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AGRILEG 163

WITH PROPOSED AMENDMENTS
FROM FRANCE AND GERMANY **09/11/2006**

PRESIDENCY NOTE

to : Special Committee on Agriculture

No. prev. doc. : 13545/06

No. Cion prop. : 5101/06

Subject : Proposals for Council Regulations
- on organic production and labelling of organic products
- amending Regulation (EC) no. 2092/91 on organic production of agricultural products and indications referring thereto in agricultural products and foodstuffs

Delegations will find attached the Presidency compromise text on the proposal for a Council Regulation on organic production and labelling of organic products.

Dans un souci de clarification de la proposition de la Présidence, les autorités françaises vous prient de trouver ci-joint quelques commentaires et propositions rédactionnelles. Elles comptent également sur la Présidence ainsi que sur la Commission pour traduire dans le texte les demandes d'amélioration et de clarification émanant de plusieurs Etats membres. En effet, la simplification du règlement ne devrait pas engendrer des difficultés d'application, mais au contraire, aboutir à des règles transparentes, équitables et justifiées, compréhensibles par les opérateurs comme par les consommateurs.

Exceptionnellement et de manière à faciliter le travail de la Présidence, les propositions rédactionnelles sont faites directement en anglais dans les deux propositions de la Présidence, documents 13584/06 du 25/10/2006 et 14551/06 du 31/10/2006.

TITLE I
AIM, SCOPE AND DEFINITIONS

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 inspection system;

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- (b) the use of indications referring to organic production in labelling and advertising of products referred to in paragraph 2.

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 or seed;
- (c) feed.

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.

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).

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 and with the detailed rules adopted by the Commission for the application of 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 farming production of an organic product up to and including its processing, storage, 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" shall mean any natural or legal person who produces, prepares or imports from a third country, with a view to the subsequent marketing thereof, products as referred to in Article 1, or who markets such products, or who contracts out any of the activities to a third party ;
- (c) "plant production" means the operations on the agricultural holding involved in producing, processing, packaging and labelling as organic products of agricultural crop products produced on that holding including collection of wild plant products for commercial purposes;
- (d) "livestock production" means the operations on the agricultural holding involved in producing, processing, packaging and labelling as products of organic production, domestic or domesticated terrestrial animals produced on that holding (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;
- (g) "preparation" means the operations of preserving and/or processing of organic products (including slaughter and cutting for livestock products), and also packaging, labelling 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, terms, indications, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, ring or collar accompanying or referring to a product;
- (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;

Deleted: means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the organic business under their control

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¹ OJ L 223, 15.8.2006, p.1.

(k) "competent authority"; means the authority of a Member State competent for the enforcement of the provisions set out under this Regulation and the detailed rules adopted by the Commission for the application of this Regulation or any other authority to which that competence has been conferred in whole or in part; it shall also include, where appropriate, the corresponding authority of a third country;

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(ka) 'inspection and certification authority' means the authority of a Member State competent for the inspection and certification in the organic production sector in accordance with the provisions set out under this Regulation and the detailed rules adopted by the Commission for the application of this Regulation or any other authority to which that competence has been conferred in whole or in part; it shall also include, where appropriate, the corresponding authority of a third country;

(kb) 'inspection and certification body' means the independent body carrying out inspection and certification in the organic production sector in accordance with the provisions set out under this Regulation and the detailed rules adopted by the Commission for the application of this Regulation and which has been approved and is supervised for that purpose by the competent authority; it shall also include, where appropriate, the corresponding body operating in a third country and for which special approval rules apply;

(l) 'certificate' means a written confirmation issued by an inspection and certification authority or body that a specific product or range of products of a specific operator is found to comply with the rules applicable to organic production

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(kk) "control authority" means a public administrative organization to which the competent authority has conferred its competence to carry out the controls; ¶

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(kkk) "control body" means an independent private third party to which the competent authority has

(m) "mark of conformity" means the assertion of conformity t of a specific product or range of products of a specific operator to a particular set of standards or other normative documents concerning the organic farming method in the form of a mark;

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(n) "ingredients" has the meaning given by Article 6 (4) of Directive 2000/13/EC of the European Parliament and of the Council¹;

(na) 'list of ingredients' means the list of ingredients referred to in Article 6 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;

(p) "genetically modified organism GMO" means an organism as defined in Article 2 of Directive 2001/18/EC, and which is not obtained through the techniques of genetic modifications listed in annexe I B of directive 2001/18/EC "

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(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

¹ OJ L 109, 6.5.2000, p. 29.

² OJ L 230, 19.8.1991, p. 1.

of the European Parliament and of the Council¹;

(t) "equivalent" in describing different requirements, systems or measures, means consistency with regard to meeting the same objectives and principles and sufficiency with regard to the requirements to provide the same level of assurance of conformity and same general rules;

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(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, subject to the conditions of Article 1 of Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (OJ L 66, 13.3.1999, p. 16–23);

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(w) "mass caterers" means restaurants, hospitals, canteens and other similar food business preparing organic products for sale or delivery to the final consumer;

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(x) "primary farming production" means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes the harvesting of wild products;

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(y) "agricultural primary products" means products of primary farming production including products of soil and of stock farming;

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Deleted: (z) . "unprocessed products" means foodstuffs and other products that have not undergone . processing, and includes products that have been divided, parted, severed, sliced, boned, . minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen . or thawed;¶

¶ (zz) . "processed food" means foodstuffs resulting from the processing of unprocessed products for . use as food. The products may contain more than one ingredient of agricultural origin and contain ingredients that are necessary for their manufacture or . to give them specific characteristics. ¶

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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 the whole organic food and feed chain 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;

¹ OJ L 268, 18.10.2003, p. 29.

- (iii) makes responsible use of the natural resources, such as water, soil, organic matter, energy and air and to safeguard those resources;
 - (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; or Deleted: on the market
 - (iii) the use of external inputs referred to in paragraph (b) contributes to unacceptable environmental impacts; (the scope if this § must be clarified)

- (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

Specific 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; Deleted: outdoors
- (l) excluding rearing chemically induced polyploid animals; Deleted: artificially
- (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

Specific 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 principles:

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- (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 to a minimum extent and only in case of essential technological 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 food with care, preferably by use of biological, mechanical and physical methods.

Article 6a

Specific 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 principles:

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- (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.

**TITLE III
PRODUCTION RULES**

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Article 7a
General Requirements

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

Article 7 a(i)

This regulation shall apply without prejudice to other Community provisions or national provisions, in conformity with Community law, concerning products specified in article 1, such as provisions governing the production, preparation, marketing, labelling and inspection, including legislation in foodstuffs and animal nutrition.

Article 7aa
Prohibition on the use of GMOs

1. GMOs and products produced from or by GMOs shall not be used as or in 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 providing the labelling of the products in question not being in conformity with those Regulations.
3. (Question : In what cases would the § apply ? – The rule remains that GMOs are prohibited !)
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. In particular, on the basis of scientific evidence or technical progress, the Commission may establish a specific tolerance threshold for adventitious or technically unavoidable presence of GMOs in seeds used in organic production. (N.B. = A

Deleted: The provisions laid down in the first subparagraph shall not apply in the case where detailed rules as regards specific tolerance thresholds for the adventitious or technically unavoidable presence of GMOs in seeds used in organic production, have been adopted under paragraph (4).

specific threshold for seed used in organic farming should not be set unless a threshold has already been set in general rules and that threshold is deemed too high for organic farming).

Article 7aaa

Prohibition on the use of ionising radiation

The use of ionising radiation for treatment of unprocessed or processed organic products for food or feed or their ingredients 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 which are not all managed under organic production. As regards animals different species shall be involved. 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 included in the restricted list 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 a immediate threat to a crop, plant protection products may only be used if they have been included in the restricted list 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.
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 included in the restricted list 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).

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Article 8a

Production rules for seaweed and other crop aquaculture

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1. The collection of wild 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.

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 included in the restricted list for this purpose, under Article 11.

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3. To be completed by : For the farming of micro algae or aquatic plants, the following criteria shall be defined :

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- areas, soil or ponds, water quality, fertilisers, plant protection products
- products for cleaning and disinfection of ponds and installations used for crop aquaculture.

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:

¹ The Water Framework Directive 2000/60/EC (OJ L 327, 22.10.2000, p1) will not be fully implemented until 2015, in the mean time 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, p47).

² OJ L 226, 25.06.2004, p 119.

- (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) ~~(comment: A special rule concerning knowledge and skills that applies to organic farmers only is not necessary.)~~

Deleted: 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;

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(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;

~~(iv bis) manure from organic farms shall only be used in organic farming;~~

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(v) organic livestock shall be kept separate from other livestock. However, grazing of common land ~~(in French : terres domaniales ou communales = collectively managed 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 is justified for safety, welfare or veterinary reasons or it concerns certain holdings where cattle must be kept tethered; special conditions and welfare requirements will be laid down in the implementing rules referred to in Article 32 (a);~~

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(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 by 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) obtaining feed for livestock primarily 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 included in the restricted list 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;

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- (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) vaccinations or any other 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 included in the restricted list under Article 11.
2. With regard to animal welfare rules referred to in paragraph 1, Member States may apply stricter rules to the livestock produced within their territory, provided these rules are applicable also to non-organic production and provided that these rules are in compliance with Community law.
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).

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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, stocking densities and water quality, shall ensure that developmental, physiological and behavioral 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) ~~chemical~~ 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;

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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

Question : are these "organic" bivalve molluscs and other species really different from others, not organically grown ?

- (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;
 - (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 included in the restricted list under Article 11.

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2. With regard to animal welfare rules referred to in paragraph 1, Member States may apply stricter rules to animals produced within their territory, provided these rules are applicable also to non-organic production and provided that these rules are in compliance with Community law.
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).

implemented until 2015, in the mean time 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).

Article 11

Products and substances used in farming and criteria for their inclusion in restricted lists

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1. The Commission shall in accordance with the procedure referred to in Article 31 (2) include in a restricted list the products and substances, which may be used in organic farming for the following purposes:

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(a) plant protection products;

(aa) products for cleaning and disinfection of crops and crops products after harvesting.

(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.

The listed products and substances may only be used under the specific conditions laid down in the implementing rules adopted by the Commission in accordance with paragraph 3 subparagraph 1 and in so far as the corresponding use is authorised 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 inclusion of the products and substances referred to in paragraph 1 in restricted lists 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:

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(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;

(iii) feed of animal origin, with the exception of milk and milk products, eggs, honey, fish, other marine animals and products derived there from, shall not be used for food producing animals.

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.

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(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).

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(comment: This rule may cause distortions to the free movement of products)

Deleted: 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) in so far as it respects Community law. The Member state concerned must inform the other Member states and the Commission of its regulation.

Inserted: The Member state concerned must inform the other Member states and the Commission of its regulation.

Deleted: 5. . The use of products and substances from categories different from those mentioned under . paragraph 1 and 4 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 inspection 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 start of the conversion period, may be taken into account, in so far as certain conditions concur;
 - (f) animals and animal products produced until the conversion period referred to in subparagraph (c) is completed shall not be marketed with indications referred to in Articles 17 and 18 used in labelling and advertising.
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).

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CHAPTER 2

PRODUCTION OF PROCESSED FEED

Article 13

General rules on the production rules of processed feed

1. Production of processed organic feed shall be kept separate in time or space from production of processed non organic feed.

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1.a. Where appropriate, the criteria with regard to feed contained in the rules for animal production under Article 9 (d) and the implementing rules adopted by the Commission must be met.

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).

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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; ~~(e)~~ in order to determine whether a product is produced mainly from ingredients of agricultural origin as referred to in subparagraph (a), added water and cooking 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 included in the restricted list in accordance with Article 15;

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(c) non-organic agricultural ingredients may be used only if they have been included in the restricted list in accordance with Article 15 or have been provisionally authorized by a Member State;

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(cc) food from conversion contains only one crop ingredient of agricultural origin.

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(d) an organic ingredient shall not be present together with the same ingredient in non-organic form or from conversion;

2. Substances and techniques 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.

Deleted: (e) . in order to determine whether a product is produced mainly from ingredients of . agricultural origin as referred to in subparagraph (a), added water and salt shall not be . taken into account;

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.
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 inclusion of products and substances for use in organic production 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 permitted 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

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fulfil given dietary requirements taken 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 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 inclusion of the products and substances referred to in paragraph 1 in the restricted list and lay down particular conditions and limits for their use, and, if necessary, on withdrawal of products.

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Where a Member State considers that a product or a substance should be added to the relevant restricted list or that amendments should be made thereto, it shall ensure that the other Member States and the Commission are officially provided with documents laying down the reasons for the inclusion and/or the amendments; the Commission shall submit these documents to the committee referred to in Article 31 (2).

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, adopt provisions for the granting of exceptions from the production rules laid down in Chapters 1 to 3.

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2. Provisions as referred to in paragraph 1 shall be kept to a minimum and where appropriate limited in time and may only be adopted for in the following cases:

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- (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;

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Inserted: under quality or origin label (AOP, IGP; STG)

- (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.

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- 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.

Deleted: or with the procedure referred to in Article 31 (1a) draw up guidelines for the competent authorities

TITLE IV LABELLING

Article 17

Use of terms **and indications** referring to organic production

- 1. For the purposes of this Regulation a product shall be regarded as bearing indications 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, or their usual derivatives (such as bio, eco etc.) or diminutives, alone or combined, shall be regarded as indications referring to the organic production method throughout the Community and in any Community language, unless they are not applied to agricultural products in foodstuffs or feedingstuffs or other products originating from agriculture or clearly have no connection with this method of production:

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- 2. The labelling and advertising of a product specified in Article 1(2) may refer to the organic production method throughout the Community and in any Community language only where the product, its ingredients or feed materials, satisfy the requirements set out under this Regulation and under the implementing rules adopted by the Commission in accordance with the procedure referred to in Article 31(2) and where the product has been produced, prepared or imported by an operator who is subject to the inspection measures laid down in Articles 22 and 23.

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As regards unprocessed and processed food the reference to the organic production method 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;

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(iii) the list of ingredients distinguishes between organic ingredients and conventional ones :

- (b) in the list of ingredients and in the same visual field as the sales description provided that:
- (i) the processed food complies with Article 14;
 - (ii) at least 70 % by weight, of its ingredients of agricultural origin are organic;
 - (iii) the term also appears in a separate statement set in the same visual field as the sales description and indicating the percentage of the organic ingredients. This statement shall not appear in a colour, size and style of lettering more prominent than the sales description of the product and be in the following form: "X % of the ingredients of agricultural origin are organic";
- (c) **only** in the list of ingredients provided that:
- (i) the processed food complies with Article 14.

Where the term appears in the list of ingredients it may only appear in relation to the organic ingredients and in the same colour, identical size and style of lettering as the other indications in the list of ingredients, and with indication of the concerned %.

1. Any reference to the organic production method referred to in paragraph 1 shall not be used in the labelling or advertising of 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.

3 a. In accordance with provisions laid down in Regulation (EEC) No. 40/1994:

- (a) An application for registration of a trademark which is in breach of paragraph 2 shall be refused.
- (b) Trademarks registered in breach of paragraph 2 shall be invalidated.
- (c) The use of a trademark corresponding of the situations referred to in paragraph 2 shall be refused.

4. Member States shall take the measures necessary to prevent fraudulent use of the reference to the organic production method in labelling or advertising.
5. 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 in the labelling or advertising, reference is made to the organic production method, as referred to in Article 17(2), the following indications shall also appear in the labelling:

Deleted: 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 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.¶

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(a) the code number referred to in Article 22(6) of the inspection and certification authority or body¹ to which the operator who has carried out the most recent production or preparation operation is subject;

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(b) the Community logo referred to in Article 19 as regards² unprocessed products and processed food referred to in Article 17 (1) (a);

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Germany is not in favour of a compulsory logo.; France can accept the non compulsory logo.

(c) an indication of origin. This indication shall appear in a separate statement set in the same visual field as the Community logo referred to in Article 19 or in absence of that logo in the same visual field as the sales description. It shall be in the following form: 'EU', 'non-EU' or 'EU/non-EU' (or country).

Deleted: It shall indicate the place in which the primary production of all agricultural ingredients, as appropriate, has taken place. This statement shall not appear in a colour, size and style of lettering more prominent than the sales description of the product and be in the following form: "X GROWN", where X shall indicate one contiguous region, a country,

The use of the indication of origin as referred to in subparagraph (c) shall be optional for food composed of more than one ingredient from agricultural origin.

The use of the Community logo as referred to in Article 19 and the indication of origin as referred to in subparagraph (c) shall be optional for products imported from third countries. However, where the Community logo as referred to in Article 19 appears in the labelling, the indication of origin as referred to in subparagraph (c) shall appear in the labelling of primary, unprocessed products and processed products (including products composed from several ingredients from agricultural origin).

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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.

In addition, 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
Community logo

The Commission shall, in accordance with the procedure referred to in Article 31(2), define a Community logo which may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation. It shall in all cases only contain the following wording: "**ORGANIC FARMING – EC REGULATION**"; The Community logo shall not be used in the case of conversion products and processed food as referred to in Article 17 (1) (b) and (c).

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Article 20

This Article has to be deleted or drafted alternatively:

Unfair competition

All practices of unfair competition are prohibited. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial

¹ How to codify for certifying bodies of imported products ?

² "agricultural primary products" are not defined in Article 2.

practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (OJ L 149, 11.6.2005, p. 22–39), Council Directive of 10 September 1984 concerning misleading and comparative advertising (OJ L 250, 19.9.1984, p. 17) amended by Directive 97/55/EC of European Parliament and of the Council of 6 October 1997 (OJ L 290, 23.10.1997, p. 18) and Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (OJ L 298, 17.10.1989, p. 23) shall apply.

Article 21
Specific labelling requirements

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

- (a) organic feed;
- (b) conversion products of plant origin;
- (c) organic food prepared by mass caterers.

TITLE V
CONTROLS¹

Article 22 a
Official Controls

- 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.
- 2. Member states shall ensures that any operator complying with this regulation is entitled to be covered by a system of official controls.
- 3. The Commission shall make public the name and address of the authorities and bodies referred to in paragraph 1 or in article 22 and update it periodically.

Deleted: Use of claims¶

¶
1. . General claims that a particular set of private organic standards is stricter, more organic or . otherwise superior to the rules laid down in this Regulation, or to any other set of organic . standards, may not be used on labels or in advertising.¶
¶
. However, indications referring to specific elements of the production method used for a . certain product may be used in the labelling or advertising on condition that they are true . statements of fact and otherwise in conformity with Community provisions.¶
¶
2. . Member States shall take the measures necessary to ensure compliance with the conditions set . out in this Article.¶
¶
3. . The Commission may in accordance with the procedure referred to in Article 31(2) adopt . measures in order to ensure compliance with this Article.¶

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¹ In this title, there is confusion between official controls (OFFC) under RCE n° 882/2004 and certifying operations of products carried out by authorities or inspection and certification bodies of organic products.

Article 22

Inspection system

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1. Member States shall set up an inspection system operated by one or more designated inspection and certification authorities and/or by approved private inspection and certification bodies to which the operators referred to in Article 23(1) in conjunction with paragraph 2 shall be subject. The designated inspection and certification authorities and the approved inspection and certification bodies must satisfy the requirements laid down in the conditions of 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.

Deleted: 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

2. The inspection system shall comprise at least the application of the precautionary and inspection measures specified in the implementing rules adopted by the Commission in accordance with the procedure referred to in Article 31(2). The nature and frequency of the inspections shall be determined by the inspection authorities or bodies, on the basis of an assessment of the risk of the occurrence of irregularities or infringements as regards compliance with the requirements laid down in this Regulation. In any case all operators, with the possible exception of operators as described in Article 23 (2 (a) and (b)), shall be subject to a physical inspection at least once a year.

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3. For the application of the inspection system operated by private inspection and certification bodies, Member States shall designate an authority responsible for the approval and supervision of such bodies.

4. For the approval of a private inspection and certification body, the following criteria shall be taken into account:

(a) the standard inspection procedure to be followed, containing a detailed description of the inspection measures and precautions that the body undertakes to impose on operators subject to its inspection;

(b) the penalties that the body intends to apply where irregularities and/or infringements are found;

(c) the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability;

(d) the objectivity and independence of the inspection and certification body vis-à-vis the operators subject to its inspection.

5. Member States shall attribute a code number to each designated inspection and certification authority and approved inspection and certification body.

6. After an inspection and certification body has been approved, the competent authority shall:

(a) ensure that the inspections carried out by the inspection body are objective and independent;

- (b) verify the effectiveness of its inspections;
- (c) take cognizance of any irregularities and/or infringements found and penalties 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 1 sentence 2 or paragraph 4 or fails to satisfy the requirements laid down in paragraphs 7, 8 and 9.

- 7. The inspection and certification authorities and the approved inspection and certification bodies referred to in paragraph 1 shall ensure that at least the precautionary and inspection measures referred to in paragraph 2 are applied to operators subject to their inspection.
- 8. Inspection and certification bodies shall give the competent authority access to their offices and facilities and provide any information and assistance deemed necessary by the competent authority for the fulfilment of its obligations according to this Regulation.

(N.B. : each member state approves control bodies in their territory).

- 9. The inspection and certification authorities and 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 inspections on 31 December of the previous year, a summary report of the inspection activities carried out during the previous year shall be provided by 31 March each year.

Article 23

Adherence to the inspection system

- 1. Any operator who produces, prepares, stores or imports from a third country products in the meaning of Article 1(2) with a view to the subsequent marketing thereof, or who markets such products, prior to placing any products on the market, shall:

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

Where an operator contracts out any of those 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 inspection system.

- 2. Member States may exempt from the application of paragraph 1:
 - (a) wholesalers dealing only with pre-packaged products (Comment DE: A definition for "pre-packaged product"s is needed) provided they do not import from a third country such products or they have not contracted out any activity to a third party or;

Deleted: The competent authority may:¶
 . a) . . confer to one or more other control authorities its control competences;¶
 . b) . . delegate control tasks to one or more control bodies.¶

Deleted: 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 as most recently notified by a publication in the *Official Journal of the European Union, C series* and be approved by the competent authorities

Deleted: 4. . Control bodies and control authorities 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.¶

5. . The competent authorities may not delegate or confer the following tasks to the control bodies: ¶

<#>the supervision and audit of other control bodies; ¶

<#> 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).¶

6. . Member States shall attribute a code number to each control authority or control body performing control tasks as referred to in paragraph (3).

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- (b) operators who sell products directly to the final consumer or user provided they do not produce, prepare, store other than in local connection with the point of sale or import such products from a third country or have not contracted out those activities to a third party.

2. a) Member States shall designate an authority or 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 inspection expenses, is entitled to be covered by the inspection system. Deleted: control
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4. The competent authorities shall keep an updated list containing the names and addresses of operators subject to the inspection system and must make it available. Deleted: control
5. The Commission shall adopt according to the procedure referred to in Article 31(2) 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

Products' accompanying document

1. The control inspection authorities and the inspection bodies referred to in Article 22(3) shall provide a formal written products' accompanying document to any such operator who is subject to their inspections and who in the sphere of his activities, meets the requirements laid down in this Regulation. The products' accompanying document shall at least permit the identification of the operator and the type or range of products as well as the period for which the statement is valid. Deleted: Operator's licence
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2. The model of the products' accompanying document referred to in paragraph 1 shall be drawn up in accordance with the procedure referred to in Article 31(2). Deleted: operator's licence

Article 24
Certification

- 1
1. The inspection and certification authorities and the inspection and certification bodies may provide operators which are subject to the inspection system with formal certification documents such as a letter or a certificate, including the right to use their marks of conformity with organic standards, certifying the conformity of their products concerned with the provisions applied to organic production.
 2. An inspection and certification authority may not refuse to grant certificates or the use of its mark of conformity for any product that meets the requirements laid down in this Regulation.
 3. In all cases, members states ensure that the inspection system as set up allows products to be traced at every stage of production, preparation and distribution, to give consumers guarantees that organic products have been produced in compliance with this regulation.

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Deleted: Control authorities may not refuse to grant the right of use of their marks of conformity to any operator, who, in the sphere of his activities, meets the requirements laid down in this Regulation.¶
2. . Approved control bodies may not refuse to grant the right of use of their marks of conformity to any operator, who in the sphere of his activities has been controlled by another control body, where the latter has assessed and certified conformity with private organic standards equivalent to those of the first control body.¶
¶
3. . Control bodies which refuse to grant the right of use of their mark of conformity, shall provide proof that the private organic standards under which the operator concerned has already been certified are not equivalent to its own standards.¶
. Fees collected for the granting of the mark of conformity shall be reasonable.

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Article 25
Measures in case of infringements and irregularities

1. The inspection and certification authorities and the inspection and certification bodies shall,
 - (a) Where a irregularity is found as regards compliance with the requirements laid down in this Regulation, ensure that ~~no reference to the organic production method is made in the labelling or advertising for~~ 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 for the integrity of the organic certification and to the nature and particular circumstances of the irregular activities;
 - (b) Where a ~~severe~~ infringement or an infringement with prolonged effect is found, prohibit the operator concerned from marketing products with ~~reference to the organic production method in the labelling or advertising~~ for a period to be agreed with the competent authority of the Member State ~~where the particular circumstances indicate that such measure is required, effective and proportionate to prevent future irregularities.~~
2. Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between ~~inspection and certification authorities and the inspection and certification~~ bodies concerned, as well as to the competent authorities, Member States and, where appropriate, to the Commission.

The level of communication shall be determined by each party concerned depending on the severity and the extent of the irregularity or infringement found.

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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 inspection and certification authorities and the inspection and certification bodies shall exchange with other inspection and certification authorities and inspection and certification bodies relevant information on the results of their inspections. They may also exchange such information on their own initiative.

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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 with indications referring to the organic production method provided that:

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(a) the product complies with the provisions set out in Titles I, II, III and IV of this Regulation and its implementing rules ;

(b) the operator in the third country on all stages of production, preparation, distribution and export of the product concerned has been subject to control of an inspection authority or body recognised in accordance with paragraph 2;

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(c) the operators concerned shall provide to the national competent authority a copy of a formal products' accompanying document as referred to in Article 23a, issued by the inspection body or inspection authority referred to in subparagraph (b), when products are release for free circulation in the Community.

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2. The Commission shall in accordance with the procedure referred to in Article 31(2) recognise the inspection bodies and inspection authorities competent to carry out inspection and certification of organic products and to issue the formal written products' accompanying document referred to in paragraph 1 in that third country, and establish a list of these inspection bodies and inspection authorities.

The inspection bodies shall satisfy the requirements laid down in the conditions of 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*.

When examining requests for recognition, the Commission shall invite the inspection body or authority to supply all the necessary information. The Commission may also entrust experts under its authority 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 body or authority concerned and of repeating that examination regularly after the recognition of the

inspection authority or body in that third country. The nature and frequency of the examinations shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions applied in the Community to imports from third countries.

The Commission assisted by the Member States ensures appropriate supervision of recognised inspection bodies and inspection authorities.

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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:

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(a) the product has been produced in accordance with production standards equivalent to the production rules laid down in Titles III and IV in connection with Titles I, II and VII applied to organic production in the Community;

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(b) the operators were subject to inspection measures of equivalent effectiveness to those referred to in Title V and such inspection measures will be permanently and effectively applied;

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Deleted: which are equivalent to those of the Community control system

(c) the operators on all stages of production, preparation and distribution in the third country have submitted their activities to an inspection system recognised in accordance with paragraph 2 or per operator one inspection body recognised in accordance with paragraph 3; (N.B. = one operator = only one inspection body).

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(d) the product is covered by a certificate of inspection issued by the competent authorities or inspection bodies of a third country recognised in accordance with paragraph 2, or by a inspection body or inspection authority recognised in accordance with paragraph 3, which confirms that the product satisfies the conditions set out in this paragraph.

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The certificate referred to in this paragraph must 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 inspection body and/or inspection authority 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 apply rules equivalent to those laid down in Titles III an IV in connection with Titles I, II and VII and system of inspection has been recognized, equivalent to those applied in the Community in accordance with Title V and establish a list of these countries. The assessment of equivalency should take into account *Codex Alimentarius* guidelines CAC/GL 32.

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When examining requests for recognition, the Commission shall invite the third country to supply all the necessary information. The Commission may entrust experts under its authority with the task of examining on-the-spot the rules of production and the inspection arrangements of the third country concerned and shall repeat that examination regularly after the recognition of the third country. The nature and frequency of the examinations

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shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions applied in the Community to imports from third countries.

3. For products imported from a third country which is not recognised under paragraph 2 the Commission shall in accordance with the procedure referred to in Article 31(2) recognise the inspection bodies competent to carry out inspections and issue certificates of inspections in that third country for the purpose of paragraph 1, and establish a list of these inspection bodies. The list must specify, for each inspection body, the third countries concerned and the production standards used. The assessment of equivalency should take into account *Codex Alimentarius* guidelines CAC/GL 32.

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The Commission shall examine any request for recognition lodged by a public or private inspection body in a third country.

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When examining requests for recognition, the Commission shall invite the inspection body to supply all the necessary information. The Commission may also entrust **experts under its authority** with the task of examining on-the-spot the rules of production and the inspection activities carried out in the third country by the inspection body concerned **and shall repeat that examination regularly after the recognition of the inspection body in that the third country.** The nature and frequency of the examinations shall be determined on the basis of an assessment of the risk of the occurrence of irregularities or infringements of the provisions applied in the Community to imports from third countries.

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The Commission assisted by the Member States ensures appropriate supervision of recognised control bodies and authorities. The Commission can also withdraw the recognition of control bodies not in compliance with this regulation.

TITLE VII
FINAL AND TRANSITIONAL RULES

Article 28

Free movement of organic products

Competent authorities, inspection authorities and inspection 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 inspection authority or inspection body located in another Member State, in so far as those products meet the requirements of this Regulation. In particular, no additional inspections or financial burdens in addition to those foreseen in Title V of this Regulation may be imposed.

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Article 29

Transmission of information to the Commission

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

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

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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.

¹ OJ L 184, 17.7.1999, p. 23.

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:

- (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 inspection system established under Title V, in particular as regards minimum inspection requirements an precautionary measures, supervision and audit, the specific criteria for delegation of tasks to inspection authorities or to private inspection bodies and the criteria for approval, accreditation 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 inspection bodies, including the publication of lists of recognised third countries and inspection bodies, and as regards the certificate referred to in Article 27a(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.

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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 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, and for certain crop production, 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.

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Pending the inclusion of detailed processing, labelling and control rules for products originating from mass caterers, where existing, 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,
- CS: ekologické,
- DA: økologisk,
- DE: ökologisch, biologisch,
- ET: mahe, ökoloogiline,
- EL: βιολογικό,
- EN: organic,
- FR: biologique,
- GA: orgánach,
- IT: biologico,
- LV: bioloģiskā,
- LT: ekologiškas,
- HU: ökológiai,
- MT: organiku,
- NL: biologisch,
- PL: ekologiczne,
- PT: biológico,
- SK: ekologické,
- SL: ekološki,
- FI: luonnonmukainen,
- SV: ekologisk.