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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 in the Annex the Presidency text, which has been jointly prepared by Austria and Finland, on the proposal for a Council Regulation on organic production and labelling of organic products.

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, including avoiding misleading labelling and other forms of consumer information.

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

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

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

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 at all stages of production, preparation and distribution;
- (aa) "stages of production, preparation and distribution" means any stage from and including the primary production of an organic product up to and including its storage, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;
- (b) 'organic' means coming from or related to organic production;
- (bb) "operator" means the natural or legal persons responsible for ensuring that the requirements of this Regulation are met within the organic business under their control;
- (c) 'plant production' means production of agricultural crop products including harvesting of wild plant products for commercial purposes;
- (d) 'livestock production' means the production of domestic or domesticated terrestrial animals (including insects);
- [(e) 'aquaculture' means the rearing or cultivation of aquatic organisms using techniques designed to increase the production beyond the natural capacity of the environment, where the organisms remain the property of a natural or legal person throughout the rearing or cultivation stage, up to and including harvesting;]
- (f) 'conversion' means the transition from non organic to organic farming;
- (g) 'preparation' means the operations of preserving and/or processing of organic products (including slaughter and cutting for livestock products), and also packaging and/or alterations made to the labelling concerning the organic production method;
- (h) the definitions of 'food', 'feed' and 'placing on the market' given in Regulation (EC) No 178/2002 shall apply;
- (i) 'labelling' means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, 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;
- (k) the definitions of 'competent authority' and 'control body' given in Regulation (EC) No 882/2004 shall apply;
- [(l) 'certificate' means a written confirmation issued by a competent authority or a control body that an operator or a specific lot of products is found to comply with the principles and rules applicable to organic production;]

- [(m) ‘mark of conformity’ means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;]
- (n) ‘ingredients’ has the meaning given by Article 6(4) of Directive 2000/13/EC of the European Parliament and of the Council¹;
- (o) ‘plant protection products’ means products as defined in Article 2, point 1 of Council Directive 91/414/EEC²;
- (p) ‘genetically modified organism (GMO)’ means an organism as defined in Article 2 of Directive 2001/18/EC of the European Parliament and of the Council³;
- (q) ‘produced from GMOs’ means derived in whole or in part, from GMOs but not containing or consisting of GMOs⁴ ;
- (r) ‘produced by GMOs’ means containing or consisting of metabolites of GMOs;
- (s) ‘feed additives’ means products as defined in Article 2(a) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council⁵;
- (t) ‘equivalent’ in describing different systems or measures, means that they are capable of meeting the same objectives and principles;
- (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;
- (w) ‘mass caterers’ means restaurants, hospitals, canteens and other similar food business preparing organic products at the point of sale or delivery to the final consumer.

¹ OJ L 109, 6.5.2000, p. 29.

² OJ L 230, 19.8.1991, p. 1.

³ OJ L 106, 17.4.2001, p. 1.

⁴ The meaning of this definition will be clarified in recital.

⁵ OJ L 268, 18.10.2003, p. 29.

TITLE II
OBJECTIVES AND PRINCIPLES FOR ORGANIC PRODUCTION

Article 3
Objectives

The organic production shall pursue the following objectives:

- (a) to establish a sustainable management system for agriculture that:
 - (i) respects nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals;
 - (ii) contributes to a high level of biological diversity;
 - (iii) makes responsible use of the natural resources, such as water, soil, organic matter and air;
 - (iv) respects high animal welfare standards and in particular meets animals' species-specific behavioural needs;
- (b) to aim at producing products of high quality instead of maximising production;
- (c) to aim at producing a wide variety of foods and other agricultural products that responds to consumers' demand for goods produced by use of processes and substances that do not harm the environment, 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;
 - (iii) exclude the use of ionising radiation for treatment of organic products or their ingredients;
 - (iiia) exclude the use of GMOs;
 - (iv) are based on risk assessment, precautionary and preventive measures;

- (b) restricting the use of external inputs of any type. Where they are required they are limited to:
 - (i) inputs from other organic production systems;
 - (ii) natural or naturally-derived substances;
 - (iii) low solubility mineral fertilizers;
- (c) unless the use is justified for specific environmental reasons, strictly limiting the use of chemically synthesised inputs to the following exceptional cases where:
 - (i) appropriate systems management practices do not exist;
 - (ii) biological or mechanical practices, or natural or naturally derived substances are not available on the market in organic form;
- (d) where necessary adapting, within the frame of this Regulation, the rules of organic production take account of sanitary status, regional differences in climate and to local conditions, stages of development and specific husbandry practices.

Article 5

Principles applicable to farming

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

- (a) maintaining and enhancing soil life and natural soil fertility, preventing and combating 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 and plant health by preventative techniques including selection of appropriate breeds and varieties;
- (f) obtaining feed for livestock primarily from the holding, where the animals are kept or other organic holdings in the same region;
- (g) observing a high level of animal welfare;

- (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 outdoors;
- (l) excluding rearing artificially induced polyploid animals;
- (m) maintaining as regards aquaculture production the biodiversity of natural aquatic ecosystems, the health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystem;
- (n) feeding aquatic organisms with feed from sustainable fisheries or with organic feed composed of agricultural ingredients from organic farming and of natural non-agricultural substances.

Article 6

Principles applicable to processing

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

- (a) producing organic food and feed from organic agricultural ingredients , except where an organic ingredient is not available on the market in organic form;
- (b) restricting the use of additives, other 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 nutritional purposes;
- (c) excluding substances and processing methods that might mislead the consumer regarding the true nature of the product.

TITLE III
PRODUCTION RULES

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 7aa

Prohibition on the use of GMOs

1. GMOs and products produced from or [by] GMOs shall not be used as food, feed, processing aids, [active substances in] plant protection products, (including plant strengthening products), fertilisers, soil conditioners, seeds, vegetative propagating material, microorganisms 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 Council Regulation 1829/2003 or Council Regulation 1830/2003. They 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.
3. For the purpose of the prohibition referred to in paragraph (1) concerning products not being food or feed, or products produced [by] GMOs, operators using such non organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or [by] GMOs.
4. In order to establish that the presence of GMOs and products produced from or [by] GMOs are adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

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 livestock different species should be involved, as regards plants different varieties or varieties that can be easily differentiated should be involved.

Where, in accordance with the second subparagraph, not all units of a farm 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 from organic production;
 - (c) in addition, only fertilisers and soil conditioners may be used if they have been approved 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 of natural enemies, the choice of species and varieties, crop rotation, cultivation techniques and thermal processes;
 - (g) in the case of a threat to a crop, plant protection products may only be used if they have been approved under Article 11;
 - (gg) for enhancing and maintaining plant health, plant strengthening products may only be used if they have been approved under Article 11;
 - (h) 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 edible 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 approved 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.

Article 9

Livestock production rules

1. In addition to the general farm production rules laid down in Article 7, the following rules shall apply to livestock production:

- (a) with regard to the origin of the animals:
 - (i) organic livestock shall be born and raised on organic holdings;
 - (ii) for breeding purposes, non-organically raised animals may be brought onto a holding under specific conditions to be established in accordance with the procedure referred to in Article 31(2);
- (b) with regard to husbandry practices and housing conditions:
 - [(i) personnel keeping animals shall possess the necessary knowledge and competence 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 outdoors, preferably pasture, whenever weather conditions and the state of the ground allow this;
 - (iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;
 - (v) organic livestock shall be kept separate from other livestock. However, grazing of common land by organic animals and of organic land by non-organic animals is permitted under certain restrictive conditions;
 - (vi) tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time and justified for safety, welfare or veterinary reasons;
 - (vii) duration of transport of livestock shall be minimised;
 - (viii) any suffering, including mutilation, shall be kept to a minimum;

- (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 hormone treatment, unless in order to treat reproduction disorders;
 - (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:
- (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 approved under Article 11;
 - (iv) growth promoters and synthetic amino-acids shall not be used;
 - (v) suckling mammals shall be fed with natural, preferably maternal, milk;
- (e) with regard to disease prevention and veterinary treatment:
- (i) disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions;

- (ii) disease outbreaks shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary, when the use of phytotherapeutic, homeopathic and other products is inappropriate;
 - (iii) courses of treatments with chemically synthesised allopathic veterinary medicinal products, with the exception of vaccinations, treatments for parasites and any compulsory eradication schemes established on basis of Community law shall be limited;
- (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 approved under Article 11.
2. With regard to animal welfare rules referred to in letters (a) to (e) above, 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.

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 to be established in accordance with the procedure referred to in Article 31(2);
 - (b) with regard to husbandry practices:
 - (i) personnel keeping animals shall possess the necessary knowledge and competence 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 ethological 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 insure that the welfare of animals is maintained;

- (vi) any suffering of the animals shall be kept to a minimum;
- (c) with regard to breeding:
- (i) cloning and production of monosex strains, except by hand selection, shall not be used;
 - (ii) the appropriate breeds 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 in accordance with the procedure referred to in Article 31(2);
- (d) with regard to feed:
- (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;
 - (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 approved under Article 11;
 - (iv) growth promoters and synthetic amino-acids shall not be used;
- (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, high quality feed, appropriate stocking density, and breed and strain selection;
 - (ii) disease outbreaks should be dealt with according to a veterinary health plan. Where treatment is necessary, animals shall be treated immediately to avoid suffering to the animal; chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary, when the use of phytotherapeutic, homeopathic and other products is inappropriate;
 - (iii) the use of immunological veterinary medicines is allowed;
 - (iv) species-specific conditions for the use of chemically synthesised allopathic veterinary medicinal may be established in accordance with the procedure referred to in Article 31(2).

Article 11
Use of certain products and substances in farming

1. The following products and substances may be used in organic farming:
 - (a) plant protection products including plant strengthening products;
 - (b) fertilisers and soil conditioners;
 - (c) non-organic feed materials from plant origin, feed material from animal and mineral origin;
 - (d) feed additives; certain products used in animal nutrition and processing aids;
 - (e) products for cleaning and disinfection in livestock buildings and installations;
 - [(f) other substances.]

2. Their approval is subject to the objectives and principles laid down in Title II and the following general and specific criteria:
 - a) The following shall apply to all products and substances:
 - i) their use is necessary for sustained production and essential for its intended use;
 - ii) their use does not result in unacceptable effects on the environment or contribute to the contamination thereof and;
 - iii) they should 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 approved alternatives are not available;
 - iv) their use has the lowest negative impact on human, animal or plant health.
 - b) In addition, the following shall apply to fertilisers and soil conditioners:
 - i) 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.
 - c) The following shall apply to plant protection products:
 - i) their use is essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or breeding alternatives or other effective management practices are not available;
 - ii) if products are obtained by chemical processes 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 addition, the following shall apply to paragraphs (1) (c) and 1 (d):
- i) their use is 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 can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used;
 - iii) feed of animal origin, with the exception of milk and milk products, eggs, fish, other marine animals and products derived therefrom, shall not be used for food producing animals.
3. The Commission shall, in accordance with the procedure referred to in Article 31(2), decide on approval of the products and lay down particularly conditions and limits as regards the agricultural products that they can be applied to, the application method, the dosage, the time limits for use and the contact with agricultural products. The Commission shall also decide on withdrawal of products or amendments.

Article 12 **Conversion**

1. The following rules shall apply to a farm on which organic production is commenced:
- (a) the conversion period starts when the operator has notified and subjected his organic business to the control system;
 - (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) animals existing on the holding may be deemed organic after a specific period;
 - (e) milk, milk products and honey from formerly non organic animals may be sold as organic after a specific period ;
 - [(f) on a single farm unit partly under organic and partly in conversion to organic production, the farmer shall keep the organically produced and in conversion products separate and keep adequate records to show the separation;]
 - (g) a previous period may be recognised retroactively as being part of the conversion period under certain conditions;

- (h) animals and products shall not be marketed with indications referred to in Articles 17 and 18 and used in labelling and advertising of products until the conversion period referred to in subparagraph (c) is completed.
2. The periods referred to in paragraph (1) (c to e) and the conditions in paragraph (1) shall be defined in accordance with the procedure referred to in Article 31(2).

CHAPTER 2

PRODUCTION OF PROCESSED FEED

Article 13

General rules on the production 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.
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.

CHAPTER 3

PRODUCTION OF PROCESSED FOOD

Article 14

General rules on the production of processed food

0. Production of processed organic food shall be kept separate in time or space from production of processed 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, water or certain types of salt;
 - (b) additives, processing aids, flavourings, preparations of micro-organisms, minerals, trace elements, vitamins, aminoacids and other micronutrients and salt shall be used only if they have been approved in accordance with article 15;
 - (c) non-organic agricultural ingredients shall be used only if they have been approved in accordance with article 15 or have been provisionally authorized by a Member State in accordance with the provisions approved under the procedure referred to in Article 31 (2);

However, non-organic agricultural ingredients may be used in the preparation of organic food by mass caterers according to the provisions laid down in accordance with the procedure referred to in Article 31 (2).

- (d) In a product as referred to in Article 1(2) paragraphs (a) and (b) an ingredient obtained according to the requirements set out in this Regulation shall not be present together with the same ingredient not obtained according to the requirements or originating from conversion.
2. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic food or correct the results of negligence in the processing of these products shall not be used.

Article 15

Use of certain products and substances in processing

1. The following products and substances may be used in the production of organic processed food:
- a) additives, processing aids, flavourings, preparations of micro-organisms, minerals, trace elements, vitamins, aminoacids and other micronutrients and salt;
 - b) agricultural ingredients which are not available in organic form.
2. Their approval is subject to the objectives and principles laid down in Title II and the following general and specific criteria:

The following shall apply to all products and substances:

- i) their use is necessary for the processing and essential for its intended use;
- ii) their use does not result in, or contribute to, harmful effects on the environment;
- iii) approved alternatives are not available.

3. In addition, the following shall apply to paragraph 1 (a):
 - i) they are used only if it has been shown that, without having recourse to them, it is impossible to produce or preserve the food;
 - ii) they 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.
4. The Commission shall, in accordance with the procedure referred to in Article 31(2), decide on approval of the products and substances referred to in paragraph 1 and lay down in particular conditions and limits for their use. The Commission shall also decide on withdrawal of products or amendments.

CHAPTER 4 FLEXIBILITY

Article 16

Exceptional production rules

1. The Commission may, in accordance with the procedure referred to in Article 31(2) and the conditions set out in paragraph 2 and subject to the objectives and principles laid down in Title II, provide for the granting of exceptions from the production rules laid down in Chapters 1 to 3.
2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and may only be provided for in the following cases:
 - (a) where they are necessary in order to enable farm units initiating organic production to become viable;
 - (b) where they are necessary in order to ensure that organic production can be maintained on holdings confronted with climatic, geographical or structural constraints;
 - (c) 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;
 - (d) 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;
 - (e) where they are necessary in order to solve specific problems related to the management of organic livestock;
 - (f) where they are necessary in order to ensure production of well established food products in organic form;

- (g) where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances;
 - (h) where restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation;
 - (i) where it is necessary to use additives and other ingredients as set out in Article 14 (1) (b) legally required in the foodstuffs in which they are incorporated or food and feed additives and processing aids of non agricultural origin and such substances are not available on the market not produced from or by GMOs’.
3. The Commission may in accordance with the procedure referred to in Article 31(2) lay down specific conditions, or with the procedure referred to in Article 31 (1a) draw up guidelines for the competent authorities, for the application of exceptions provided for under paragraph 1.

TITLE IV LABELLING

Article 17

Use of terms referring to organic production

1. The terms listed in Annex I, their derivatives or diminutives, alone or combined, may be used throughout the Community and in any Community language for the labelling and advertising of a product or its ingredients which satisfies the requirements set out under this Regulation.

Where these terms are used for processed food in compliance with Article 14 at least 95% by weight, of the ingredients of agricultural origin shall be organic.

However, these terms may also be used for processed food in compliance with Article 14 where less than 95% by weight of the ingredients of agricultural origin are organic provided that they are only used in the list of ingredients and only in relation to ingredients of agricultural origin obtained in accordance with this Regulation; this indication shall appear in the same colour and with an identical size and style of lettering as the other indications in the list of ingredients.

2. The terms referred to in paragraph 1 shall not be used anywhere in the Community and in any Community language for the labelling and advertising 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 or practices used in labelling or advertising liable to mislead the consumer or user by suggesting that a product or its ingredients satisfy the requirements set out under this Regulation shall not be used.

3. The terms referred to in paragraph 1 shall not be used for a product for which it has to be indicated in the labelling that it contains GMOs, consists of GMOs or is produced from GMOs according to Community provisions.

4. In accordance with provisions laid down in Regulation (EEC) No. 40/1994:
 - (a) An application for registration of a trademark corresponding to one of the situations referred to in paragraph 2 shall be refused.
 - (b) Trademarks registered in breach of the first subparagraph shall be invalidated.
 - (c) The use of a trademark corresponding to one of the situations referred to in subparagraph 2 shall be refused.
5. Member States shall take the measures necessary to ensure compliance with this Article.
6. The Commission may in accordance with the procedure referred to in Article 31(2) adapt the list of terms set out in Annex I.

Article 18

Compulsory indications

1. Where terms are used as referred to in Article 17(1), the following indications shall also appear in the labelling:
 - (a) the code number referred to in Article 22(7) of the authority or control body to which the operator who has carried out the most recent production or preparation operation is subject;
 - (b) [where the logo referred to in Article 19 is not used, at least one of the indications listed in Annex II in capital lettering]. They shall only be used as regards to products which are referred to in Article 17 (1) subparagraphs 1 and 2.
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.
3. The Commission shall in accordance with the procedure referred to in Article 31(2) adapt the list of indications set out in Annex II.
4. In the labelling of products imported from third countries, the code number or the name of the authority or the control body of the third country in accordance with Article 1 (a) shall appear. The use of the indications referred to in paragraph 1(b) shall be optional.

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.

Article 20
Use of claims

1. General claims that a particular set of private or national 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 only 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.

Article 21
Specific labelling requirements

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

- (a) organic feed;
- (b) conversion products of plant origin;
- (c) products originating from mass caterers.

TITLE V CONTROLS

Article 22 Control system¹

1. Member States shall set up a system of controls and designate the competent authority or authorities responsible for controls in respect of the obligations established by this Regulation in conformity with Regulation (EC) Nr. 882/2004.
2. In the context of this Regulation the nature and frequency of the controls shall be determined on the basis of an analysis of the risk of breach of its provisions. In any case all operators shall be subject to a verification of compliance at least once a year.
3. The competent authority may
 - a) confer to one or more other authorities its control competences;
 - b) delegate control tasks to one or more control bodies.

Control bodies operating as verification of compliance and certification of conformity 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 authority or authorities.
4. Control bodies shall give the competent authority or authorities 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 Article.
5. The competent authority or authorities may not delegate the following tasks to the control bodies operating as certification bodies:
 - (a) the supervision and audit of other control bodies operating as certification bodies;
 - (b) the competence to grant exceptions, as referred to in Article 16, unless this is provided for in the specific conditions laid down by the Commission in accordance with Article 16(3).
6. Member States shall attribute a code number to each authority or control body operating as certification body.

¹ The Presidency will draft a new text following a document that the Commission undertook to prepare on the implementation of Regulation 882/2004 and the specific rules set out in Title V.

8. The authorities or control bodies shall by 31 January each year at the latest transmit to the competent authority a list of the operators which were subject to their controls on 31 December of the previous year., a summary report of the control activities carried out during the previous year shall be provided by 31 March each year.

Article 23

Adherence to the control system

1. Any operator prior to placing any products on the market, shall:
 - (a) notify his activity to a competent authority of the Member State where the activity is carried out;
 - (b) submit his undertaking to the control system.

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

2. Member States may exempt from the application of this Article:
 - (a) wholesalers dealing only with prepackaged products provided they do not import from a third country such products or;
 - (b) operators who sell products directly to the final consumer or user provided they do not produce, prepare, store other than in connection with the point of sale or import such products from a third country.
3. Member States shall ensure that any operator who complies with the rules of this Regulation, is entitled to be covered by the control system.
4. Member States shall ensure that any operator who complies with the rules of this Regulation, and who pays a reasonable fee as a contribution to the control expenses, is entitled to be covered by the control system.
5. The competent authority shall keep an updated list containing the names and addresses of operators subject to the control system.

Article 24¹

Certification

1. The competent authority and the approved control bodies may grant certificates, including the right to use their marks of conformity with organic standards, to operators which are subject to the control system.

¹ The Presidency undertook to draft a new text. The Commission, for its part, undertook to prepare a document explaining the rationale of this Article.

2. A competent 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. A control body may not refuse to grant certificates or the use of its mark of conformity for any product that has been certified by another approved control body, where the latter control body has assessed and certified conformity with organic standards equivalent to those of the first control body.

A control body which refuses to grant a certificate or the use of its mark of conformity, shall provide proof that the organic standards under which the product concerned has already been certified are not equivalent to its own standards.

Fees collected for the granting of the certificate or the mark of conformity shall be reasonable.

Article 25

Measures in case of infringements and irregularities

1. Where a severe irregularity is found as regards compliance with the requirements laid down in this Regulation, the authority or control body operating as certification body shall ensure that the terms, indications and the logo referring to the organic production method are not used on the entire lot or production run affected by this irregularity;

Where a manifest infringement or an infringement with prolonged effect is found, the authority or control body operating as certification body shall prohibit the operator concerned from marketing products with terms, indications and the logo referring to the organic production method for a period to be agreed with the competent authority of the Member State.

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

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

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

Article 26

Exchange of information

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

TITLE VI
TRADE WITH THIRD COUNTRIES

Article 27

Imports from third countries

1. A product imported from a third country may be placed on the Community market labelled as organic provided that:
 - (a) the product has been produced in accordance with production standards equivalent to those applied to organic production in the Community;
 - (b) the operators have been subject to control arrangements 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 a control system recognised in accordance with paragraph 2 or one or more control bodies recognised in accordance with paragraph 3;
 - (d) the product is covered by a certificate issued by the competent authorities or control bodies of a third country recognised in accordance with paragraph 2, or by a control body recognised in accordance with paragraph 4, which confirms that the product satisfies the conditions set out in this paragraph.

2. The Commission shall in accordance with the procedure referred to in Article 31(2) recognise the third countries whose production standards and control systems are equivalent to those applied in the Community and establish a list of these countries. The assessment of equivalency should take into account *Codex Alimentarius* guidelines CAC/GL 32.

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

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 control bodies competent to carry out controls and issue certificates in that third country for the purpose of paragraph 1, and establish a list of these control bodies. The assessment of equivalency should take into account *Codex Alimentarius* guidelines CAC/GL 32.

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

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

The Commission assisted by Member States ensures appropriate supervision of recognised control bodies according to the control system as set out in Title V.

TITLE VII FINAL AND TRANSITIONAL RULES

Article 28 **Free movement of organic products**

Member States may not, on grounds relating to the method of production, to labelling or to the presentation of that method, prohibit or restrict the marketing of organic products that meet the requirements of this Regulation.

Article 29 **Transmission of information to the Commission**

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

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

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 **Committees on organic production**

1. The Commission shall be assisted by an advisory and regulatory Committee on organic production.
 - 1a. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply.
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 4(3) 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 control system established under Title V, in particular as regards minimum control requirements, supervision and audit, the specific criteria for delegation of tasks to private control bodies and the criteria for approval and withdrawal of such bodies;
- (d) detailed rules as regards the rules on imports from third countries laid down in Title VI, in particular as regards the criteria and procedures to be followed with regard to the recognition under Article 27 of third countries and control bodies, including the publication of lists of recognised third countries and control bodies, and as regards the certificate referred to in Article 27(1), point (d).

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

Measures to facilitate the transition from the rules established by Regulation (EEC) No 2092/91 to this Regulation may 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 certain plant cultures, the rules provided for labelling in Article 17 and for the controls in Articles 22 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.

[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.

Indications referred to in Article 18(1)(b)

- UE-ECOLÓGICO,
- EU-EKOLOGICKÉ,
- EU-ØKOLOGISK,
- EU-ÖKOLOGISCH,
- EL-MAHE,
- EL-ÖKOLOGILINE,
- EE-BIOΛΟΓΙΚΟ,
- EU-ORGANIC,
- UE-BIOLOGIQUE,
- AE-ORGÁNACH,
- UE-BIOLOGICO,
- ES-BIOLOGISKĀ,
- ES-EKOLOGIŠKAS,
- EU-ÖKOLÓGIAI,
- EU-ORGANIKU,
- EU-BIOLOGISCH,
- UE-EKOLOGICZNE
- EU-EKOLOGICKE,
- EU-EKOLOSKI,
- EU-LUONNONMUKAINEN,
- EU-EKOLOGISK.