



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 22 December 2006

17085/06

**Interinstitutional File:
2005/0278 (CNS)**

LIMITE

AGRILEG 230

NOTE

from : General Secretariat of the Council

to : Special Committee of Agriculture

No. Cion prop. : 5101/06

Subject : Proposals for Council Regulations on organic production and labelling of organic products

Delegations will find attached the consolidated text of the general approach agreed by the Agriculture/Fisheries Council on 19-20 December 2006.

Draft

Proposals for Council Regulations on organic production and labelling of organic products

**TITLE I
AIM, SCOPE AND DEFINITIONS¹**

*Article 1
Aim and scope*

1. This Regulation provides the basis for the sustainable development of organic production while ensuring the effective functioning of the internal market, guaranteeing fair competition, ensuring consumer confidence and protecting consumer interests.

It establishes common objectives and principles to underpin the rules set out under this Regulation concerning:

- (a) all stages of production, preparation and distribution of organic products and their controls;
 - (b) the use of indications referring to organic production in labelling and advertising.
2. This Regulation shall apply to the following products originating from agriculture, including aquaculture, where such products are placed on the market or intended to be placed on the market:
 - (a) live or unprocessed agricultural products;
 - (b) processed agricultural products for use as food;
 - (c) feed;
 - (d) vegetative propagating material and seeds for cultivation.

The products of hunting and fishing of wild animals shall not be considered as organic production

In addition to subparagraph 1 it shall also apply to yeasts used as food or feed.

¹ The following recital on GMOs is added:
"Whereas, it is the aim to have the lowest possible presence of GMOs in organic products, the existing labelling thresholds represent ceilings which are exclusively linked to the adventitious and technically unavoidable presence of GMOs".

3. This Regulation shall apply to any operator involved in activities at any stage of production, preparation and distribution of products as set out in Article 1 (2).

However, mass caterers shall not be subject to this Regulation. Member States may apply national rules, or on the absence thereof private standards, on labelling and control of products originating from mass caterers, in so far as said rules comply with Community Law.

4. This Regulation shall apply without prejudice to other community provisions or national provisions, in conformity with Community law concerning products specified in this Article, such as provisions governing the production, preparation, marketing, labelling and control, including legislation in foodstuffs and animal nutrition.

Article 2 **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (a) "organic production" means the use of the production method in compliance with the rules established in this Regulation at all stages of production, preparation and distribution;
- (aa) "stages of production, preparation and distribution" means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;
- (b) "organic" means coming from or related to organic production;
- (bb) "operator" means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the organic business under their control;
- (c) "plant production" means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (d) "livestock production" means the production of domestic or domesticated terrestrial animals (including insects);
- (e) the definition of "aquaculture" given in Regulation (EC) No. 1198/2006¹ shall apply;
- (f) "conversion" means the transition from non organic to organic farming within a given period of time, during which the provisions concerning the organic production have been applied;

¹ OJ L 223, 15.8.2006, p.1.

- (g) "preparation" means the operations of preserving and/or processing of organic products (including slaughter and cutting for livestock products), and also packaging and/or alterations made to the labelling concerning the organic production method;
- (h) the definitions of "food", "feed" and "placing on the market" given in Regulation (EC) No. 178/2002 shall apply;
- (i) "labelling" means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, board, ring or collar accompanying or referring to a product;
- (ii) "pre-packaged foodstuff" has the meaning given by Article 1 (3) (b) of Directive 2000/13/EC of the European Parliament and of the Council¹;
- (j) "advertising" means any representation to the public, by any means other than a label, that is intended or is likely to influence and shape attitude, beliefs and behaviours in order to promote directly or indirectly the sale of organic products;
- (k) "competent authority" means the central authority of a Member State competent for the organisation of official controls in the field of organic production in accordance with the provisions set out under this Regulation, or any other authority on which that competence has been conferred to; it shall also include, where appropriate, the corresponding authority of a third country;
- (kk) "control authority" means a public administrative organisation of a Member State to which the competent authority has conferred, in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding authority of a third country or the corresponding authority operating in a third country;
- (kkk) "control body" means an independent private third party carrying out inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding body of a third country or the corresponding body operating in a third country;
- (m) "mark of conformity" means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;
- (n) "ingredients" has the meaning given by Article 6 (4) of Directive 2000/13/EC of the European Parliament and of the Council;
- (o) "plant protection products" means products as defined in Article 2, point 1 of the Council Directive 91/414/EEC²;

¹ OJ L 109, 6.5.2000, p. 29

² OJ L 230, 19.8.1991, p. 1.

- (p) "Genetically modified organism (GMO)" means an organism as defined in Article 2 (2) of Directive 2001/18 and which is not obtained through the techniques of genetic modifications listed in Annex I.B of Directive 2001/18;
- (q) "produced from GMOs" means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (r) "produced by GMOs" means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;
- (s) "feed additives" means products as defined in Article 2 (a) of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council¹;
- (t) "equivalent", in describing different systems or measures, means that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (u) "processing aid" means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product;
- (v) "ionising radiation" means radiation as defined in Article 1 of Directive 96/29/EURATOM.

¹ OJ L 268, 18.10.2003, p. 29.

TITLE II OBJECTIVES AND PRINCIPLES FOR ORGANIC PRODUCTION

Article 3 **Objectives**

The organic production shall pursue the following general objectives:

- (a) to establish a sustainable management system for agriculture that:
 - (i) respects nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals and balance between them;
 - (ii) contributes to a high level of biological diversity;
 - (iii) makes responsible use of energy and the natural resources, such as water, soil, organic matter and air;
 - (iv) respects high animal welfare standards and in particular meets animals' species-specific behavioural needs;
- (b) to aim at producing products of high quality;-
- (c) to aim at producing a wide variety of foods and other agricultural products that respond to consumers' demand for goods produced by use of processes that do not harm the environment, human health, plant health or animal health and welfare.

Article 4 **Overall principles**

Organic production shall be based on the following principles:

- (a) the appropriate design and management of biological processes based on ecological systems using system-internal natural resources by methods that:
 - (i) use living organisms and mechanical production methods;
 - (ii) practice land-related crop cultivation and livestock production or aquaculture which complies with the principle of sustainable exploitation of fisheries;
 - (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products;

- (iv) are based on risk assessment, and use of precautionary and preventive measures, when appropriate;
- (b) restricting the use of external inputs. Where they are required or the appropriate management practices and methods referred to in paragraph (a) do not exist, they are limited to:
 - (i) inputs from organic production ;
 - (ii) natural or naturally-derived substances;
 - (iii) low solubility mineral fertilizers;
- (c) strictly limiting the use of chemically synthesised inputs to exceptional cases where:
 - (i) the appropriate management practices do not exist; and
 - (ii) where the external inputs referred to in paragraph (b) are not available on the market; or
 - (iii) the use of external inputs referred to in paragraph (b) contributes to unacceptable environmental impacts;
- (d) where necessary adapting, within the frame of this Regulation, the rules of organic production taking account of sanitary status, regional differences in climate and local conditions, stages of development and specific husbandry practices.

Article 5
Principles applicable to farming

In addition to the overall principles set out in Article 4, organic farming shall be based on the following specific principles:

- (a) maintaining and enhancing soil life and natural soil fertility, soil stability and soil biodiversity preventing and combating soil compaction and soil erosion, and nourishing plants primarily through the soil ecosystem;
- (b) minimising the use of non-renewable resources and off-farm inputs;
- (c) recycling wastes and by-products of plant and animal origin as input in plant and livestock production;
- (d) taking account of the local or regional ecological balance when taking production decisions;
- (e) maintaining animal health by encouraging the natural immunological defence of the animal, as well as the selection of appropriate breeds and husbandry practices;

- (ee) maintaining plant health by preventative measures, such as the choice of appropriate species and varieties resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and the protection of natural enemies of pests;
- (f) practising site-adapted and land-related livestock production;
- (g) observing a high level of animal welfare respecting species-specific needs;
- (h) producing products of organic livestock production from animals that since birth or hatching and throughout their life have been raised on organic holdings;
- (i) choosing breeds having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems;
- (j) feeding livestock with organic feed composed of agricultural ingredients from organic farming and of natural non-agricultural substances;
- (k) applying animal husbandry practices, which enhance the immune system and strengthen the natural defence against diseases, in particular including regular exercise and access to open air areas and pastureland where appropriate;
- (l) excluding rearing artificially induced polyploid animals;
- (m) maintaining as regards aquaculture production, the biodiversity of natural aquatic ecosystems, over time the health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystem;
- (n) feeding aquatic organisms with feed from sustainable exploitation of fisheries as defined in Article 3 of Regulation 2371/2002¹ or with organic feed composed of agricultural ingredients from organic farming and of natural non-agricultural substances.

Article 6

Principles applicable to processing of organic food

In addition to the overall principles set out in Article 4, the production of processed organic food shall be based on the following specific principles:

- (a) producing organic food from organic agricultural ingredients, except where an ingredient is not available on the market in organic form;
- (b) restricting the use of food additives, non organic ingredients with mainly technological and sensory functions as well as micronutrients and processing aids, so that they are used to a minimum extent and only in case of essential technological need or for particular nutritional purposes;

¹ OJ

- (c) excluding substances and processing methods that might be misleading regarding the true nature of the product;
- (d) processing food with care, preferably by use of biological, mechanical and physical methods.

Article 6a

Principles applicable to processing of organic feed

In addition to the overall principles set out in Article 4, the production of processed organic feed shall be based on the following specific principles:

- (a) producing organic feed from organic feed materials, except where a feed material is not available on the market in organic form;
- (b) restricting the use of feed additives and processing aids to a minimum extent and only in case of essential technological or zootechnical need or for particular nutritional purposes;
- (c) excluding substances and processing methods that might be misleading regarding the true nature of the product;
- (d) processing of feed with care, preferably by use of biological, mechanical and physical methods.

**TITLE III
PRODUCTION RULES**

Article 7a

General Requirements

Operators shall comply with the production rules set out in this Title and those laid down in implementing rules mentioned in Article 32(a).

Article 7aa

Prohibition on the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production.

2. For the purpose of the prohibition referred to in paragraph 1 concerning GMOs or products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed or provided pursuant to Directive of the European Parliament and of the Council 2001/18/EC, Regulation of the European Parliament and the Council 1829/2003 or Regulation of the European Parliament and the Council 1830/2003.

Operators may assume that no GMOs or products produced from GMOs have been used in the manufacture of purchased food and feed products when the latter are not labelled, or accompanied by a document, pursuant to those Regulations, unless they have obtained other information indicating that labelling of the products in question is not in conformity with those Regulations.

3. For the purpose of the prohibition referred to in paragraph (1) concerning products not being food or feed, or products produced by GMOs, operators using such non organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.
4. In accordance with the procedure referred to in Article 31 (2) the Commission shall decide on measures implementing the prohibition on the use of GMOs and products produced from or by GMOs.

Article 7aaa

Prohibition on the use of ionising radiation

The use of ionising radiation for treatment of organic food or feed, or of raw materials used in organic food or feed is prohibited.

CHAPTER 1 FARM PRODUCTION

Article 7

General farm production rules

The entire agricultural holding shall be managed in compliance with the requirements applicable to organic production.

However, in accordance with specific conditions to be laid down in accordance with the procedure referred to in Article 31 (2), a holding may be split up into clearly separated units or aquaculture production sites which are not all managed under organic production. As regards animals different species shall be involved. As regards aquaculture the same species may be involved, provided that there is adequate separation between the production sites. As regards plants different varieties that can be easily differentiated shall be involved.

Where, in accordance with the second subparagraph, not all units of a holding are used for organic production, the farmer shall keep the land, animals, and products used for, or produced by, the organic units separate from those used for, or produced by, the non-organic units and keep adequate records to show the separation.

Article 8 **Plant production rules**

1. In addition to the general rules laid down in Article 7, the following rules shall apply to organic plant production:
 - (a) organic plant production shall use tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion;
 - (b) fertility and biological activity of the soil shall be maintained and increased by multi-annual crop rotation including legumes and other green manure crops, application of livestock manure or organic material, preferably composted, from organic production;
 - (bb) the use of biodynamic preparations is allowed;
 - (c) in addition, fertilisers and soil conditioners may only be used if they have been authorised for use in organic production under Article 11;
 - (d) mineral nitrogen fertilisers shall not be used;
 - (e) all plant production techniques used shall prevent or minimise any contribution to contamination of the environment;
 - (f) prevention of damage caused by pests, diseases and weeds shall rely primarily on the protection by natural enemies, the choice of species and varieties, crop rotation, cultivation techniques and thermal processes;
 - (g) in the case of an established threat to a crop, plant protection products may only be used if they have been authorised for use in organic production under Article 11;

- (h) for the production of products other than seed and vegetative propagating material only organically produced seed and propagating material shall be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons;
 - (i) products for cleaning and disinfection in plant production shall be used only if they have been authorised for use in organic production under Article 11.
2. The collection of wild plants and parts thereof, growing naturally in natural areas, forests and agricultural areas is considered an organic production method provided that:
 - (a) those areas have not, for a period of at least three years before the collection, received treatments with products other than those authorised for use in organic production under Article 11;
 - (b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.
 3. The measures necessary for the implementation of the production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 31 (2).

Article 8a

Production rules for seaweed

1. The collection of edible seaweeds and parts thereof, growing naturally in the sea, is considered an organic production method provided that:
 - (a) the growing areas are of high ecological quality as defined by EU Water Legislation¹ and are not unsuitable from a health point of view. Pending more detailed rules to be introduced in implementing legislation wild edible seaweeds shall not be collected in areas which would not meet the criteria for Class A or Class B areas as defined in Annex II of Regulation 854/2004²;
 - (b) the collection does not affect the long term stability of the natural habitat or the maintenance of the species in the collection area.

¹ The Water Framework Directive 2000/60/EC (OJ L 327, 22.10.2000, p1) will not be fully implemented until 2015, in the meantime relevant parts of the water legislation shall apply (including the Directive 79/923/EEC on the quality required of shellfish waters (OJ L 281, 10.11.1979, p 47).

² OJ L 226, 25.06.2004, p 119.

2. The farming of seaweeds shall take place in coastal areas with environmental and health characteristics at least equivalent to those outlined in paragraph 1 in order to be considered organic and in addition:
 - (a) sustainable practices shall be used in all stages of production from collection of juvenile seaweed to harvesting;
 - (b) to ensure that a wide gene-pool is maintained, collection of juvenile seaweed in the wild should take place on a regular basis to supplement indoor culture stock;
 - (c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production under Article 11.
3. The measures necessary for the implementation of production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 11.

Article 9

Livestock production rules

1. In addition to the general farm production rules laid down in Article 7, the following rules shall apply to livestock production:
 - (a) with regard to the origin of the animals:
 - (i) organic livestock shall be born and raised on organic holdings;
 - (ii) for breeding purposes, non-organically raised animals may be brought onto a holding under specific conditions. Such animals and their products may be deemed organic after compliance with the conversion period referred to in Article 12 (1) (c);
 - (iii) animals existing on the holding at the beginning of the conversion period and their products may be deemed organic after compliance with the conversion period referred to in Article 12 (1) (c);
 - (b) with regard to husbandry practices and housing conditions:
 - (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;
 - (ii) husbandry practices, including stocking densities, and housing conditions shall ensure that developmental, physiological and ethological needs of animals are met;
 - (iii) the livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation;

- (iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;
 - (v) organic livestock shall be kept separate from other livestock. However, grazing of common land by organic animals and of organic land by non-organic animals is permitted under certain restrictive conditions;
 - (vi) tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time and justified for safety, welfare or veterinary reasons;
 - (vii) duration of transport of livestock shall be minimised;
 - (viii) any suffering, including mutilation, shall be kept to a minimum during the entire life of the animal, including at the time of slaughter;
 - (ix) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods. They shall keep enough distance from sources that may lead to contamination of beekeeping products or to poor health of the bees;
 - (x) hives and materials used in beekeeping shall be mainly made of natural materials;
 - (xi) the destruction of bees in the combs as a method associated with the harvesting of beekeeping products is prohibited;
- (c) with regard to breeding:
- (i) reproduction shall use natural methods. However, artificial insemination is allowed;
 - (ii) reproduction shall not be induced by treatment with hormones or similar substances, unless as a form of veterinary therapeutic treatment in case of an individual animal;
 - (iii) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;

- (iv) appropriate breeds shall be chosen. The choice of breeds shall also contribute to the prevention of any suffering and to avoiding the need for mutilation of animals;
- (d) with regard to feed:
- (0) primarily obtaining feed for livestock from the holding where the animals are kept or other organic holdings in the same region;
 - (i) livestock shall be fed with organic feed that meets the animal's nutritional requirements at the various stages of its development. A part of the ration may contain feed from holdings in conversion to organic farming;
 - (ii) livestock with the exception of bees shall have permanent access to pasture or roughage;
 - (iii) non organic feed materials from plant origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorized for use in organic production under Article 11;
 - (iv) growth promoters and synthetic amino-acids shall not be used;
 - (v) suckling mammals shall be fed with natural, preferably maternal, milk;
- (e) with regard to disease prevention and veterinary treatment:
- (i) disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions;
 - (ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate, in particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;
 - (iii) the use of immunological veterinary medicines is allowed;
 - (iv) treatments related to the protection of human and animal health imposed on the basis of Community legislation shall be allowed;
- (f) with regard to cleaning and disinfection, products for cleaning and disinfection in livestock buildings and installations, shall be used only if they have been authorized for the use in organic production under Article 11.

2. *(text has been deleted)*
3. The measures and conditions necessary for the implementation of the production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 31 (2).

Article 10

Production rules for aquaculture animals

1. In addition to the general farm production rules laid down in Article 7, the following rules shall apply to aquaculture animals production:
 - (a) with regard to the origin of the aquaculture animals:
 - (i) organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and organic holdings;
 - (ii) when young stock from organic broodstock or holdings are not available, non-organically produced animals may be brought onto a holding under specific conditions;
 - (b) with regard to husbandry practices:
 - (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;
 - (ii) husbandry practices, including feeding, design of installations, stocking densities and water quality, shall ensure that developmental, physiological and behavioural needs of animals are met;
 - (iii) husbandry practices shall minimise negative environmental impact from the holding, including the escape of farmed stock;
 - (iv) organic animals shall be kept separate from other aquaculture animals;
 - (v) transport shall ensure that the welfare of animals is maintained;
 - (vi) any suffering of the animals including the time of slaughtering shall be kept to a minimum;
 - (c) with regard to breeding:
 - (i) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;

- (ii) the appropriate strains compatible with the objectives and principles of organic production shall be chosen;
 - (iii) species-specific conditions for broodstock management, breeding and juvenile production shall be established;
- (d) with regard to feed for fish and crustaceans:
- (i) animals shall be fed with feed that meets the animal's nutritional requirements at the various stages of its development;
 - (ii) the plant fraction of feed shall originate from organic production and the feed fraction derived from aquatic animals shall originate from sustainable exploitation of fisheries;
 - (iii) in the case of non-organic feed materials from plants origin, feed materials from animal and mineral origin, feed additives, certain products used in animal nutrition and processing aids shall be used only if they have been authorised for use in organic production under Article 11;
 - (iv) growth promoters and synthetic amino-acids shall not be used;
- (dd) with regard to bivalve molluscs and other species which are not fed by man but feed on natural plankton:
- (i) such filter-feeding animals shall receive all their nutritional requirements from nature except in the case of juveniles reared in hatcheries and nurseries;
 - (ii) they shall be grown in waters which meet the criteria for Class A or Class B areas as defined in Annex II of Regulation 854/2004¹;
 - (iii) the growing areas shall be of high ecological quality as defined by EU Water Legislation²;
- (e) with regard to disease prevention and veterinary treatment:
- (i) disease prevention shall be based on keeping the animals in optimal conditions by appropriate siting, optimal design of the holdings, the application of good husbandry and management practices, including regular cleaning and disinfection of premises, high quality feed, appropriate stocking density, and breed and strain selection;

¹ OJ L 226, 25.06.2004, p 119.

² The Water Framework Directive 2000/60/EC (OJ L 327, 22.10.2000, p1) will not be fully implemented until 2015, in the meantime relevant parts of the water legislation shall apply (including the Directive 79/923/EEC on the quality required of shellfish waters (OJ L 281, 10.11.1979, p 47).

- (ii) disease shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phytotherapeutic, homeopathic and other products is inappropriate, in particular restrictions with respect to courses of treatment and withdrawal periods shall be defined;
 - (iii) the use of immunological veterinary medicines is allowed;
 - (iv) treatments related to the protection of human and animal health imposed on the basis of Community legislation shall be allowed.
- (f) With regard to cleaning and disinfection, products for cleaning and disinfection in ponds, cages, buildings and installations, shall be used only if they have been authorised for use in organic production under Article 11.
2. *(text has been deleted)*
3. The measures and conditions necessary for the implementation of the production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 31 (2).

Article 11

Products and substances used in farming and criteria for their authorisation

1. The Commission shall in accordance with the procedure referred to in Article 31 (2) authorize for use in organic production and include in a restricted list the products and substances, which may be used in organic farming for the following purposes:
- (a) plant protection products;
 - (b) fertilisers and soil conditioners;
 - (c) non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition;
 - (d) feed additives and processing aids;
 - (e) products for cleaning and disinfection of ponds, cages, buildings and installations for animal production;
 - (f) products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.

Products and substances contained in the restricted list may only be used in so far as the corresponding use is authorized in general agriculture in the Member States concerned in accordance with the relevant Community provisions or national provisions in conformity with Community law.

2. The authorization of the products and substances referred to in paragraph 1 is subject to the objectives and principles laid down in Title II and the following general and specific criteria which shall be evaluated as a whole:
 - (a) their use is necessary for sustained production and essential for its intended use;
 - (b) all products and substances shall be of plant, animal, microbial or mineral origin except if products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available;
 - (c) in the case of products referred to in paragraph (1) (a), the following shall apply:
 - (i) their use is essential for the control of a harmful organism or a particular disease for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available;
 - (ii) if products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be approved only if their conditions for use preclude any direct contact with the edible parts of the crop;
 - (d) in the case of products referred to in paragraph (1) (b), their use is essential for obtaining or maintaining the fertility of the soil or to fulfil specific nutrition requirements of crops, or specific soil-conditioning purposes;
 - (e) in the case of products referred to in paragraph (1) (c) and 1 (d), the following shall apply:
 - (i) they are necessary to maintain animal health, animal welfare and vitality and contribute to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned or without having recourse to such substances, it is impossible to produce or preserve such feed;
 - (ii) feed of mineral origin, trace elements, vitamins or provitamins are of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorized for use in organic production.
3. (a) The Commission may, in accordance with the procedure referred to in Article 31(2), lay down conditions and limits as regards the agricultural products to which the products and substances referred to in paragraph 1 can be applied to, the application method, the dosage, the time limits for use and the contact with agricultural products and, if necessary, decide on withdrawal of these products and substances.

- (b) Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States.
 - (c) Products and substances used before adoption of this Regulation for purposes corresponding to those laid down in paragraph 1 of this Article, may continue to be used after said adoption. The Commission may in any case withdraw such products or substances in accordance with Article 31(2).
4. Member States may regulate, within their territory, the use of products and substances in organic farming other than those listed in paragraph (1) (a) to (f) for purposes different than those mentioned in paragraph (1) (a) to (f) provided their use is subject to objectives and principles laid down in Title II and the general and specific criteria set out in paragraph 2, and in so far as it respects Community law. The Member State concerned shall inform other Member States and the Commission of such national rules.
5. The use of products and substances from categories different from those mentioned under paragraph 1 and 4, subject to the objectives and principles laid down in Title II and the general criteria in this Article, is allowed in organic farming.

Article 12 **Conversion**

1. The following rules shall apply to a farm on which organic production is started:
- (a) the conversion period shall start at the earliest when the operator has notified and subjected his holding to the control system in accordance with Article 23 (1);
 - (b) during the conversion period all rules established by this Regulation shall apply;
 - (c) conversion periods specific to the type of crop or animal production shall be defined;
 - (d) on a holding or unit partly under organic production and partly in conversion to organic production, the farmer shall keep the organically produced and in conversion products separate and animals separate or readily separable and keep adequate records to show the separation;
 - (e) in order to determine the conversion period referred to above, a period immediately preceding the date of the start of the conversion period, may be taken into account, in so far as certain conditions concur;
 - (f) animals and animal products produced during the conversion period referred to in subparagraph (c) shall not be marketed with indications referred to in Articles 17 and 18 used in labelling and advertising of products.

2. The measures and conditions necessary for the implementation of the rules contained in this Article, and in particular the periods referred to in paragraph (1) (c to f) shall be defined in accordance with the procedure referred to in Article 31(2).

CHAPTER 2

PRODUCTION OF PROCESSED FEED

Article 13

General rules on the production of processed feed

1. Production of processed organic feed shall be kept separate in time or space from production of processed non organic feed.
2. Organic feed materials, or feed materials from production in conversion, shall not enter simultaneously with the same feed materials produced by non organic means into the composition of the organic feed product.
3. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.
4. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic feed, that correct the results of negligence in the processing or that otherwise may mislead regarding the true nature of these products shall not be used.
5. The measures and conditions necessary for the implementation of the production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 31 (2).

Chapter 3

PRODUCTION OF PROCESSED FOOD

Article 14

General rules on the production of processed food

0. Preparation of processed organic food shall be kept separate in time or space from non-organic food.

1. The following conditions shall apply to the composition of organic processed food:
 - (a) the product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin added water and salt shall not be taken into account;
 - (b) only additives, processing aids, flavourings, water, salt, preparations of micro-organisms and enzymes, minerals, trace elements, vitamins, as well as aminoacids and other micronutrients in foodstuffs for particular nutritional uses may be used in so far they have been authorized for use in organic production in accordance with Article 15;
 - (c) non-organic agricultural ingredients may be used only if they have been authorized for use in organic production in accordance with Article 15 or have been provisionally authorized by a Member State;
 - (d) an organic ingredient shall not be present together with the same ingredient in non-organic form or from conversion;
 - (e) food produced from in conversion crops shall contain only one crop ingredient of agricultural origin.
2. Substances and techniques, other than by adding natural flavourings, that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of these products or that otherwise may mislead regarding the true nature of these products shall not be used.

The measures necessary for the implementation of the production rules contained in this Article, and in particular regarding processing methods, the conditions for the provisional authorization by Member States mentioned in paragraph 1 (c) and the conditions for the use of non-organic agricultural ingredients in the preparation of organic food by mass caterers, shall be adopted in accordance with the procedure referred to in Article 31 (2).

Article 14a

General rules on the production of organic yeast

1. For the production of organic yeast only organically produced substrates shall be used. Other products and substances may only be used in so far as they have been authorized for use in organic production in accordance with Article 15.
2. Organic yeast shall not be present in organic food or feed together with non-organic yeast.
3. Detailed production rules may be laid down in accordance with the procedure referred to in Article 31 (2).

Article 15

Criteria for certain products and substances in processing

1. The authorization of products and substances for use in organic production and their inclusion in the restricted list referred to in Article 14(1) (b) and (c) shall be subject to the objectives and principles laid down in Title II and the following criteria, which shall be evaluated as a whole:
 - (i) alternatives authorized in accordance with this chapter are not available;
 - (ii) without having recourse to them, it is impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of the Community legislation.

In addition, the products and substances referred to in Article 14(1) (b) are found in nature and may only have undergone mechanical, physical, biological, enzymatic or microbial processes, except if such products and substances from such sources are not available in sufficient quantities or qualities on the market.

2. The Commission shall, in accordance with the procedure referred to in Article 31(2), decide on authorization of the products and substances and their inclusion in the restricted list referred to in paragraph 1 and lay down specific conditions and limits for their use, and, if necessary, on withdrawal of products.

Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in this paragraph should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States.

CHAPTER 4

FLEXIBILITY

Article 16

Exceptional production rules

1. The Commission may, in accordance with the procedure referred to in Article 31(2) and the conditions set out in paragraph 2 and subject to the objectives and principles laid down in Title II, provide for the granting of exceptions from the production rules laid down in Chapters 1 to 3.
2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and where appropriate limited in time and may only be provided for in the following cases:

- (a) where they are necessary in order to ensure that organic production can be initiated or maintained on holdings confronted with climatic, geographical or structural constraints;
 - (b) where it is necessary in order to ensure access to feed, seed and vegetative propagating material, live animals and other farm inputs, where such inputs are not available on the market in organic form;
 - (c) where it is necessary in order to ensure access to ingredients of agricultural origin, where such ingredients are not available on the market in organic form;
 - (d) where they are necessary in order to solve specific problems related to the management of organic livestock;
 - (e) where they are necessary with regard to the use of specific products and substances in the processing referred to in Article 14 (1) (b) in order to ensure production of well established food products in organic form;
 - (f) where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances;
 - (g) where it is necessary to use food additives and other substances as set out in Article 14 (1) (b) or feed additives and other substances as set out in Article 11 (1) (d) and such substances are not available on the market not produced from or by GMOs;
 - (h) where the use of food additives and other substances as set out in Article 14(1)(b) or feed additives as set out in Article 11(1)(d) is required on the basis of Community law or national law.
3. The Commission may in accordance with the procedure referred to in Article 31(2) lay down specific conditions for the application of exceptions provided for under paragraph 1.

TITLE IV LABELLING

Article 17

Use of terms referring to organic production

1. For the purposes of this Regulation a product shall be regarded as bearing terms referring to the organic production method where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials are described in terms suggesting to the purchaser that the product, its ingredients or feed materials have been obtained in accordance with the rules laid down in this Regulation. In particular, the terms listed in the Annex, their derivatives or diminutives, such as "bio" and "eco", alone or combined, may be used throughout the Community and in any Community language for the labelling and advertising of a product which satisfy the requirements set out under or pursuant to this Regulation.

The labelling and advertising of a product referred to in Article 1 (2)(a) may use terms referring to the organic production method only where all the ingredients of that product have been produced in accordance with the requirements laid down in this Regulation.

2. The terms referred to in paragraph 1 shall not be used anywhere in the Community and in any Community language for the labelling, advertising and commercial documents of a product which does not satisfy the requirements set out under this Regulation, unless they are not applied to agricultural products in food or feed or clearly have no connection with organic production.

Furthermore, any terms, including terms used in trademarks, or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients satisfy the requirements set out under this Regulation shall not be used.

3. The terms referred to in paragraph 1 shall not be used for a product for which it has to be indicated in the labelling or advertising that it contains GMOs, consists of GMOs or is produced from GMOs according to Community provisions.
4. As regards processed food, the terms referred to in paragraph 1 may be used
 - (a) in the sales description provided that:
 - (i) the processed food complies with Article 14;
 - (ii) at least 95% by weight, of its ingredients of agricultural origin are organic;
 - (b) only in the list of ingredients, provided that the food complies with Article 14 (0), 14 (1)(a), 14 (1)(b) and 14(1)(d);
 - (c) in the list of ingredients and in the same visual field as the sales description, provided that:
 - (i) the main ingredient is wild fish or wild game;
 - (ii) it contains other ingredients of agricultural origin that are all organic;
 - (iii) the food complies with Article 14 (0), 14 (1)(a), 14 (1)(b) and 14(1)(d).

The list of ingredients shall indicate which ingredients are organic.

In the case where points (b) and (c) of this paragraph apply, the list of ingredients shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of ingredients of agricultural origin.

The terms and the indication of percentage referred to in the first subparagraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients.

5. Member States shall take the measures necessary to ensure compliance with this Article.
6. The Commission may in accordance with the procedure referred to in Article 31(2) adapt the list of terms set out in the Annex.

Article 18
Compulsory indications

1. Where terms as referred to in Article 17(1) are used:
 - (a) the code number referred to in Article 22(6) of the control authority or control body to which the operator who has carried out the most recent production or preparation operation is subject, shall also appear in the labelling;
 - (b) the Community logo referred to in Article 19 (1) as regards pre-packaged food shall also appear on the packaging;
 - (c) where the Community logo is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed, shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:
 - "EU Agriculture", where the agricultural raw material has been farmed in the EU;
 - "non-EU Agriculture", where the agricultural raw material has been farmed in third countries;
 - "EU/non-EU Agriculture", where part of the agricultural raw materials has been farmed in the Community and a part of it has been farmed in a third country.

The mention "EU" or "non-EU" referred to in the first subparagraph may be replaced or supplemented by a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.

The indication referred to in the first subparagraph may not take into account ingredients that are less than 2% of the total quantity of raw materials of agricultural origin.

The indication referred to in the first subparagraph shall not appear in a colour, size and style of lettering more prominent than the sales description of the product.

The use of the Community logo as referred to in Article 19 (1) and the indication referred to in the first subparagraph shall be optional for products imported from third countries. However, where the Community logo as referred to in Article 19 (1) appears in the labelling, the indication referred to in the first subparagraph shall also appear in the labelling.

2. The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.
3. The Commission shall in accordance with the procedure referred to in Article 31(2) lay down specific criteria as regards the presentation, composition and size of the indications referred to in paragraph 1 (a) and (c).

Article 19

Organic production logos

1. The Community organic production logo may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.

The Community logo shall not be used in the case of conversion products and food as referred to in Article 17 (4) (b) and (c).

2. National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.
3. The Commission shall, in accordance with the procedure referred to in Article 31(2), lay down specific criteria as regards presentation, composition, size and design of the Community logo.

Article 20 is deleted

Article 21

Specific labelling requirements

The Commission shall in accordance with the procedure referred to in Article 31(2) establish specific labelling and composition requirements applicable to:

- (a) organic feed;
- (b) conversion products of plant origin;
- (c) vegetative propagating material and seeds for cultivation.

TITLE V
CONTROLS

Article 22
Control system

1. Member States shall set up a system of controls and designate one or more competent authorities responsible for controls in respect of the obligations established by this Regulation in conformity with Regulation (EC) No 882/2004.
- 1a In addition to the conditions laid down in Regulation (EC) No 882/2004, the control system set up under this Regulation shall comprise at least the application of precautionary and control measures to be adopted by the Commission in accordance with the procedure referred to in Article 31(2).
2. In the context of this Regulation the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation. In any case, all operators with the exception of wholesalers dealing only with pre-packaged products and operators selling to the final consumer or user as described in Article 23 (2) , shall be subject to a verification of compliance at least once a year.
3. The competent authority may
 - a) confer to one or more other control authorities its control competences. Control authorities shall offer adequate guarantees of objectivity and impartiality, and have at their disposal the qualified staff and resources necessary to carry out their functions;
 - b) delegate control tasks to one or more control bodies. In that case, the Member States shall designate authorities responsible for the approval and supervision of such bodies.
- 3aa The competent authority may delegate control tasks to a particular control body only if the conditions laid down in Article 5(2) of Regulation (EC) No 882/2004 are satisfied, and in particular if
 - (a) there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out;
 - (b) there is proof that the control body:

- (i) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;
 - (ii) has a sufficient number of suitable qualified and experienced staff; and
 - (iii) is impartial and free from any conflict of interest as regards the exercise of the tasks delegated to it;
- (c) the control body is accredited to the European Standard EN 45011 or ISO Guide 65 ‘General requirements for bodies operating product certification systems’ of the version as most recently notified by a publication in the *Official Journal of the European Union, C series* and is approved by the competent authorities;
- (d) the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority;
- (e) there is an effective coordination between the delegating competent authority and the control body.
- 3a In addition to the provisions of paragraph 3aa, the competent authority shall take into account the following criteria whilst approving a control body:
- (a) the standard control procedure to be followed, containing a detailed description of the control measures and precautions that the body undertakes to impose on operators subject to its control;
 - (b) the measures that the control body intends to apply where irregularities and/or infringements are found.
4. The competent authorities may not delegate or confer the following tasks to the control bodies;
- (a) the supervision and audit of other control bodies;
 - (b) the competence to grant exceptions, as referred to in Article 16, unless this is provided for in the specific conditions laid down by the Commission in accordance with Article 16(3).
5. In accordance with Article 5(3) of Regulation (EC) No 882/2004, competent authorities delegating control tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.

- 5a In addition to the provisions of paragraph 5, the competent authority shall
- (a) ensure that the controls carried out by the control body are objective and independent;
 - (b) verify the effectiveness of its controls;
 - (c) take cognizance of any irregularities or infringements found and corrective measures applied;
 - (d) withdraw approval of that body where it fails to satisfy the requirements referred to in (a) and (b) or no longer fulfils the criteria indicated in paragraph 3a or fails to satisfy the requirements laid down in paragraphs 6a, 6aa and 7.
6. Member States shall attribute a code number to each control authority or control body performing control tasks as referred to in paragraph (3).
- 6a Control authorities and control bodies shall give the competent authorities access to their offices and facilities and provide any information and assistance deemed necessary by the competent authorities for the fulfilment of their obligations according to this Article.
- 6aa The control authorities and control bodies shall ensure that at least the precautionary and control measures referred to in paragraph 1a are applied to operators subject to their control.
- 6aaa Member States shall ensure that the control system as set up allows, in accordance with Article 18 of Regulation (EC) N° 178/2002, for traceability of each product at all stages of production, preparation and distribution, notably to give consumers guarantees that organic products have been produced in compliance with the requirements set out in this Regulation.
7. The control authorities and control bodies shall by 31 January each year at the latest transmit to the competent authorities a list of the operators which were subject to their controls on 31 December of the previous year. A summary report of the control activities carried out during the previous year shall be provided by 31 March each year.

Article 23

Adherence to the control system

1. Any operator who produces, prepares, stores or imports from a third country products in the meaning of Article 1 (2) or who places such products on the market, shall prior to placing any products labelled as organic or in conversion to organic on the market:

- (a) notify his activity to the competent authorities of the Member State where the activity is carried out;
- (b) submit his undertaking to the control system referred to in Article 22.

The first paragraph shall apply also to exporters who export products produced in compliance with the production rules laid down in this Regulation.

Where an operator contracts out any of the activities to a third party, that operator shall nonetheless be subject to the requirements referred to in points (a) and (b), and the subcontracted activities shall be subject to the control system.

2. Member States may exempt from the application of this Article operators who sell products directly to the final consumer or user provided they do not produce, prepare, store other than in connection with the point of sale or import such products from a third country or have not contracted out such activities to a third party.
- 2a Member States shall designate an authority or approve a body for the reception of such notifications.
3. Member States shall ensure that any operator who complies with the rules of this Regulation, and who pays a reasonable fee as a contribution to the control expenses, is entitled to be covered by the control system.
4. The control authorities and control bodies shall keep an updated list containing the names and addresses of operators subject to the control system. This list shall be made available to the interested parties.
5. The Commission, in accordance with the procedure referred to in Article 31(2), shall adopt implementing rules to provide details of the notification and submission procedure referred to in paragraph 1 in particular with regard to the information included in the notification referred to in paragraph 1 point a.

Article 23a

Documentary evidence

1. The control authorities and the control bodies referred to in Article 22(3) shall provide documentary evidence to any such operator who is subject to their controls and who in the sphere of his activities, meets the requirements laid down in this Regulation. The documentary evidence shall at least permit the identification of the operator and the type or range of products as well as the period of validity.
2. The operator shall verify the documentary evidence of his suppliers.

3. The form of the documentary evidence referred to in paragraph 1 shall be drawn up in accordance with the procedure referred to in Article 31(2), taking into account the advantages of electronic certification.

Article 24 is deleted

Article 25

Measures in case of infringements and irregularities

1. 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 the terms, indications and the logo referring to the organic production method are not used on the entire lot or production run affected by this irregularity, where such measure is proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities.

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 with terms, indications and the logo referring to the organic production method for a period to be agreed with the competent authority of the Member State.

2. Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the concerned control bodies, control authorities, competent authorities, Member States and, where appropriate, to the Commission.

The level of communication shall depend on the severity and the extent of the irregularity or infringement found.

The Commission may in accordance with the procedure referred to in Article 31(2) lay down specifications regarding the form and modalities of such communications.

Article 26

Exchange of information

Upon request duly justified by the necessity to guarantee that a product has been produced in accordance with this Regulation, the competent authorities and the control bodies shall exchange with other competent authorities and control bodies relevant information on the results of their controls. They may also exchange such information on their own initiative.

TITLE VI
TRADE WITH THIRD COUNTRIES

Article 27

Import of compliant products

1. A product imported from a third country may be placed on the Community market labelled as organic provided that:
 - (a) the product complies with the provisions set out in Titles II, III and IV of this Regulation;
 - (b) all operators, including the exporters, have been subject to control by a control authority or control body recognised in accordance with paragraph 2;
 - (c) the operators concerned shall be able to provide at any time, to the importers or the national authorities, documentary evidence as referred to in Article 23a, issued by the control authority or control body referred to in subparagraph (b).
2. The Commission shall in accordance with the procedure referred to in Article 31(2) recognise the control authorities and control bodies referred to in paragraph 1 (b), including control authorities and control bodies as referred to in Article 22, competent to carry out controls and to issue the documentary evidence referred to in paragraph 1 (c) in third countries, and establish a list of these control authorities and control bodies.

The control bodies shall be accredited to the European Standard EN 45011 or ISO Guide 65 'General requirements for bodies operating product certification systems' of the version most recently notified by a publication in the *Official Journal of the European Union, C series*. The control bodies shall undergo regular on-the-spot evaluation, surveillance and multi-annual re-assessment of their activities by the accreditation body.

When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information. The Commission may also entrust experts with the task of examining on-the-spot the rules of production and the control activities carried out in the third country by the control authority or control body concerned.

The recognised control bodies or control authorities shall provide the assessment reports issued by the accreditation body or, as appropriate, the competent authority on the regular on-the-spot evaluation, surveillance and multi-annual re-assessment of their activities.

Based on the assessment reports, the Commission assisted by the Member States ensures appropriate supervision of the recognised control authorities and control bodies by regularly reviewing their recognition. The nature of the supervision shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions set out in this Regulation.

Article 27a

Import of products providing equivalent guarantees

1. A product imported from a third country may also be placed on the Community market labelled as organic provided that:
 - (a) the product has been produced in accordance with production rules equivalent to those referred to in Titles III and IV;
 - (b) the operators have been subject to control measures of equivalent effectiveness to those referred to in Title V and such control measures have been permanently and effectively applied;
 - (c) the operators at all stages of production, preparation and distribution in the third country have submitted their activities to a control system recognised in accordance with paragraph 2 or to a control authority or control body recognised in accordance with paragraph 3;
 - (d) the product is covered by a certificate issued by the competent authorities, control authorities or control bodies of the third country recognised in accordance with paragraph 2, or by a control authority or control body recognised in accordance with paragraph 3, which confirms that the product satisfies the conditions set out in this paragraph.

The certificate referred to in this subparagraph shall accompany the goods, in the original copy, to the premises of the first consignee; thereafter the importer must keep the certificate at the disposal of the control authority or the control body for not less than two years.

2. The Commission may in accordance with the procedure referred to in Article 31(2) recognise the third countries whose system of production complies with principles and production rules equivalent to those laid down in Titles II, III and IV and whose control measures are of equivalent effectiveness to those laid down in Title V, and establish a list of these countries. The assessment of equivalency shall take into account *Codex Alimentarius* guidelines CAC/GL 32.

When examining requests for recognition, the Commission shall invite the third country to supply all the necessary information. The Commission may entrust experts with the task of examining on-the-spot the rules of production and the control measures of the third country concerned.

By 31 March of each year, the recognised third countries shall send a concise annual report to the Commission regarding the implementation and the enforcement of the control measures established in the third country.

Based on the information in these annual reports, the Commission assisted by the Member States ensures appropriate supervision of the recognised third countries by regularly reviewing their recognition. The nature of the supervision shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions set out in this Regulation.

3. For products not imported under Article 27 and not imported from a third country which is recognised under paragraph 2, the Commission may, in accordance with the procedure referred to in Article 31(2), recognise the control authorities and control bodies, including control authorities and control bodies as referred to in Article 22, competent to carry out controls and issue certificates in third countries for the purpose of paragraph 1, and establish a list of these control authorities and control bodies. The assessment of equivalency shall take into account *Codex Alimentarius* guidelines CAC/GL 32.

The Commission shall examine any request for recognition lodged by a control authority or control body in a third country.

When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information. The control body or the control authority shall undergo regular on-the-spot evaluation, surveillance and multi-annual re-assessment of their activities by an accreditation body or, as appropriate, by a competent authority. The Commission may also entrust experts with the task of examining on-the-spot the rules of production and the control measures carried out in the third country by the control authority or control body concerned.

The recognised control bodies or control authorities shall provide the assessment reports issued by the accreditation body or, as appropriate, the competent authority on the regular on-the-spot evaluation, surveillance and multi-annual re-assessment of their activities.

Based on these assessment reports, the Commission assisted by the Member States ensures appropriate supervision of recognised control authorities and control bodies by regularly reviewing their recognition. The nature of the supervision shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions set out in this Regulation.

TITLE VII FINAL AND TRANSITIONAL RULES

Article 28 **Free movement of organic products**

1. Competent authorities, control authorities and control bodies may not, on grounds relating to the method of production, to the labelling or to the presentation of that method, prohibit or restrict the marketing of organic products controlled by another control authority or control body located in another Member State, in so far as those products meet the requirements of this Regulation. In particular, no additional controls or financial burdens in addition to those foreseen in Title V of this Regulation may be imposed.
2. Member States may within their territory apply stricter rules to organic plant and livestock production, where these rules are applicable also to non-organic production and provided that they are in conformity with Community law and do not prohibit or restrict the marketing of organic products produced outside the territory of the Member State concerned.

Article 29
Transmission of information to the Commission

Member States shall regularly transmit the following information to the Commission:

- (a) the names and addresses of the competent authorities and where appropriate their code numbers and their marks of conformity;
- (b) lists of control authorities and bodies and their code numbers and, where appropriate, their marks of conformity. The Commission shall publish regularly the list of control authorities and bodies.

Article 30
Statistical information

Member States shall transmit to the Commission statistical information necessary for the implementation and follow-up of this Regulation. This statistical information shall be defined within the context of the Community Statistical Programme.

Article 31
Committee on organic production

1. The Commission shall be assisted by a regulatory Committee on organic production.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply¹.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.
4. The Committee shall adopt its rules of procedure.

Article 32
Implementing rules

The Commission shall in accordance with the procedure referred to in Article 31(2) and subject to the objectives and principles laid down in Title II adopt detailed rules for the application of this Regulation. They shall include in particular the following:

¹ OJ L 184, 17.7.1999, p. 23.

- (a) detailed rules as regards the production rules laid down in Title III, in particular as regards the specific requirements and conditions to be respected by operators;
- (b) detailed rules as regards the labelling rules laid down in Title IV;
- (c) detailed rules as regards the control system established under Title V, in particular as regards minimum control requirements, supervision and audit, the specific criteria for delegation of tasks to private control bodies and the criteria for approval and withdrawal of such bodies;
- (d) detailed rules as regards the rules on imports from third countries laid down in Title VI, in particular as regards the criteria and procedures to be followed with regard to the recognition under Article 27 of third countries and control bodies, including the publication of lists of recognised third countries and control bodies, and as regards the certificate referred to in Article 27 (a) (1), point (d);
- (e) detailed rules as regards the free movement of organic products laid down in Article 28 and the transmission of information to the Commission in Article 29 in Title VII.

Article 33

Repeal of Regulation (EEC) No 2092/91

1. Regulation (EEC) No 2092/91 is hereby repealed from 1 January 2009.
2. References to the repealed Regulation (EEC) No 2092/91 shall be construed as references to this Regulation.

Article 34

Transitional measures

Where necessary measures to facilitate the transition from the rules established by Regulation (EEC) No 2092/91 to this Regulation shall be adopted in accordance with the procedure referred to in Article 31(2).

Article 34a

Report to the Council

1. The Commission shall, not later than 31 December 2011, submit a report to the Council.
2. The report shall, in particular, review the experience gained from the application of this Regulation and consider in particular the following issues:

- a) the scope and in particular organic food prepared by mass caterers;
 - b) the prohibition on the use of GMOs, including the availability of products not produced by GMOs, the vendor declaration, the feasibility of specific tolerance thresholds and their impact on the organic sector;
 - c) the functioning of the internal market and controls system, assessing in particular that the established practices do not lead to unfair competition or barriers to the production and marketing of organic products.
3. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 35
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*.

Where the detailed production rules are not laid down for certain animal species for certain aquatic plants and certain microalgae the rules provided for labelling in Article 17 and for the controls in Title V shall apply. Pending the inclusion of detailed production rules, national rules or in the absence thereof private standards accepted or recognised by the Member States shall apply.

It shall apply as from 1 January 2009.

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

Done at Brussels,

For the Council

The President

Terms referred to in Article 17(1)

- ES: ecológico, biológico
- CS: ekologické, biologické
- DA: økologisk,
- DE: ökologisch, biologisch,
- ET: mahe, ökoloogiline,
- EL: βιολογικό,
- EN: organic,
- FR: biologique,
- GA: orgánach,
- IT: biologico,
- LV: bioloģiskā,
- LT: ekologiškas,
- LU: biologesch
- HU: ökológiai,
- MT: organiku,
- NL: biologisch,
- PL: ekologiczne,
- PT: biológico,
- SK: ekologické, biologický
- SL: ekološki,
- FI: luonnonmukainen,
- SV: ekologisk.