt(II) carbonate	
	3b305	Cobalt(II) sulphate heptahydrate	

▼**M16**

ID numbers or Functional groups		Substance	Description, conditions for use
	E4 Copper	Basic cupric carbonate, monohydrate Cupric oxide Cupric sulphate, pentahydrate	
	3b409	Dicopper chloride trihydroxide (TBCC)	
	E5 Manganese	Manganous oxide Manganous sulfate, monohydrate Manganous carbonate	
	E6 Zinc	Zinc oxide Zinc sulphate monohydrate Zinc sulphate heptahydrate	
	3b609	Zinc chloride hydroxide monohydrate (TBZC)	
	E7 Molybdenum	Sodium molybdate	
	E8 Selenium	Sodium selenite Sodium selenate	
	3b8.10, 3b8.11, 3b8.12, 3b813 and 3b817	Selenised yeast inactivated	

4. ZOOTECHNICAL ADDITIVES

ID number or Functional groups	Substance	Description, conditions for use
4a, 4b, 4c and 4d	Enzymes and microorganism in the category of ‘Zootechnical additives’	

▼M2

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)

   — Phosporic acid (dairy equipment)

   — Formaldehyde

   — Cleaning and disinfection products for teats and milking facilities

   — Sodium carbonate

▼M15

2. Products for cleaning and disinfection for aquaculture animals and seaweed production referred to in Articles 6e(2), 25s(2) and 29a.

2.1. Subject to compliance with relevant Union and national provisions as referred to in Article 16(1) of Regulation (EC) No 834/2007, and in particular with Regulation (EU) No 528/2012 of the European Parliament and of the Council [1], products used for cleaning and disinfection of equipment and facilities in the absence of aquaculture animals may contain the following active substances:

   — ozone

   — sodium hypochlorite

   — calcium hypochlorite

   — calcium hydroxide

   — calcium oxide

   — caustic soda

   — alcohol

   — copper sulphate: only until 31 December 2015

   — potassium permanganate

   — tea seed cake made of natural camelia seed (use restricted to shrimp production)

   — mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

▼**M15**

2.2. Subject to compliance with relevant Union and national provisions as referred to in Article 16(1) of Regulation (EC) No 834/2007, and in particular with Regulation (EU) No 528/2012 and Directive 2001/82/EC of the European Parliament and of the Council [1], products used for cleaning and disinfection of equipment and facilities in the presence as well as in the absence of aquaculture animals may contain the following active substances:

— limestone (calcium carbonate) for pH control

— dolomite for pH correction (use restricted to shrimp production)

— sodium chloride

— hydrogen peroxide

— sodium percarbonate

— organic acids (acetic acid, lactic acid, citric acid)

— humic acid

— peroxyacetic acids

— peracetic and peroctanoic acids

— iodophores (only in the presence of eggs).

[1] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

▼B

ANNEX VIII

▼M1

Certain products and substances for use in production of processed organic food, yeast and yeast products referred to in Article 27(1)(a) and Article 27a(a)

▼M16

_____

▼B

SECTION A — FOOD ADDITIVES, INCLUDING CARRIERS

For the purpose of the calculation referred to in Article 23(4)(a)(ii) of Regulation (EC) No 834/2007, food additives marked with an asterisk in the column of the code number, shall be calculated as ingredients of agricultural origin.

►M16 — ◄	Code	Name	Preparation of foodstuffs of		Specific conditions
			plant origin	animal origin	
►M16 — ◄	E 153	Vegetable carbon		X	Ashy goat cheese Morbier cheese
►M16 — ◄	E 160b*	Annatto, Bixin, Norbixin		X	Red Leicester cheese Double Gloucester cheese Cheddar Mimolette cheese
►M16 — ◄	E 170	Calcium carbonate	X	X	Shall not be used for colouring or calcium enrichment of products
►M16 — ◄	►M16 E 220	Sulphur dioxide	X	X (Only for mead)	In fruit wines (*) and mead with and without added sugar): 100 mg (**) ◄
	►M16 E 224	Potassium metabisulphite	X	X (Only for mead)	In fruit wines (*) and mead with and without added sugar): 100 mg (**) ◄
					►M16 (*) In this context, 'fruit wine' is defined as wine made from fruits other than grapes (including cider and perry). ◄ ►M16 (**) Maximum levels available from all sources, expressed as SO_2 in mg/l. ◄
▼M2 ►M16 — ◄	E 223	Sodium metabisulphite		X	Crustaceans (2)

▼B

►M16 —◄	Code	Name	Preparation of foodstuffs of		Specific conditions
			plant origin	animal origin	
►M16 —◄	E 250 or E 252	Sodium nitrite Potassium nitrate		X X	For meat products ([1]): For E 250: indicative ingoing amount expressed as $NaNO_2$: 80 mg/kg For E 252: indicative ingoing amount expressed as $NaNO_3$: 80 mg/kg For E 250: maximum residual amount expressed as $NaNO_2$: 50 mg/kg For E 252: maximum residual amount expressed as $NaNO_3$: 50 mg/kg
►M16 —◄	E 270	Lactic acid	X	X	
►M16 —◄	E 290	Carbon dioxide	X	X	
►M16 —◄	E 296	Malic acid	X		
►M16 —◄	E 300	Ascorbic acid	X	X	Meat products ([2])
►M16 —◄	E 301	Sodium ascorbate		X	Meat products ([2]) in connection with nitrates and nitrites
►M16 —◄	►M16 E 306 (*)	Tocopherol-rich extract	X	X	Anti-oxidant ◄
►M16 —◄	►M16 E 322 (*)	Lecithins	X	X	Milk products ([2]) Only when derived from organic raw material (***) ◄ ►M16 (***) As from 1 January 2019. ◄
►M16 —◄	E 325	Sodium lactate		X	Milk-based and meat products
►M16 —◄	►M16 E 330	Citric acid	X	X ◄	
▼M2					
►M16 —◄	E 330	Citric acid		X	Crustaceans and molluscs ([2])
▼B					
►M16 —◄	►M16 E 331	Sodium citrates	X	X ◄	

▼B

►M16 —◄	Code	Name	Preparation of foodstuffs of		Specific conditions
			plant origin	animal origin	
►M16 —◄	E 333	Calcium citrates	X		
►M16 —◄	►M16 E 334	Tartaric acid (L(+)–)	X	X (Only for mead) ◄	
►M16 —◄	E 335	Sodium tartrates	X		
►M16 —◄	E 336	Potassium tartrates	X		
►M16 —◄	E 341 (i)	Monocalcium-phosphate	X		Raising agent for self raising flour
▼M8 ►M16 —◄	E 392*	Extracts of rosemary	X	X	Only when derived from organic production
▼B ►M16 —◄	E 400	Alginic acid	X	X	Milk-based products (2)
►M16 —◄	E 401	Sodium alginate	X	X	Milk-based products (2)
►M16 —◄	E 402	Potassium alginate	X	X	Milk-based products (2)
►M16 —◄	E 406	Agar	X	X	Milk-based and meat products (2)
►M16 —◄	E 407	Carrageenan	X	X	Milk-based products (2)
►M16 —◄	E 410*	Locust bean gum	X	X	
►M16 —◄	E 412*	Guar gum	X	X	
►M16 —◄	E 414*	Arabic gum	X	X	
►M16 —◄	E 415	Xanthan gum	X	X	
▼M16	E 418	Gellan gum	X	X	High-acyl form only
▼B ►M16 —◄	►M16 E 422	Glycerol	X		From plant origin. For plant extracts and flavourings ◄
►M16 —◄	E 440 (i)*	Pectin	X	X	Milk-based products (2)

▼B

►M16 —◄	Code	Name	Preparation of foodstuffs of		Specific conditions
			plant origin	animal origin	
►M16 —◄	E 464	Hydroxypropyl methyl cellulose	X	X	Encapsulation material for capsules
►M16 —◄	►M16 E 500	Sodium carbonate	X	X ◄	
►M16 —◄	E 501	Potassium carbonates	X		
►M16 —◄	E 503	Ammonium carbonates	X		
►M16 —◄	E 504	Magnesium carbonates	X		
►M16 —◄	E 509	Calcium chloride		X	Milk coagulation
►M16 —◄	E 516	Calcium sulphate	X		Carrier
►M16 —◄	►M16 E 524	Sodium hydroxide	X		Surface treatment of 'Laugengebäck' and regulation of acidity in organic flavourings ◄
►M16 —◄	►M16 E 551	Silicon dioxide gel or colloidal solution	X	X	For herbs and spices in dried powdered form Flavourings and propolis ◄
►M16 —◄	E 553b	Talc	X	X	Coating agent for meat products
▼M16	E 901	Beeswax	X		As a glazing agent for confectionary only. Beeswax from organic beekeeping
	E 903	Carnauba wax	X		As a glazing agent for confectionary only. Only when derived from organic raw material
▼B ►M16 —◄	E 938	Argon	X	X	
►M16 —◄	E 939	Helium	X	X	

▼B

►M16 —◄	Code	Name	Preparation of foodstuffs of		Specific conditions
			plant origin	animal origin	
►M16 —◄	E 941	Nitrogen	X	X	
►M16 —◄	E 948	Oxygen	X	X	
▼M16	E 968	Erythritol	X	X	Only when derived from organic production without using ion exchange technology

▼B

(1) This additive can only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available.
(2) The restriction concerns only animal products.

▼B

SECTION B — PROCESSING AIDS AND OTHER PRODUCTS, WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION

▼M16 _____

▼B

►M16 —◄	Name	Preparation of foodstuffs of plant origin	Preparation of foodstuffs of animal origin	Specific conditions
►M16 —◄	Water	X	X	Drinking water within the meaning of Council Directive 98/83/EC
►M16 —◄	Calcium chloride	X		Coagulation agent
►M16 —◄	Calcium carbonate	X		
►M16 —◄	Calcium hydroxide	X		
►M16 —◄	Calcium sulphate	X		Coagulation agent
►M16 —◄	Magnesium chloride (or nigari)	X		Coagulation agent
►M16 —◄	Potassium carbonate	X		Drying of grapes
►M16 —◄	Sodium carbonate	►M16 X	X ◄	
►M16 —◄	Lactic acid		X	For the regulation of the pH of the brine bath in cheese production ([1])
►M16 —◄	►M16 Citric acid	X	X ◄	
►M16 —◄	►M16 Sodium hydroxide	X		For sugar(s) production. For oil production excluding olive oil production ◄
►M16 —◄	Sulphuric acid	X	X	Gelatine production ([1]) Sugar(s) production ([2])
►M16 —◄	Hydrochloric acid		X	Gelatine production For the regulation of the pH of the brine bath in the processing of Gouda-, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas
►M16 —◄	Ammonium hydroxide		X	Gelatine production
►M16 —◄	Hydrogen peroxide		X	Gelatine production

▼B

►M16 —◄	Name	Preparation of foodstuffs of plant origin	Preparation of foodstuffs of animal origin	Specific conditions
►M16 —◄	Carbon dioxide	X	X	
►M16 —◄	Nitrogen	X	X	
►M16 —◄	Ethanol	X	X	Solvent
►M16 —◄	Tannic acid	X		Filtration aid
►M16 —◄				
►M16 —◄	Egg white albumen	X		
►M16 —◄	Casein	X		
►M16 —◄	Gelatin	X		
►M16 —◄	Isinglass	X		
►M16 —◄	►M16 Vegetable oils	X	X	Greasing, releasing or anti-foaming agent. Only when derived from organic production ◄
►M16 —◄	Silicon dioxide gel or colloidal solution	X		
►M16 —◄	Activated carbon	X		
►M16 —◄	Talc	X		In compliance with the specific purity criteria for food additive E 553b
►M16 —◄	►M16 Bentonite	X	X	Sticking agent for mead [1] ◄
▼M16 ——				
▼B				
►M16 —◄	Celluose	X	X	Gelatine production [1]
►M16 —◄	Diatomaceous earth	X	X	Gelatine production [1]
►M16 —◄	Perlite	X	X	Gelatine production [1]
►M16 —◄	Hazelnut shells	X		

▼B

►M16 —◄	Name	Preparation of foodstuffs of plant origin	Preparation of foodstuffs of animal origin	Specific conditions
►M16 —◄	Rice meal	X		
►M16 —◄	►M16 Beeswax	X		Releasing agent. Beeswax from organic beekeeping ◄
►M16 —◄	►M16 Carnauba wax	X		Releasing agent. Only when derived from organic raw material ◄
▼M16	Acetic acid/vinegar		X	Only when derived from organic production. For fish processing, only from biotechnological source, except if produced by or from GMO
	Thiamin hydrochloride	X	X	Only for use in processing of fruit wines, including cider and perry and mead
	Diammonium phosphate	X	X	Only for use in processing of fruit wines, including cider and perry and mead
	Wood fibre	X	X	The source of timber should be restricted to certified, sustainably harvested wood. Wood used must not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from micro-organisms)

▼B

(1) The restriction concerns only animal products.
(2) The restriction concerns only plant products.

▼M1

SECTION C — PROCESSING AIDS FOR THE PRODUCTION OF YEAST AND YEAST PRODUCTS

Name	Primary yeast	Yeast confections/ formulations	Specific conditions
Calcium chloride	X		
Carbon dioxide	X	X	
Citric acid	X		For the regulation of the pH in yeast production
Lactic acid	X		For the regulation of the pH in yeast production
Nitrogen	X	X	
Oxygen	X	X	
▼M16 Potato starch	X	X	For filtering Only when derived from organic production
▼M1 Sodium carbonate	X	X	For the regulation of the pH
▼M16 Vegetable oils	X	X	Greasing, releasing or anti-foaming agent Only when derived from organic production

▼M7

ANNEX VIIIa

Products and substances authorised for use or addition in organic products of the wine sector referred to in Article 29c

Type of treatment in accordance with Annex I A to Regulation (EC) No 606/2009	Name of products or substances	Specific conditions, restrictions within the limits and conditions set out in Regulation (EC) No 1234/2007 and Regulation (EC) No 606/2009
Point 1: Use for aeration or oxygenation	— Air — Gaseous oxygen	
Point 3: Centrifuging and filtration	— Perlite — Cellulose — Diatomeceous earth	Use only as an inert filtering agent
Point 4: Use in order to create an inert atmosphere and to handle the product shielded from the air	— Nitrogen — Carbon dioxide — Argon	
Points 5, 15 and 21: Use	— Yeasts ([1])	
Point 6: Use	— Di-ammonium phosphate — Thiamine hydrochloride	
Point 7: Use	— Sulphur dioxide — Potassium bisulphite or potassium metabisulphite	(a) The maximum sulphur dioxide content shall not exceed 100 milligrams per litre for red wines as referred to in point 1(a) of Part A of Annex I B to Regulation (EC) No 606/2009 and with a residual sugar level lower than 2 grams per litre; (b) The maximum sulphur dioxide content shall not exceed 150 milligrams per litre for white and rosé wines as referred to in point 1(b) of Part A of Annex I B to Regulation (EC) No 606/2009 and with a residual sugar level lower than 2 grams per litre; (c) For all other wines, the maximum sulphur dioxide content applied in accordance with Annex I B to Regulation (EC) No 606/2009 on 1 August 2010, shall be reduced by 30 milligrams per litre.

▼M7

Type of treatment in accordance with Annex I A to Regulation (EC) No 606/2009	Name of products or substances	Specific conditions, restrictions within the limits and conditions set out in Regulation (EC) No 1234/2007 and Regulation (EC) No 606/2009
Point 9: Use	— Charcoal for oenological use	
Point 10: Clarification	— Edible gelatine (2) — Plant proteins from wheat or peas (2) — Isinglass (2) — Egg white albumin (2) — Tannins (2)	
	— Casein — Potassium caseinate — Silicon dioxide — Bentonite — Pectolytic enzymes	
Point 12: Use for acidification purposes	— Lactic acid — L(+)Tartaric acid	
Point 13: Use for deacidification purposes	— L(+)Tartaric acid — Calcium carbonate — Neutral potassium tartrate — Potassium bicarbonate	
Point 14: Addition	— Aleppo pine resin	
Point 17: Use	— Lactic bacteria	
Point 19: Addition	— L-Ascorbic acid	

▼M7

Type of treatment in accordance with Annex I A to Regulation (EC) No 606/2009	Name of products or substances	Specific conditions, restrictions within the limits and conditions set out in Regulation (EC) No 1234/2007 and Regulation (EC) No 606/2009
Point 22: Use for bubbling	— Nitrogen	
Point 23: Addition	— Carbon dioxide	
Point 24: Addition for wine stabilisation purposes	— Citric acid	
Point 25: Addition	— Tannins (2)	
Point 27: Addition	— Meta-tartaric acid	
Point 28: Use	— Acacia gum (2) (= gum arabic)	
Point 30: Use	— Potassium bitartrate	
Point 31: Use	— Cupric citrate	
Point 31: Use	— Copper sulphate	Authorised until 31 July 2015
Point 38: Use	— Oak chips	
Point 39: Use	— Potassium alginate	
Type of treatment in accordance with Annex III, point A(2)(b) to Regulation (EC) No 606/2009	— Calcium sulphate	Only for ‘vino generoso’ or ‘vino generoso de licor’

(1) For the individual yeast strains: if available, derived from organic raw material.
(2) Derived from organic raw material if available.

▼B

ANNEX IX

Ingredients of agricultural origin which have not been produced organically referred to in Article 28

1. UNPROCESSED VEGETABLE PRODUCTS AS WELL AS PRODUCTS DERIVED THEREFROM BY PROCESSES

1.1. **Edible fruits, nuts and seeds:**

— acorns	*Quercus* spp.
— cola nuts	*Cola acuminata*
— gooseberries	*Ribes uva-crispa*
— maracujas (passion fruit)	*Passiflora edulis*
— raspberries (dried)	*Rubus idaeus*
— red currants (dried)	*Ribes rubrum*

1.2. **Edible spices and herbs:**

— pepper (Peruvian)	*Schinus molle* L.
— horseradish seeds	*Armoracia rusticana*
— lesser galanga	*Alpinia officinarum*
— safflower flowers	*Carthamus tinctorius*
— watercress herb	*Nasturtium officinale*

1.3. **Miscellaneous:**

Algae, including seaweed, permitted in non-organic foodstuffs preparation

2. VEGETABLE PRODUCTS

2.1. **Fats and oils whether or not refined, but not chemically modified, derived from plants other than:**

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

2.2. **The following sugars, starches and other products from cereals and tubers:**

— fructose

— rice paper

— unleavened bread paper

— starch from rice and waxy maize, not chemically modified

▼B

2.3. **Miscellaneous:**

— pea protein *Pisum* spp.

— rum, only obtained from cane sugar juice

— kirsch prepared on the basis of fruits and flavourings as referred to in Article 27(1)(c).

3. ANIMAL PRODUCTS

aquatic organisms, not originating from aquaculture, and permitted in no-organic foodstuffs preparation

— gelatin

— whey powder '*herasuola*'

— casings

▼B

ANNEX X

Species for which organically produced seed or seed potatoes are available in sufficient quantities and for a significant number of varieties in all parts of the Community referred to in Article 45(3)

▼M3

ANNEX XI

A. **Organic logo of the EU, referred to in Article 57**

1. The Organic logo of the EU shall comply with the model below:

2. The reference colour in Pantone is Green Pantone No 376 and Green (50 % Cyan + 100 % Yellow), when a four-colour process is used.

3. The Organic logo of the EU can also be used in black and white as shown, only where it is not practicable to apply it in colour:

4. If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.

5. If a symbol is used in colour on a coloured background, which makes it difficult to see, a delimiting outer line around the symbol can be used to improve contrast with the background colours.

6. In certain specific situations where there are indications in a single colour on the packaging, the Organic logo of the EU may be used in the same colour.

7. The Organic logo of the EU must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for very small packages.

8. The Organic logo of the EU may be associated with graphical or textual elements referring to organic farming, under the condition that they do not modify or change the nature of the Organic logo of the EU, nor any of the indications mentioned at Article 58. When associated to national or private logos using a green colour different from the reference colour mentioned in point 2, the Organic logo of the EU may be used in that non-reference colour.

▼M4

———————

▼M3

B. **Code numbers referred to in Article 58**

The general format of the code numbers is as follows:

AB-CDE-999

Where:

1. 'AB' is the ISO code as specified in Article 58(1)(a) for the country where the controls take place; and

2. 'CDE' is a term, indicated in three letters to be decided by the Commission or each Member State, like 'bio' or 'öko' or 'org' or 'eko' establishing a link with the organic production method as specified in Article 58(1)(b); and

3. '999' is the reference number, indicated in maximum three digits, to be attributed, as specified in Article 58(1)(c) by:

   (a) each Member State's competent authority to the Control Authorities or Control Bodies to which they have delegated control tasks in accordance with Article 27 of Regulation (EC) No 834/2007;

   (b) the Commission, to:

      (i) the Control Authorities and Control Bodies referred to in Article 3(2)(a) of Commission Regulation (EC) No 1235/2008 ([1]) and listed in Annex I to that Regulation;

      (ii) the third countries' competent authorities or Control Bodies referred to in Article 7(2)(f) of Regulation (EC) No 1235/2008 and listed in Annex III to that Regulation;

      (iii) the Control Authorities and Control Bodies referred to in Article 10(2)(a) of Regulation (EC) No 1235/2008, and listed in Annex IV to that Regulation;

   (c) each Member State's competent authority to the Control Authority or Control Body which has been authorised until 31 December 2012 for issuing the certificate of inspection in accordance with Article 19(1) fourth subparagraph of Regulation (EC) No 1235/2008 (import authorisations), upon proposal of the Commission.

The Commission shall make the code numbers available to the public by any appropriate technical means, including publication on the Internet.

([1]) OJ L 334, 12.12.2008, p. 25.

▼M2

ANNEX XII

Model of documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in ►M6 Article 68(1) ◄ of this Regulation

<table>
<tr><td colspan="2">Documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007

1. Document Number:</td></tr>
<tr><td>2. Name and address of operator:
main activity (producer, processor, importer, etc.):</td><td>3. Name, address and code number of control body/ authority:</td></tr>
<tr><td>4. Product groups/Activity:
— Plant and plant products:
— Seaweed and seaweed products:
— Livestock and livestock products:
— Aquaculture animals and aquaculture animal products:
— Processed products:</td><td>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</td></tr>
<tr><td>6. Validity period:
Plant products from ..... to .....
Seaweed products from ..... to .....
Livestock products from ..... to .....
Aquaculture animal products from ..... to .....
Processed products from ..... to .....</td><td>7. Date of control(s):</td></tr>
<tr><td colspan="2">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.

Date, place:

Signature on behalf of the issuing control body/authority:</td></tr>
</table>

▼M6

ANNEX XIIa

Model of complementary documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007 referred to in Article 68(2) of this Regulation

Complementary documentary evidence to the operator according to Article 29(1) of Regulation (EC) No 834/2007
1.1. Number of the document: 1.2. Reference to the documentary evidence provided in accordance with Article 29(1) of Regulation (EC) No 834/2007: ([1])
2. Specific characteristics of the production method used by the operator, referred to in Article 68(2) of Regulation (EC) No 889/2008: ([2])
3. This document has been issued on the basis of Article 29(1) of Regulation (EC) No 834/2007 and Article 68(2) of Regulation (EC) No 889/2008. The declared operator has submitted his activities under control, and meets the requirements laid down in those Regulations. Date, place: Signature and stamp on behalf of the issuing control body/authority:
([1]) Insert number of the documentary evidence provided in accordance with Article 68(1) of, and Annex XII to, this Regulation. ([2]) Insert the relevant entry set out in Annex XIIb to this Regulation.

▼M6

ANNEX XIIb

Entry referred to in the second subparagraph of Article 68(2):

— *In Bulgarian:* Животински продукти, произведени без използване на антибиотици

— *In Spanish:* Productos animales producidos sin utilizar antibióticos

— *In Czech:* Živočišné produkty vyprodukované bez použití antibiotik

— *In Danish:* Animalske produkter, der er produceret uden brug af antibiotika

— *In German:* Ohne Anwendung von Antibiotika erzeugte tierische Erzeugnisse

— *In Estonian:* Loomsed tooted, mille tootmisel ei ole kasutatud antibiootikume

— *In Greek:* Ζωικά προϊόντα που παράγονται χωρίς τη χρήση αντιβιοτικών

— *In English:* Animal products produced without the use of antibiotics

— *In French:* produits animaux obtenus sans recourir aux antibiotiques

▼M10

— *In Croatian:* Proizvodi životinjskog podrijetla dobiveni bez uporabe antibiotika

▼M6

— *In Italian:* Prodotti animali ottenuti senza l'uso di antibiotici

— *In Latvian:* Dzīvnieku izcelsmes produkti, kuru ražošanā nav izmantotas antibiotikas

— *In Lithuanian:* nenaudojant antibiotikų pagaminti gyvūniniai produktai

— *In Hungarian:* Antibiotikumok alkalmazása nélkül előállított állati eredetű termékek

— *In Maltese:* Il-prodotti tal-annimali prodotti mingħajr l-użu tal-antibijotiċi

— *In Dutch:* Zonder het gebruik van antibiotica geproduceerde dierlijke producten

— *In Polish:* Produkty zwierzęce wytwarzane bez użycia antybiotyków

— *In Portuguese:* Produtos de origem animal produzidos sem utilização de antibióticos

— *In Romanian:* Produse de origine animală obținute a se recurge la antibiotice

— *In Slovak:* Výrobky živočíšneho pôvodu vyrobené bez použitia antibiotík

— *In Slovenian:* Živalski proizvodi, proizvedeni brez uporabe antibiotikov

— *In Finnish:* Eläintuotteet, joiden tuotannossa ei ole käytetty antibiootteja

— *In Swedish:* Animaliska produkter som produceras utan antibiotika

▼B

ANNEX XIII

Model of a vendor declaration referred to in Article 69

Vendor declaration according to Article 9(3) of Council Regulation (EC) No 834/2007	
Name, address of vendor:	
Identification (e.g. lot or stock number):	Product name:
Components: (Specify all components existing in the product/used the last in the production process) …… …… …… …… ……	
I declare that this product was manufactured neither 'from' nor 'by' GMOs as those terms are used in Articles 2 and 9 of Council Regulation (EC) No 834/2007. I do not have any information which could suggest that this statement is inaccurate. Thus, I declare that the above named product complies with Article 9 of Regulation (EC) No 834/2007 regarding the prohibition on the use of GMOs. I undertake to inform our customer and its control body/authority immediately if this declaration is withdrawn or modified, or if any information comes to light which would undermine its accuracy. I authorise the control body or control authority, as defined in Article 2 of Council Regulation (EC) No 834/2007, which supervises our customer to examine the accuracy of this declaration and if necessary to take samples for analytic proof. I also accept that this task may be carried out by an independent institution which has been appointed in writing by the control body. The undersigned takes responsibility for the accuracy of this declaration.	
Country, place, date, signature of vendor:	Company stamp of vendor (*if appropriate*):

▼**M2**

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)*

Production system	Ongrowing farm systems must be fed from open systems. The flow rate must ensure a minimum of 60 % oxygen saturation for stock and must ensure their comfort and the elimination of farming effluent.
Maximum stocking density	Salmonid species not listed below 15 kg/m^3 Salmon 20 kg/m^3 Brown trout and Rainbow trout 25 kg/m^3 ►**M15** Arctic charr 25 kg/m^3 ◄

Section 2

Organic production of salmonids in sea water:

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

Maximum stocking density	10 kg/m^3 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 [= Scopthalmus maximux])*, red porgy *(Pagrus pagrus [= Sparus pagrus])*, red drum *(Sciaenops ocellatus)* and other Sparidae, and spinefeet (*Siganus* spp.)

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

Section 4

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

Containment system	Traditional salt pans transformed into aquaculture production units and similar earth ponds in tidal areas

▼M2

Production system	There shall be adequate renewal of water to ensure the welfare of the species, At least 50 % of the dikes must have plant cover Wetland based depuration ponds required
Maximum stocking density	4 kg/m^3

Section 5

Organic production of Sturgeon in fresh water:

Species concerned: *Acipenser* family

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

Section 6

Organic production of fish in inland waters:

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

Production system	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. 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 shall be carried out in compliance with Annex I to Regulation (EC) No 889/2008 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 are prohibited. 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. For grow-out ‘polyculture’ shall be used on condition that the criteria laid down in the present specifications for the other species of lakes fish are duly adhered to.
Farming yield	The total production of species is limited to 1 500 kg of fish per hectare per year.

▼M2

Section 7

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

Establishment of production unit/s	Location to be in sterile clay areas to minimise environmental impact of pond construction. Ponds to be built with the natural pre-existing clay. Mangrove destruction is not permitted.
Conversion time	Six months per pond, corresponding to the normal lifespan of a 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^2 Maximum instantaneous biomass: 240 g/m^2

▼M15

Section 7a

Organic production of crayfish:

Species concerned: *Astacus astacus*, *Pacifastacus leniusculus*.

Maximum stocking density:	For small-sized crayfish (< 20 mm): 100 individuals per m^2. For crayfish of intermediate size (20-50 mm): 30 individuals per m^2. For adult crayfish (> 50 mm): 10 individuals per m^2, provided that adequate hiding places are available.

▼M2

Section 8

Molluscs and echinoderms:

Production systems	Long-lines, rafts, bottom culture, net bags, cages, trays, lantern nets, bouchot poles and other containment systems. For mussel cultivation on rafts the number of drop-ropes shall not exceed one per square meter of surface area. The maximum drop-rope length shall not exceed 20 metres. Thinning-out of drop-ropes shall not take place during the production cycle, however sub-division of drop ropes shall be permitted without increasing stocking density at the outset.

▼**M2**

Section 9

Tropical fresh water fish: milkfish *(Chanos chanos)*, tilapia (*Oreochromis* spp.), siamese catfish (*Pangasius* spp.):

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

Section 10

Other aquaculture animal species: none

▼**M9**

ANNEX XIIIb

Topics to be covered by the national competent authority in the organic data referred to in Article 92f

1. Information on the competent authority for the organic production
   - — which body is the competent authority
   - — resources available to the competent authority
   - — description of audits performed by the competent authority (how, by whom)
   - — documented procedure of the competent authority
2. Description of the control system for organic production
   - — system of control bodies and/or control authorities
   - — registered operators covered by the control system — minimum annual inspection
   - — how is the risk based approach applied
3. Information on control bodies/authorities
   - — list of control bodies/authorities
   - — tasks delegated to the control bodies/conferred to control authorities
   - — supervision of delegated control bodies (by whom and how)
   - — coordination of activities in case of more than one control body/authority
   - — training of staff performing the controls
   - — announced/unannounced inspections and visits

▼M9

ANNEX XIIIc

Templates for the organic data referred to under Article 92f

Report on official controls in the organic sector

Country:
Year:

1) Information on controls of operators:

Code number of control body or control authority	Number of registered operators per control body or control authority	Number of registered operators						Number of annual inspections						Number of additional risk based visits						Total number of inspections/visits					
		Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)
MS-BIO-01																									
MS-BIO-02																									
MS-BIO-…																									
Total																									

(*) Agricultural producers include agricultural producers only, producers that are also processors, producers that are also importers, other mixed producers not elsewhere classified (n.e.c.).

(**) Processors include processors only, processors that are also importers, other mixed processors n.e.c.

(***) Other operators include traders (wholesalers, retailers), other operators n.e.c.

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▼M9

Code number of control body or control authority or Name of Competent Authority	Number of registered operators						Number of samples analysed						Number of samples indicating breach of Regulations (EC) No 834/2007 and (EC) No 1235/2008					
	Agri-cultural Produc-ers (*)	Aqua-culture animal productio-n units	Processors (**)	Importers	Exporters	Other operators (***)	Agri-cultural Producers (*)	Aqua-culture animal productio-n units	Processors (**)	Importers	Exporters	Other operators (***)	Agri-cultural Producers (*)	Aqua-culture animal productio-n units	Processors (**)	Importers	Exporters	Other operators (***)
MS-BIO-01																		
MS-BIO-02																		
MS-BIO-…																		
Total																		

(*) Agricultural producers include agricultural producers only, producers that are also processors, producers that are also importers, other mixed producers not elsewhere classified (n.e.c.).

(**) Processors include processors only, processors that are also importers, other mixed processors n.e.c.

(***) Other operators include traders (wholesalers, retailers), other operators n.e.c.

▼M9

Code number of control body or control authority	Number of registered operators						Number of irregularities or infringements found (1)						Number of measures applied on the lot or the production run (2)						Number of measures applied on the operator (3)					
	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)
MS-BIO-01																								
MS-BIO-02																								
MS-BIO-…																								
Total																								

(*) Agricultural producers include agricultural producers only, producers that are also processors, producers that are also importers, other mixed producers not elsewhere classified (n.e.c.).

(**) Processors include processors only, processors that are also importers, other mixed processors n.e.c.

(***) Other operators include traders (wholesalers, retailers), other operators n.e.c.

(1) Only irregularities and infringements which affect the organic status of products and/or have resulted in a measure being applied are included.

(2) Where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the control authority or control body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities (as referred to in first subparagraph of Article 30(1) of Regulation (EC) No 834/2007).

(3) Where a severe infringement or an infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be agreed with the competent authority of the Member State (as referred to in second subparagraph of Article 30(1) of Regulation (EC) No 834/2007).

▼M9

2) Information on supervision and audits:

Code number of control body or control authority	Number of registered operators							Document review and office audit (1) (Number of operator files checked)						Number of review audits (2)						Number witness audits (3)					
	Number of registered operators per control body or control authority	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)	Agricultural Producers (*)	Aquaculture animal production units	Processors (**)	Importers	Exporters	Other operators (***)
MS-BIO-01																									
MS-BIO-02																									
MS-BIO-…																									
Total																									

(*) Agricultural producers include agricultural producers only, producers that are also processors, producers that are also importers, other mixed producers not elsewhere classified (n.e.c.).

(**) Processors include processors only, processors that are also importers, other mixed processors n.e.c.

(***) Other operators include traders (wholesalers, retailers), other operators n.e.c.

(1) Document review of the relevant general documents describing the structure, functioning and quality management of the control body. Office audit of the control body, including checking of operator files and verification of handling of non-conformities and complaints, including the minimum control frequency, the use of risk based approach, unannounced and follow-up visits, the sampling policy and the exchange of information with other control bodies and control authorities.

(2) Review audit: inspection of an operator by the competent authority to verify compliance with the operating procedures of the control body and to verify its effectiveness.

(3) Witness audit: observation by the competent authority of an inspection by an inspector of the control body.

▼M9

3) Conclusions on the control system for the organic production:

Code number of control body or control authority	Withdrawal of the approval			Actions taken to ensure effective operation of the control system for the organic production (enforcement)
	Yes/No	From (date)	To (date)	
MS-BIO-01				
MS-BIO-02				
MS-BIO-…				

Statement of overall performance of the control system for the organic production:

▼B

ANNEX XIV

Correlation Table referred to in Article 96

Regulation (EEC) No 2092/91	(1) Regulation (EC) No 207/93 (2) Regulation (EC) No 223/2003 (3) Regulation (EC) No 1452/2003	This Regulation
—		Article 1
—		Article 2(a)
Article 4(15)		Article 2(b)
Annex III, C (first indent)		Article 2(c)
Annex III, C (second indent)		Article 2(d)
—		Article 2(e)
—		Article 2(f)
—		Article 2(g)
—		Article 2(h)
Article 4(24)		Article 2(i)
—		Article 3(1)
Annex I.B, 7.1 and 7.2		Article 3(2)
Annex I.B, 7.4		Article 3(3)
Annex I.A, 2.4		Article 3(4)
Annex I.A, 2.3		Article 3(5)
—		Article 4
Article 6(1), Annex I.A, 3		Article 5
Annex I.A, 5		Article 6
Annex I.B and C (titles)		Article 7
Annex I.B, 3.1		Article 8(1)
Annex I.C, 3.1		Article 8(2)
Annex I.B, 3.4, 3.8, 3.9, 3.10, 3.11		Article 9(1) to (4)
Annex I.C, 3.6		Article 9(5)

▼B

Regulation (EEC) No 2092/91	(1) Regulation (EC) No 207/93 (2) Regulation (EC) No 223/2003 (3) Regulation (EC) No 1452/2003	This Regulation
Annex I.B, 8.1.1		Article 10(1)
Annex I.B, 8.2.1		Article 10(2)
Annex I.B, 8.2.2		Article 10(3)
Annex I.B, 8.2.3		Article 10(4)
Annex I.B, 8.3.5		Article 11(1)
Annex I.B, 8.3.6		Article 11(2)
Annex I.B, 8.3.7		Article 11(3)
Annex I.B, 8.3.8		Article 11(4), (5)
Annex I.B, 6.1.9, 8.4.1 to 8.4.5		Article 12(1) to (4)
Annex I.B, 6.1.9		Article 12(5)
Annex I.C, 4, 8.1 to 8.5		Article 13
Annex I.B, 8.1.2		Article 14
Annex I.B, 7.1, 7.2		Article 15
Annex I.B, 1.2		Article 16
Annex I.B, 1.6		Article 17(1)
Annex I.B, 1.7		Article 17(2)
Annex I.B, 1.8		Article 17(3)
Annex I.B, 4.10		Article 17(4)
Annex I.B, 6.1.2		Article 18(1)
Annex I.B, 6.1.3		Article 18(2)
Annex I.C, 7.2		Article 18(3)
Annex I.B, 6.2.1		Article 18(4)

▼B

Regulation (EEC) No 2092/91	(1) Regulation (EC) No 207/93 (2) Regulation (EC) No 223/2003 (3) Regulation (EC) No 1452/2003	This Regulation
Annex I.B, 4.3		Article 19(1)
Annex I.C, 5.1, 5.2		Article 19(2) to (4)
Annex I.B, 4.1, 4.5, 4.7 and 4.11		Article 20
Annex I.B, 4.4		Article 21
Article 7		Article 22
Annex I.B, 3.13, 5.4, 8.2.5 and 8.4.6		Article 23
Annex I.B, 5.3, 5.4, 5.7 and 5.8		Article 24
Annex I.C, 6		Article 25
Annex III, E.3 and B		Article 26
Article 5(3) and Annex VI, part A and B		Article 27
Article 5(3)		Article 28
Article 5(3)	(1): Article 3	Article 29
Annex III, B.3		Article 30
Annex III.7		Article 31
Annex III, E.5		Article 32
Annex III.7a		Article 33
Annex III, C.6		Article 34
Annex III.8 and A.2.5		Article 35
Annex I.A, 1.1 to 1.4		Article 36
Annex I.B, 2.1.2		Article 37
Annex I.B, 2.1.1, 2.2.1,2.3 and Annex I.C, 2.1, 2.3		Article 38
Annex I.B, 6.1.6		Article 39

▼B

Regulation (EEC) No 2092/91	(1) Regulation (EC) No 207/93 (2) Regulation (EC) No 223/2003 (3) Regulation (EC) No 1452/2003	This Regulation
Annex III, A1.3 and b		Article 40
Annex I.C, 1.3		Article 41
Annex I.B, 3.4 (first indent and 3.6(b))		Article 42
Annex I.B, 4.8		Article 43
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