

# Official Journal

## of the European Union

L 189

English edition

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Volume 50

20 July 2007

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## I

*(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)*

## REGULATIONS

**Council Regulation (EC) No 834/2007****of 28 June 2007****on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament <sup>(1)</sup>,

Whereas:

- (1) Organic production is an overall system of farm management and food production that combines best environmental practices, a high level of biodiversity, the preservation of natural resources, the application of high animal welfare standards and a production method in line with the preference of certain consumers for products produced using natural substances and processes. The organic production method thus plays a dual societal role, where it on the one hand provides for a specific market responding to a consumer demand for organic products, and on the other hand delivers public goods contributing to the protection of the environment and animal welfare, as well as to rural development.
- (2) The share of the organic agricultural sector is on the increase in most Member States. Growth in consumer demand in recent years is particularly remarkable. Recent reforms of the common agricultural policy, with its emphasis on market-orientation and the supply of quality products to meet consumer demands, are likely to further stimulate the market in organic produce. Against this background the legislation on organic production plays an increasingly important role in the agricultural policy framework and is closely related to developments in the agricultural markets.
- (3) The Community legal framework governing the sector of organic production should pursue the objective of ensuring

fair competition and a proper functioning of the internal market in organic products, and of maintaining and justifying consumer confidence in products labelled as organic. It should further aim at providing conditions under which this sector can progress in line with production and market developments.

- (4) The Communication from the Commission to the Council and the European Parliament on a European Action Plan for Organic Food and Farming proposes to improve and reinforce the Community's organic farming standards and import and inspection requirements. In its conclusions of 18 October 2004, the Council called on the Commission to review the Community legal framework in this field with a view to ensure simplification and overall coherence and in particular to establish principles encouraging harmonisation of standards and, where possible, to reduce the level of detail.
- (5) It is therefore appropriate to define more explicitly the objectives, principles and rules applicable to organic production, in order to contribute to transparency and consumer confidence as well as to a harmonised perception of the concept of organic production.
- (6) To that end, Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs <sup>(2)</sup> should be repealed and replaced by a new regulation.
- (7) A general Community framework of organic production rules should be established with regard to plant, livestock, and aquaculture production, including rules for the collection of wild plants and seaweeds, rules on conversion, as well as rules on the production of processed food,

<sup>(1)</sup> Opinion delivered on 22 May 2007 (not yet published in the Official Journal).

<sup>(2)</sup> OJ L 98, 22.7.1991, p. 1. Regulation as last amended by Commission Regulation (EC) No 394/2007 (OJ L 98, 13.4.2007, p. 3).

- including wine, and feed and organic yeast. The Commission should authorise the use of products and substances and decide on methods to be used in organic farming and in the processing of organic food.
- (8) The development of organic production should be facilitated further, in particular by fostering the use of new techniques and substances better suited to organic production.
- (9) Genetically modified organisms (GMOs) and products produced from or by GMOs are incompatible with the concept of organic production and consumers' perception of organic products. They should therefore not be used in organic farming or in the processing of organic products.
- (10) The aim is to have the lowest possible presence of GMOs in organic products. The existing labelling thresholds represent ceilings which are exclusively linked to the adventitious and technically unavoidable presence of GMOs.
- (11) Organic farming should primarily rely on renewable resources within locally organised agricultural systems. In order to minimise the use of non-renewable resources, wastes and by-products of plant and animal origin should be recycled to return nutrients to the land.
- (12) Organic plant production should contribute to maintaining and enhancing soil fertility as well as to preventing soil erosion. Plants should preferably be fed through the soil eco-system and not through soluble fertilisers added to the soil.
- (13) The essential elements of the organic plant production management system are soil fertility management, choice of species and varieties, multiannual crop rotation, recycling organic materials and cultivation techniques. Additional fertilisers, soil conditioners and plant protection products should only be used if they are compatible with the objectives and principles of organic production.
- (14) Livestock production is fundamental to the organisation of agricultural production on organic holdings in so far as it provides the necessary organic matter and nutrients for cultivated land and accordingly contributes towards soil improvement and the development of sustainable agriculture.
- (15) In order to avoid environmental pollution, in particular of natural resources such as the soil and water, organic production of livestock should in principle provide for a close relationship between such production and the land, suitable multiannual rotation systems and the feeding of livestock with organic-farming crop products produced on the holding itself or on neighbouring organic holdings.
- (16) As organic stock farming is a land-related activity animals should have, whenever possible, access to open air or grazing areas.
- (17) Organic stock farming should respect high animal welfare standards and meet animals' species-specific behavioural needs while animal-health management should be based on disease prevention. In this respect, particular attention should be paid to housing conditions, husbandry practices and stocking densities. Moreover, the choice of breeds should take account of their capacity to adapt to local conditions. The implementing rules for livestock production and aquaculture production should at least ensure compliance with the provisions of the European Convention for the Protection of Animals kept for Farming purposes and the subsequent recommendations by its standing committee (T-AP).
- (18) The organic livestock production system should aim at completing the production cycles of the different livestock species with organically reared animals. It should therefore encourage the increase of the gene pool of organic animals, improve self reliance and thus ensure the development of the sector.
- (19) Organic processed products should be produced by the use of processing methods which guarantee that the organic integrity and vital qualities of the product are maintained through all stages of the production chain.
- (20) Processed food should be labelled as organic only where all or almost all the ingredients of agricultural origin are organic. However, special labelling provisions should be laid down for processed foods which include agricultural ingredients that cannot be obtained organically, as it is the case for products of hunting and fishing. Moreover, for the purpose of consumer information, transparency in the market and to stimulate the use of organic ingredients, it should also be made possible to refer to organic production in the ingredients list under certain conditions.
- (21) It is appropriate to provide for flexibility as regards the application of production rules, so as to make it possible to adapt organic standards and requirements to local climatic or geographic conditions, specific husbandry practices and stages of development. This should allow for the application of exceptional rules, but only within the limits of specific conditions laid down in Community legislation.
- (22) It is important to maintain consumer confidence in organic products. Exceptions from the requirements applicable to organic production should therefore be strictly limited to cases where the application of exceptional rules is deemed to be justified.

- (23) For the sake of consumer protection and fair competition, the terms used to indicate organic products should be protected from being used on non-organic products throughout the Community and independently of the language used. The protection should also apply to the usual derivatives or diminutives of those terms, whether they are used alone or combined.
- (24) In order to create clarity for consumers throughout the Community market, the EU-logo should be made obligatory for all organic pre-packaged food produced within the Community. It should otherwise be possible to use the EU-logo on a voluntary basis in the case of non pre-packaged organic products produced within the Community or any organic products imported from third countries.
- (25) It is however considered appropriate to limit the use of the EU-logo to products which contain only, or almost only, organic ingredients in order not to mislead consumers as to the organic nature of the entire product. It should therefore not be allowed to use it in the labelling of in-conversion products or processed foodstuffs of which less than 95 % of its ingredients of agricultural origin are organic.
- (26) The EU-logo should under no circumstances prevent the simultaneous use of national or private logos.
- (27) Moreover, for the sake of avoiding deceptive practices and any possible confusion amongst consumers on the Community or non-Community origin of the product, whenever the EU-logo is used, consumers should be informed about the place where the agricultural raw materials of which the product is composed have been farmed.
- (28) The Community rules should promote a harmonised concept of organic production. The competent authorities, control authorities and control bodies should refrain from any conduct that might create obstacles to the free movement of compliant products that have been certified by an authority or body located in another Member State. They should in particular not impose any additional controls or financial burdens.
- (29) For the sake of consistency with Community legislation in other fields, in the case of plant and livestock production, Member States should be allowed to apply within their own territories, national production rules which are stricter than the Community organic production rules, provided that these national rules also apply to non-organic production and are otherwise in conformity with Community law.
- (30) The use of GMOs in organic production is prohibited. For the sake of clarity and coherence, it should not be possible to label a product as organic where it has to be labelled as containing GMOs, consisting of GMOs or produced from GMOs.
- (31) In order to ensure that organic products are produced in accordance with the requirements laid down under the Community legal framework on organic production, activities performed by operators at all stages of production, preparation and distribution of organic products should be submitted to a control system set up and managed in conformity with the rules laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(1)</sup>.
- (32) It might in some cases appear disproportionate to apply notification and control requirements to certain types of retail operators, such as those who sell products directly to the final consumer or user. It is therefore appropriate to allow Member States to exempt such operators from these requirements. However, in order to avoid fraud it is necessary to exclude from the exemption those retail operators who produce, prepare or store products other than in connection with the point of sale, or who import organic products or who have contracted out the aforesaid activities to a third party.
- (33) Organic products imported into the European Community should be allowed to be placed on the Community market as organic, where they have been produced in accordance with production rules and subject to control arrangements that are in compliance with or equivalent to those laid down in Community legislation. In addition, the products imported under an equivalent system should be covered by a certificate issued by the competent authority, or recognised control authority or body of the third country concerned.
- (34) The assessment of equivalency with regard to imported products should take into account the international standards laid down in *Codex Alimentarius*.
- (35) It is considered appropriate to maintain the list of third countries recognised by the Commission as having production standards and control arrangement which are equivalent to those provided for in Community legislation. For third countries which are not included in that list, the Commission should set up a list of control authorities and control bodies recognised as being competent for the task of ensuring controls and certification in third countries concerned.
- (36) Relevant statistical information should be collected in order to obtain reliable data needed for the implementation and follow-up of this Regulation and as a tool for producers, market operators and policy makers. The statistical information needed should be defined within the context of the Community Statistical Programme.

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

- (37) This Regulation should apply from a date which gives the Commission sufficient time to adopt the measures necessary for its implementation.
- (38) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(1)</sup>.
- (39) The dynamic evolution of the organic sector, certain highly sensitive issues linked to the organic production method and the need to ensure a smooth functioning of the internal market and control system makes it appropriate to provide for a future review of the Community rules on organic farming, taking into account the experience gained from the application of these rules.
- (40) Pending the adoption of detailed Community production rules for certain animal species and aquatic plants and micro-algae, Member States should have the possibility to provide for the application of national standards or, in the absence thereof, private standards accepted or recognised by the Member States,

HAS ADOPTED THIS REGULATION:

#### 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 control;
- (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 are intended to be placed on the market:

- (a) live or unprocessed agricultural products;
- (b) processed agricultural products for use as food;

- (c) feed;
- (d) vegetative propagating material and seeds for cultivation.

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

This Regulation 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, relating to the products set out in paragraph 2.

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

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

#### Article 2

##### Definitions

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

- (a) 'organic production' means the use of the production method compliant with the rules established in this Regulation, at all stages of production, preparation and distribution;
- (b) 'stages of production, preparation and distribution' means any stage from and including the primary production of an organic product up to and including its storage, processing, transport, sale or supply to the final consumer, and where relevant labelling, advertising, import, export and subcontracting activities;
- (c) 'organic' means coming from or related to organic production;
- (d) '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;
- (e) 'plant production' means production of agricultural crop products including harvesting of wild plant products for commercial purposes;

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).



- (f) 'livestock production' means the production of domestic or domesticated terrestrial animals (including insects);
- (g) the definition of 'aquaculture' is that given in Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund <sup>(1)</sup>;
- (h) '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;
- (i) '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;
- (j) the definitions of 'food', 'feed' and 'placing on the market' are those given in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(2)</sup>;
- (k) 'labelling' means any terms, words, particulars, trade marks, brand name, pictorial matter or symbol relating to and placed on any packaging, document, notice, label, board, ring or collar accompanying or referring to a product;
- (l) the definition of 'pre-packaged foodstuff' is that given in Article 1(3)(b) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs <sup>(3)</sup>;
- (m) '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;
- (n) 'competent authority' means the central authority of a Member State competent for the organisation of official controls in the field of organic production in accordance with the provisions set out under this Regulation, or any other authority on which that competence has been conferred to; it shall also include, where appropriate, the corresponding authority of a third country;
- (o) 'control authority' means a public administrative organisation of a Member State to which the competent authority has conferred, in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding authority of a third country or the corresponding authority operating in a third country;
- (p) 'control body' means an independent private third party carrying out inspection and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding body of a third country or the corresponding body operating in a third country;
- (q) 'mark of conformity' means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;
- (r) the definition of 'ingredients' is that given in Article 6(4) of Directive 2000/13/EC;
- (s) the definition of 'plant protection products' is that given in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market <sup>(4)</sup>;
- (t) the definition of 'Genetically modified organism (GMO)' is that given in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC <sup>(5)</sup> and which is not obtained through the techniques of genetic modifications listed in Annex I.B of that Directive;
- (u) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs;
- (v) '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;
- (w) the definition of 'feed additives' is that given in Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(6)</sup>;

<sup>(1)</sup> OJ L 223, 15.8.2006, p. 1.

<sup>(2)</sup> OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

<sup>(3)</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Commission Directive 2006/142/EC (OJ L 368, 23.12.2006, p. 110).

<sup>(4)</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/31/EC (OJ L 140, 1.6.2007, p. 44).

<sup>(5)</sup> OJ L 106, 17.4.2001, p. 1. Regulation as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

<sup>(6)</sup> OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

- (x) 'equivalent', in describing different systems or measures, means that they are capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity;
- (y) '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;
- (z) the definition of 'ionising radiation' is that given in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation <sup>(1)</sup> and as restricted by Article 1(2) 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 <sup>(2)</sup>.
- (aa) 'mass catering operations' means the preparation of organic products in restaurants, hospitals, canteens and other similar food business at the point of sale or delivery to the final consumer.

## TITLE II

### OBJECTIVES AND PRINCIPLES FOR ORGANIC PRODUCTION

#### Article 3

##### Objectives

Organic production shall pursue the following general objectives:

- (a) establish a sustainable management system for agriculture that:
  - (i) respects nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals and the balance between them;
  - (ii) contributes to a high level of biological diversity;
  - (iii) makes responsible use of energy and the natural resources, such as water, soil, organic matter and air;
  - (iv) respects high animal welfare standards and in particular meets animals' species-specific behavioural needs;
- (b) aim at producing products of high quality;

- (c) aim at producing a wide variety of foods and other agricultural products that respond to consumers' demand for goods produced by the 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 natural resources which are internal to the system by methods that:
  - (i) use living organisms and mechanical production methods;
  - (ii) practice land-related crop cultivation and livestock production or practice 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 the use of precautionary and preventive measures, when appropriate;
- (b) the restriction of the use of external inputs. Where external inputs are required or the appropriate management practices and methods referred to in paragraph (a) do not exist, these shall be limited to:
  - (i) inputs from organic production;
  - (ii) natural or naturally-derived substances;
  - (iii) low solubility mineral fertilisers;
- (c) the strict limitation of the use of chemically synthesised inputs to exceptional cases these being:
  - (i) where the appropriate management practices do not exist; and
  - (ii) the external inputs referred to in paragraph (b) are not available on the market; or
  - (iii) where the use of external inputs referred to in paragraph (b) contributes to unacceptable environmental impacts;

<sup>(1)</sup> OJ L 159, 29.6.1996, p. 1.

<sup>(2)</sup> OJ L 66, 13.3.1999, p. 16. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

- (d) the adaptation, where necessary, and within the framework of this Regulation, of 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) the maintenance and enhancement of soil life and natural soil fertility, soil stability and soil biodiversity preventing and combating soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem;
- (b) the minimisation of the use of non-renewable resources and off-farm inputs;
- (c) the recycling of 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) the maintenance of animal health by encouraging the natural immunological defence of the animal, as well as the selection of appropriate breeds and husbandry practices;
- (f) the maintenance of 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;
- (g) the practice of site-adapted and land-related livestock production;
- (h) the observance of a high level of animal welfare respecting species-specific needs;
- (i) the production of products of organic livestock from animals that have been raised on organic holdings since birth or hatching and throughout their life;
- (j) the choice of breeds having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems;
- (k) the feeding of livestock with organic feed composed of agricultural ingredients from organic farming and of natural non-agricultural substances;
- (l) the application of 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;
- (m) the exclusion of rearing artificially induced polyploid animals;
- (n) the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems in aquaculture production;
- (o) the feeding of aquatic organisms with feed from sustainable exploitation of fisheries as defined in Article 3 of Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy<sup>(1)</sup> 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 specific principles:

- (a) the production of organic food from organic agricultural ingredients, except where an ingredient is not available on the market in organic form;
- (b) the restriction of the use of food additives, of non organic ingredients with mainly technological and sensory functions and of micronutrients and processing aids, so that they are used to a minimum extent and only in case of essential technological need or for particular nutritional purposes;
- (c) the exclusion of substances and processing methods that might be misleading regarding the true nature of the product;
- (d) the processing of food with care, preferably with the use of biological, mechanical and physical methods.

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59.



*Article 7***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 specific principles:

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

## TITLE III

## PRODUCTION RULES

## CHAPTER 1

**General production rules***Article 8***General requirements**

Operators shall comply with the production rules set out in this Title and with the implementing rules provided for in Article 38(a).

*Article 9***Prohibition on the use of GMOs**

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

2. For the purpose of the prohibition referred to in paragraph 1 concerning GMOs or products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup> or Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

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

3. For the purpose of the prohibition referred to in paragraph 1, with regard to 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. The Commission shall decide on measures implementing the prohibition on the use of GMOs and products produced from or by GMOs in accordance with the procedure referred to in Article 37(2).

*Article 10***Prohibition on the use of ionising radiation**

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

## CHAPTER 2

**Farm production***Article 11***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 37(2), a holding may be split up into clearly separated units or aquaculture production sites which are not all managed under organic production. As regards animals, different species shall be involved. As regards aquaculture the same species may be involved, provided that there is adequate separation between the production sites. As regards plants, different varieties that can be easily differentiated shall be involved.

Where, in accordance with the second subparagraph, not all units of a holding are used for organic production, the operator 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 12

**Plant production rules**

1. In addition to the general farm production rules laid down in Article 11, 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) the fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production;
- (c) the use of biodynamic preparations is allowed;
- (d) in addition, fertilisers and soil conditioners may only be used if they have been authorised for use in organic production under Article 16;
- (e) mineral nitrogen fertilisers shall not be used;
- (f) all plant production techniques used shall prevent or minimise any contribution to the contamination of the environment;
- (g) the 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;
- (h) in the case of an established threat to a crop, plant protection products may only be used if they have been authorised for use in organic production under Article 16;
- (i) 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;
- (j) products for cleaning and disinfection in plant production shall be used only if they have been authorised for use in organic production under Article 16.

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 treatment with products

other than those authorised for use in organic production under Article 16;

- (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 37(2).

## Article 13

**Production rules for seaweed**

1. The collection of wild seaweeds and parts thereof, growing naturally in the sea, is considered as an organic production method provided that:

- (a) the growing areas are of high ecological quality as defined by Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy <sup>(1)</sup> and, pending its implementation, of a quality equivalent to designated waters under Directive 2006/113/EC of the European Parliament and of the Council of 12 December 2006 on the quality required of shellfish waters <sup>(2)</sup>, 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 (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(3)</sup>;
- (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. In addition to this:

- (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, the collection of juvenile seaweed in the wild should take place on a regular basis to supplement indoor culture stock;

<sup>(1)</sup> OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

<sup>(2)</sup> OJ L 376, 27.12.2006, p. 14.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206. Corrected version in OJ L 226, 25.6.2004, p. 83.

(c) fertilisers shall not be used except in indoor facilities and only if they have been authorised for use in organic production for this purpose under Article 16.

3. The measures necessary for the implementation of production rules contained in this Article shall be adopted in accordance with the procedure referred to in Article 37(2).

#### Article 14

##### Livestock production rules

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to livestock production:

(a) with regard to the origin of the animals:

- (i) organic livestock shall be born and raised on organic holdings;
- (ii) for breeding purposes, non-organically raised animals may be brought onto a holding under specific conditions. Such animals and their products may be deemed organic after compliance with the conversion period referred to in Article 17(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 17(1)(c);

(b) with regard to husbandry practices and housing conditions:

- (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;
- (ii) husbandry practices, including stocking densities, and housing conditions shall ensure that the developmental, physiological and ethological needs of animals are met;
- (iii) the livestock shall have permanent access to open air areas, preferably pasture, whenever weather conditions and the state of the ground allow this unless restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation;
- (iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;
- (v) organic livestock shall be kept separate from other livestock. However, grazing of common land by organic animals and of organic land by non-organic animals is permitted under certain restrictive conditions;

(vi) tethering or isolation of livestock shall be prohibited, unless for individual animals for a limited period of time, and in so far as this is justified for safety, welfare or veterinary reasons;

(vii) duration of transport of livestock shall be minimised;

(viii) any suffering, including mutilation, shall be kept to a minimum during the entire life of the animal, including at the time of slaughter;

(ix) apiaries shall be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops or, as appropriate, of spontaneous vegetation or non-organically managed forests or crops that are only treated with low environmental impact methods. Apiaries shall be kept at sufficient distance from sources that may lead to the contamination of beekeeping products or to the 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. Artificial insemination is however allowed;

(ii) reproduction shall not be induced by treatment with hormones or similar substances, unless as a form of veterinary therapeutic treatment in case of an individual animal;

(iii) other forms of artificial reproduction, such as cloning and embryo transfer, shall not be used;

(iv) appropriate breeds shall be chosen. The choice of breeds shall also contribute to the prevention of any suffering and to avoiding the need for the mutilation of animals;

(d) with regard to feed:

(i) primarily obtaining feed for livestock from the holding where the animals are kept or from other organic holdings in the same region;

(ii) 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 which are in conversion to organic farming;

- (iii) with the exception of bees, livestock shall have permanent access to pasture or roughage;

#### Article 15

#### Production rules for aquaculture animals

- (iv) 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 authorised for use in organic production under Article 16;

1. In addition to the general farm production rules laid down in Article 11, the following rules shall apply to aquaculture animal production:

- (v) growth promoters and synthetic amino-acids shall not be used;

- (a) with regard to the origin of the aquaculture animals:

- (vi) suckling mammals shall be fed with natural, preferably maternal, milk;

- (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;

- (e) with regard to disease prevention and veterinary treatment:

- (b) with regard to husbandry practices:

- (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;

- (i) personnel keeping animals shall possess the necessary basic knowledge and skills as regards the health and the welfare needs of the animals;

- (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;

- (ii) husbandry practices, including feeding, design of installations, stocking densities and water quality shall ensure that the developmental, physiological and behavioural needs of animals are met;

- (iii) the use of immunological veterinary medicines is allowed;

- (iii) husbandry practices shall minimise negative environmental impact from the holding, including the escape of farmed stock;

- (iv) treatments related to the protection of human and animal health imposed on the basis of Community legislation shall be allowed;

- (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;

- (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 authorised for use in organic production under Article 16.

- (c) with regard to breeding:

- (i) artificial induction of polyploidy, artificial hybridisation, cloning and production of monosex strains, except by hand sorting, shall not be used;

- (ii) the appropriate strains shall be chosen;

- (iii) species-specific conditions for broodstock management, breeding and juvenile production shall be established;

2. 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 37(2).

- (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 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 authorised for use in organic production under Article 16;
  - (iv) growth promoters and synthetic amino-acids shall not be used;
- (e) 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 (EC) No 854/2004;
  - (iii) the growing areas shall be of high ecological quality as defined by Directive 2000/60/EC and, pending its implementation of a quality equivalent to designated waters under Directive 2006/113/EC;
- (f) 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.
- (g) With regard to cleaning and disinfection, products for cleaning and disinfection in ponds, cages, buildings and installations, shall be used only if they have been authorised for use in organic production under Article 16.
2. 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 37(2).
- Article 16*
- Products and substances used in farming and criteria for their authorisation**
1. The Commission shall, in accordance with the procedure referred to in Article 37(2), authorise for use in organic production and include in a restricted list the products and substances, which may be used in organic farming for the following purposes:
- (a) as plant protection products;
  - (b) as fertilisers and soil conditioners;
  - (c) as non-organic feed materials from plant origin, feed material from animal and mineral origin and certain substances used in animal nutrition;
  - (d) as feed additives and processing aids;
  - (e) as products for cleaning and disinfection of ponds, cages, buildings and installations for animal production;
  - (f) as products for cleaning and disinfection of buildings and installations used for plant production, including storage on an agricultural holding.
- Products and substances contained in the restricted list may only be used in so far as the corresponding use is 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 authorisation of the products and substances referred to in paragraph 1 is subject to the objectives and principles laid down in Title II and the following general and specific criteria which shall be evaluated as a whole:
- (a) their use is necessary for sustained production and essential for its intended use;



- (b) all products and substances shall be of plant, animal, microbial or mineral origin except where 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 authorised 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 (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 it would be impossible to produce or preserve such feed without having recourse to such substances;
  - (ii) feed of mineral origin, trace elements, vitamins or provitamins shall be of natural origin. In case these substances are unavailable, chemically well-defined analogic substances may be authorised for use in organic production.
- 3. (a) The Commission may, in accordance with the procedure referred to in Article 37(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 the withdrawal of these products and substances.
- (b) Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States.

Requests for amendment or withdrawal, as well as decisions thereon, shall be published.

- (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 37(2).

4. Member States may regulate, within their territory, the use of products and substances in organic farming for purposes different than those mentioned in paragraph 1 provided their use is subject to objectives and principles laid down in Title II and the general and specific criteria set out in paragraph 2, and in so far as it respects Community law. The Member State concerned shall inform other Member States and the Commission of such national rules.

5. The use of products and substances not covered under paragraph 1 and 4, and subject to the objectives and principles laid down in Title II and the general criteria in this Article, shall be allowed in organic farming.

#### Article 17

#### 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 his activity to the competent authorities and subjected his holding to the control system in accordance with Article 28(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 operator shall keep the organically produced and in-conversion products separate and the animals separate or readily separable and keep adequate records to show the separation;
  - (e) in order to determine the conversion period referred to above, a period immediately preceding the date of the start of the conversion period, may be taken into account, in so far as certain conditions concur;
  - (f) animals and animal products produced during the conversion period referred to in subparagraph (c) shall not be marketed with the indications referred to in Articles 23 and 24 used in the labelling and advertising of products.

2. The measures and conditions necessary for the implementation of the rules contained in this Article, and in particular the periods referred to in paragraph 1(c) to (f) shall be defined in accordance with the procedure referred to in Article 37(2).

#### CHAPTER 3

### ***Production of processed feed***

#### *Article 18*

#### **General rules on the production of processed feed**

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

2. Organic feed materials, or feed materials from production in conversion, shall not enter simultaneously with the same feed materials produced by non organic means into the composition of the organic feed product.

3. Any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesised solvents.

4. Substances and techniques that reconstitute properties that are lost in the processing and storage of organic feed, that correct the results of negligence in the processing or that otherwise may be misleading as to 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 37(2).

#### CHAPTER 4

### ***Production of processed food***

#### *Article 19*

#### **General rules on the production of processed food**

1. The preparation of processed organic food shall be kept separate in time or space from non-organic food.

2. The following conditions shall apply to the composition of organic processed food:

- (a) the product shall be produced mainly from ingredients of agricultural origin; in order to determine whether a product is produced mainly from ingredients of agricultural origin added water and 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 amino acids and other micronutrients in foodstuffs for particular nutritional uses

may be used, and only in so far as they have been authorised for use in organic production in accordance with Article 21;

- (c) non-organic agricultural ingredients may be used only if they have been authorised for use in organic production in accordance with Article 21 or have been provisionally authorised by a Member State;
- (d) an organic ingredient shall not be present together with the same ingredient in non-organic form or an ingredient in conversion;
- (e) food produced from in-conversion crops shall contain only one crop ingredient of agricultural origin.

3. 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 be misleading as to the true nature of these products shall not be used.

The measures necessary for the implementation of the production rules contained in this Article, and in particular regarding processing methods and the conditions for the provisional authorisation by Member States mentioned in paragraph 2(c), shall be adopted in accordance with the procedure referred to in Article 37(2).

#### *Article 20*

#### **General rules on the production of organic yeast**

1. For the production of organic yeast only organically produced substrates shall be used. Other products and substances may only be used in so far as they have been authorised for use in organic production in accordance with Article 21.

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 37(2).

#### *Article 21*

#### **Criteria for certain products and substances in processing**

1. The authorisation of products and substances for use in organic production and their inclusion in a restricted list of the products and substances referred to in Article 19(2)(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 authorised in accordance with this chapter are not available;

- (ii) without having recourse to them, it would be impossible to produce or preserve the food or to fulfil given dietary requirements provided for on the basis of the Community legislation.

In addition, the products and substances referred to in Article 19(2)(b) are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes, except where 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 37(2), decide on the authorisation of the products and substances and their inclusion in the restricted list referred to in paragraph 1 of this Article and lay down specific conditions and limits for their use, and, if necessary, on the withdrawal of products.

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

Requests for amendment or withdrawal, as well as decisions thereon, shall be published.

Products and substances used before adoption of this Regulation and falling under Article 19(2)(b) and (c) may continue to be used after the said adoption. The Commission may, in any case, withdraw such products or substances in accordance with Article 37(2).

## CHAPTER 5

### *Flexibility*

#### Article 22

### **Exceptional production rules**

1. The Commission may, in accordance with the procedure referred to in Article 37(2) and the conditions set out in paragraph 2 of this Article 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 4.
2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and, where appropriate, limited in time and may only be provided for in the following cases:
  - (a) where they are necessary in order to ensure that organic production can be initiated or maintained on holdings confronted with climatic, geographical or structural constraints;
  - (b) where it is necessary in order to ensure access to feed, seed and vegetative propagating material, live animals and other

farm inputs, where such inputs are not available on the market in organic form;

- (c) where it is necessary in order to ensure access to ingredients of agricultural origin, where such ingredients are not available on the market in organic form;
- (d) where they are necessary in order to solve specific problems related to the management of organic livestock;
- (e) where they are necessary with regard to the use of specific products and substances in the processing referred to in Article 19(2)(b) in order to ensure production of well established food products in organic form;
- (f) where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances;
- (g) where it is necessary to use food additives and other substances as set out in Article 19(2)(b) or feed additives and other substances as set out in Article 16(1)(d) and such substances are not available on the market other than produced by GMOs;
- (h) where the use of food additives and other substances as set out in Article 19(2)(b) or feed additives as set out in Article 16(1)(d) is required on the basis of Community law or national law.

3. The Commission may in accordance with the procedure referred to in Article 37(2) lay down specific conditions for the application of exceptions provided for under paragraph 1.

## TITLE IV

### **LABELLING**

#### Article 23

### **Use of terms referring to organic production**

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

In the labelling and advertising of live or unprocessed agricultural products terms referring to the organic production method may be used only where, in addition, all the ingredients of that product have also been produced in accordance with the requirements laid down in this Regulation.

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

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

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

4. As regards processed food, the terms referred to in paragraph 1 may be used:

- (a) in the sales description, provided that:
  - (i) the processed food complies with Article 19;
  - (ii) at least 95 % by weight, of its ingredients of agricultural origin are organic;
- (b) only in the list of ingredients, provided that the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d);
- (c) in the list of ingredients and in the same visual field as the sales description, provided that:
  - (i) the main ingredient is a product of hunting or fishing;
  - (ii) it contains other ingredients of agricultural origin that are all organic;
  - (iii) the food complies with Article 19(1), 19(2)(a), 19(2)(b) and 19(2)(d).

The list of ingredients shall indicate which ingredients are organic.

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

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

5. Member States shall take the measures necessary to ensure compliance with this Article.

6. The Commission may in accordance with the procedure referred to in Article 37(2) adapt the list of terms set out in the Annex.

#### Article 24

#### Compulsory indications

1. Where terms as referred to in Article 23(1) are used:

- (a) the code number referred to in Article 27(10) of the control authority or control body to which the operator who has carried out the most recent production or preparation operation is subject, shall also appear in the labelling;
- (b) the Community logo referred to in Article 25(1) as regards pre-packaged food shall also appear on the packaging;
- (c) where the Community logo is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed, shall also appear in the same visual field as the logo and shall take one of the following forms, as appropriate:
  - 'EU Agriculture', where the agricultural raw material has been farmed in the EU,
  - 'non-EU Agriculture', where the agricultural raw material has been farmed in third countries,
  - 'EU/non-EU Agriculture', where part of the agricultural raw materials has been farmed in the Community and a part of it has been farmed in a third country.

The abovementioned indication 'EU' or 'non-EU' may be replaced or supplemented by a country in the case where all agricultural raw materials of which the product is composed have been farmed in that country.

For the abovementioned 'EU' or 'non-EU' indication, small quantities by weight of ingredients may be disregarded provided that the total quantity of the disregarded ingredients does not exceed 2 % of the total quantity by weight of raw materials of agricultural origin.

The abovementioned 'EU' or 'non-EU' indication shall not appear in a colour, size and style of lettering more prominent than the sales description of the product.

The use of the Community logo as referred to in Article 25(1) and the indication referred to in the first subparagraph shall be optional for products imported from third countries. However, where the Community logo as referred to in Article 25(1) appears in the labelling, the indication referred to in the first subparagraph shall also appear in the labelling.

2. The indications referred to in paragraph 1 shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

3. The Commission shall, in accordance with the procedure referred to in Article 37(2), lay down specific criteria as regards the presentation, composition and size of the indications referred to in paragraph 1(a) and (c).

#### Article 25

##### Organic production logos

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

The Community logo shall not be used in the case of in-conversion products and food as referred to in Article 23(4)(b) and (c).

2. National and private logos may be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation.

3. The Commission shall, in accordance with the procedure referred to in Article 37(2), lay down specific criteria as regards presentation, composition, size and design of the Community logo.

#### Article 26

##### Specific labelling requirements

The Commission shall in accordance with the procedure referred to in Article 37(2) establish specific labelling and composition requirements applicable to:

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

#### TITLE V

#### CONTROLS

#### Article 27

##### Control system

1. Member States shall set up a system of controls and designate one or more competent authorities responsible for controls in respect of the obligations established by this Regulation in conformity with Regulation (EC) No 882/2004.

2. In addition to the conditions laid down in Regulation (EC) No 882/2004, the control system set up under this Regulation shall comprise at least the application of precautionary and control measures to be adopted by the Commission in accordance with the procedure referred to in Article 37(2).

3. In the context of this Regulation the nature and frequency of the controls shall be determined on the basis of an assessment of

the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation. In any case, all operators with the exception of wholesalers dealing only with pre-packaged products and operators selling to the final consumer or user as described in Article 28(2), shall be subject to a verification of compliance at least once a year.

4. The competent authority may:

- (a) confer its control competences to one or more other control authorities. Control authorities shall offer adequate guarantees of objectivity and impartiality, and have at their disposal the qualified staff and resources necessary to carry out their functions;
- (b) delegate control tasks to one or more control bodies. In that case, the Member States shall designate authorities responsible for the approval and supervision of such bodies.

5. The competent authority may delegate control tasks to a particular control body only if the conditions laid down in Article 5(2) of Regulation (EC) No 882/2004 are satisfied, and in particular where:

- (a) there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out;
- (b) there is proof that the control body:
  - (i) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;
  - (iii) has a sufficient number of suitable qualified and experienced staff; and
  - (iii) is impartial and free from any conflict of interest as regards the exercise of the tasks delegated to it;
- (c) the control body is accredited to the most recently notified version, by a publication in the C series of the *Official Journal of the European Union*, of European Standard EN 45011 or ISO Guide 65 (General requirements for bodies operating product certification systems), and is approved by the competent authorities;
- (d) the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority;
- (e) there is an effective coordination between the delegating competent authority and the control body.



6. In addition to the provisions of paragraph 5, the competent authority shall take into account the following criteria whilst approving a control body:

- (a) the standard control procedure to be followed, containing a detailed description of the control measures and precautions that the body undertakes to impose on operators subject to its control;
- (b) the measures that the control body intends to apply where irregularities and/or infringements are found.

7. The competent authorities may not delegate the following tasks to the control bodies;

- (a) the supervision and audit of other control bodies;
- (b) the competence to grant exceptions, as referred to in Article 22, unless this is provided for in the specific conditions laid down by the Commission in accordance with Article 22(3).

8. In accordance with Article 5(3) of Regulation (EC) No 882/2004, competent authorities delegating control tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.

9. In addition to the provisions of paragraph 8, the competent authority shall:

- (a) ensure that the controls carried out by the control body are objective and independent;
- (b) verify the effectiveness of its controls;
- (c) take cognisance of any irregularities or infringements found and corrective measures applied;
- (d) withdraw approval of that body where it fails to satisfy the requirements referred to in (a) and (b) or no longer fulfils the criteria indicated in paragraph 5, 6 or fails to satisfy the requirements laid down in paragraphs 11, 12 and 14.

10. Member States shall attribute a code number to each control authority or control body performing control tasks as referred to in paragraph 4.

11. Control authorities and control bodies shall give the competent authorities access to their offices and facilities and provide any information and assistance deemed necessary by the competent authorities for the fulfilment of their obligations according to this Article.

12. The control authorities and control bodies shall ensure that at least the precautionary and control measures referred to in paragraph 2 are applied to operators subject to their control.

13. Member States shall ensure that the control system as set up allows for the traceability of each product at all stages of production, preparation and distribution in accordance with Article 18 of Regulation (EC) No 178/2002, in particular, in order to give consumers guarantees that organic products have been produced in compliance with the requirements set out in this Regulation.

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

#### Article 28

#### Adherence to the control system

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

- (a) notify his activity to the competent authorities of the Member State where the activity is carried out;
- (b) submit his undertaking to the control system referred to in Article 27.

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

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

2. Member States may exempt from the application of this Article operators who sell products directly to the final consumer or user provided they do not produce, prepare, store other than in connection with the point of sale or import such products from a third country or have not contracted out such activities to a third party.

3. Member States shall designate an authority or approve a body for the reception of such notifications.

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 control authorities and control bodies shall keep an updated list containing the names and addresses of operators under their control. This list shall be made available to the interested parties.

6. The Commission, in accordance with the procedure referred to in Article 37(2), shall adopt implementing rules to provide details of the notification and submission procedure referred to in paragraph 1 of this Article in particular with regard to the information included in the notification referred to in paragraph 1(a) of this Article.

#### Article 29

##### Documentary evidence

1. The control authorities and the control bodies referred to in Article 27(4) shall provide documentary evidence to any such operator who is subject to their controls and who in the sphere of his activities, meets the requirements laid down in this Regulation. The documentary evidence shall at least permit the identification of the operator and the type or range of products as well as the period of validity.

2. The operator shall verify the documentary evidence of his suppliers.

3. The form of the documentary evidence referred to in paragraph 1 shall be drawn up in accordance with the procedure referred to in Article 37(2), taking into account the advantages of electronic certification.

#### Article 30

##### Measures in case of infringements and irregularities

1. Where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the control authority or control body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities.

Where a severe infringement or an infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be agreed with the competent authority of the Member State.

2. Information on cases of irregularities or infringements affecting the organic status of a product shall be immediately communicated between the control bodies, control authorities, competent authorities and Member States concerned 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 37(2), lay down specifications regarding the form and modalities of such communications.

#### Article 31

##### Exchange of information

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

#### TITLE VI

##### TRADE WITH THIRD COUNTRIES

#### Article 32

##### Import of compliant products

1. A product imported from a third country may be placed on the Community market as organic provided that:

- (a) the product complies with the provisions set out in Titles II, III and IV as well as with the implementing rules affecting its production adopted pursuant to this Regulation;
- (b) all operators, including the exporters, have been subject to control by a control authority or control body recognised in accordance with paragraph 2;
- (c) the operators concerned shall be able to provide at any time, to the importers or the national authorities, documentary evidence as referred to in Article 29, permitting the identification of the operator who carried out the last operation and the verification of compliance by that operator with points (a) and (b), issued by the control authority or control body referred to in point (b).

2. The Commission shall, in accordance with the procedure referred to in Article 37(2), recognise the control authorities and control bodies referred to in paragraph 1(b) of this Article, including control authorities and control bodies as referred to in Article 27, which are competent to carry out controls and to issue the documentary evidence referred to in paragraph 1(c) of this Article in third countries, and establish a list of these control authorities and control bodies.

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

When examining requests for recognition, the Commission shall invite the control authority or control body to supply all the necessary information. The Commission may also entrust

experts with the task of examining on-the-spot the rules of production and the control activities carried out in the third country by the control authority or control body concerned.

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

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

### Article 33

#### Import of products providing equivalent guarantees

1. A product imported from a third country may also be placed on the Community market as organic provided that:

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

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

2. The Commission may, in accordance with the procedure referred to in Article 37(2), recognise the third countries whose system of production complies with principles and production rules equivalent to those laid down in Titles II, III and IV and whose control measures are of equivalent effectiveness to those laid down in Title V, and establish a list of these countries. The assessment of equivalency shall take into account *Codex Alimentarius* guidelines CAC/GL 32.

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

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

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

3. For products not imported under Article 32 and not imported from a third country which is recognised under paragraph 2 of this Article, the Commission may, in accordance with the procedure referred to in Article 37(2), recognise the control authorities and control bodies, including control authorities and control bodies as referred to in Article 27, competent to carry out controls and issue certificates in third countries for the purpose of paragraph 1, and establish a list of these control authorities and control bodies. The assessment of equivalency shall take into account *Codex Alimentarius* guidelines CAC/GL 32.

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

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

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

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

## TITLE VII

## FINAL AND TRANSITIONAL RULES

## Article 34

**Free movement of organic products**

1. Competent authorities, control authorities and control bodies may not, on grounds relating to the method of production, to the labelling or to the presentation of that method, prohibit or restrict the marketing of organic products controlled by another control authority or control body located in another Member State, in so far as those products meet the requirements of this Regulation. In particular, no additional controls or financial burdens in addition to those foreseen in Title V of this Regulation may be imposed.

2. Member States may apply stricter rules within their territory to organic plant and livestock production, where these rules are also applicable to non-organic production and provided that they are in conformity with Community law and do not prohibit or restrict the marketing of organic products produced outside the territory of the Member State concerned.

## Article 35

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

## Article 36

**Statistical information**

Member States shall transmit to the Commission the 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 37

**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 apply.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

## Article 38

**Implementing rules**

The Commission shall, in accordance with the procedure referred to in Article 37(2), and subject to the objectives and principles laid down in Title II, adopt detailed rules for the application of this Regulation. These 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 the criteria for approval and withdrawal of such bodies and the documentary evidence referred to in Article 29;
- (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 32 and 33 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 33(1) point (d) taking into account the advantages of electronic certification;
- (e) detailed rules as regards the free movement of organic products laid down in Article 34 and the transmission of information to the Commission in Article 35.

## Article 39

**Repeal of Regulation (EEC) No 2092/91**

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

## Article 40

**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 37(2).

*Article 41***Report to the Council**

1. By 31 December 2011, the Commission shall submit a report to the Council.
2. The report shall, in particular, review the experience gained from the application of this Regulation and consider in particular the following issues:
  - (a) the scope of this Regulation, in particular as regards organic food prepared by mass caterers;
  - (b) the prohibition on the use of GMOs, including the availability of products not produced by GMOs, the vendor declaration, the feasibility of specific tolerance thresholds and their impact on the organic sector;
  - (c) the functioning of the internal market and controls system, assessing in particular that the established practices do not lead to unfair competition or barriers to the production and marketing of organic products.

3. The Commission shall, if appropriate, accompany the report with relevant proposals.

*Article 42***Entry into force and application**

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

For certain animal species, certain aquatic plants and certain micro algae, where the detailed production rules are not laid down, the rules provided for labelling in Article 23 and for the controls in Title V shall apply. Pending the inclusion of detailed production rules, national rules or, in the absence thereof, private standards accepted or recognised by the Member States shall apply.

It shall apply as from 1 January 2009.

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

Done at Luxembourg, 28 June 2007.

*For the Council*

*The President*

S. GABRIEL

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## ANNEX

## TERMS REFERRED TO IN ARTICLE 23(1)

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

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## II

*(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)*

## DECISIONS

## COUNCIL AND COMMISSION

## DECISION OF THE COUNCIL AND OF THE COMMISSION

of 25 June 2007

**on the signing, on behalf of the European Community and the European Atomic Energy Community, and provisional application of the Agreement on Scientific and Technological Cooperation between the European Community and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part**

(2007/502/EC, Euratom)

THE COUNCIL OF THE EUROPEAN UNION AND THE COMMISSION  
OF THE EUROPEAN COMMUNITIES,

HAVE DECIDED AS FOLLOWS:

Having regard to the Treaty establishing the European Community, and in particular Article 170, in conjunction with the first sentence of the first subparagraph of Article 300(2) thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the second paragraph of Article 101 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The Commission has negotiated, on behalf of the Communities, an Agreement on Scientific and Technological Cooperation between the European Community and the European Atomic Energy Community, of the one part, and the Swiss Confederation, the other part, which also provides for provisional application of the Agreement as of 1 January 2007. Provisional application would enable Swiss entities to participate in the first calls for proposals under the Seventh Framework Programme.

(2) The Agreement was initialled on 27 February 2007.

(3) The Agreement should be signed and applied on a provisional basis, pending the completion of the procedures for its formal conclusion,

*Article 1*

1. The signing of the Agreement on Scientific and Technological Cooperation between the European Community and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part, together with the Final Act, is hereby approved on behalf of the European Community and the European Atomic Energy Community, subject to the conclusion of the said Agreement.

2. The text of the Agreement is attached to this Decision.

*Article 2*

1. The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement and the Final Act on behalf of the European Community, subject to the conclusion of the said Agreement.

2. The President of the Commission is hereby authorised to designate the person(s) empowered to sign the Agreement and the Final Act on behalf of the European Atomic Energy Community, subject to the conclusion of the said Agreement.

*Article 3*

The Agreement on Scientific and Technological Cooperation between the European Community and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part, shall be applied provisionally.

*Article 4*

1. The Commission shall adopt the position of the Communities to be taken in the Switzerland/Communities Research Committee established by Article 10 of the Framework Agreement on Scientific and Technical Cooperation between the European Communities and the Swiss Confederation <sup>(1)</sup> with regard to decisions pursuant to Article 2(1) of the Agreement on the applicability in Switzerland of the rules for the establishment of the legal structures created under Articles 169 and 171 of the EC Treaty.

2. The Commission shall adopt the position of the Communities to be taken in the Switzerland/Communities Research Committee established by Article 10 of the Framework Agreement on Scientific and Technical Cooperation between the European Communities and the Swiss Confederation with regard to decisions pursuant to Article 6(2) and (3) of the

Agreement identifying regions of Switzerland that may be eligible regions benefiting from research actions under the Work Programme 'Research Potential' under the specific 'Capacities' programme.

*Article 5*

The Decision shall be published in the *Official Journal of the European Union*.

Done at Luxembourg, 25 June 2007.

*For the Council*

*The President*

A. SCHAVAN

*For the Commission*

*The President*

José Manuel BARROSO

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<sup>(1)</sup> OJ L 313, 22.11.1985, p. 6.

**AGREEMENT****on scientific and technological cooperation between the European Community and the European Atomic Energy Community, of the one part, and the Swiss Confederation, of the other part**

THE COUNCIL OF THE EUROPEAN UNION,

acting on behalf of the European Community,

and

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

(hereinafter referred to as 'the Commission'),

acting on behalf of the European Atomic Energy Community,

hereinafter referred to collectively as 'the Communities',

of the one part,

and

THE SWISS FEDERAL COUNCIL,

acting on behalf of the Swiss Confederation, hereinafter referred to as 'Switzerland',

of the other part,

hereinafter referred to as 'the Parties',

CONSIDERING that the close relationship between Switzerland and the Communities is of benefit to the Parties;

CONSIDERING the importance of scientific and technological research for the Communities and for Switzerland and their mutual interest in cooperating in this matter in order to make better use of resources and to avoid unnecessary duplication;

WHEREAS Switzerland and the Communities are currently implementing research programmes in fields of common interest;

WHEREAS the Communities and Switzerland have an interest in cooperating on these programmes to their mutual benefit;

CONSIDERING the interest of the Parties in encouraging the mutual access of their research entities to research and technological development activities in Switzerland, on the one hand, and to the Communities' Framework Programmes for research and technological development, on the other;

WHEREAS the European Atomic Energy Community and Switzerland concluded a Cooperation Agreement in 1978 in the field of controlled thermonuclear fusion and plasma physics (hereinafter referred to as the 'Fusion Agreement');

WHEREAS the Parties concluded a Framework Agreement on 8 January 1986 for scientific and technical cooperation, which entered into force on 17 July 1987 (hereinafter referred to as 'the Framework Agreement');

CONSIDERING that Article 6 of the Framework Agreement states that the cooperation aimed at by the Framework Agreement is to be carried out through appropriate agreements;

WHEREAS on 16 January 2004 the Communities and Switzerland signed an Agreement on Scientific and Technological Cooperation <sup>(1)</sup>, which was provisionally applied since 1 January 2004 and which entered into force on 16 May 2006;

<sup>(1)</sup> OJ L 32, 5.2.2004, p. 22.

CONSIDERING that Article 9(2) of the abovementioned Agreement provides for renewal of the Agreement with a view to participation in new multi-annual Framework Programmes for research and technological development, under mutually agreed conditions;

WHEREAS the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (hereinafter referred to as the 'Seventh EC Framework Programme') was adopted by Decision No 1982/2006/EC <sup>(1)</sup> and Regulation (EC) No 1906/2006 <sup>(2)</sup> of the European Parliament and of the Council, and by Council Decisions 2006/971/EC <sup>(3)</sup>, 2006/972/EC <sup>(4)</sup>, 2006/973/EC <sup>(5)</sup>, 2006/974/EC <sup>(6)</sup> and 2006/975/EC <sup>(7)</sup> and the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007 to 2011), also contributing to the creation of the European Research Area was adopted by Council Decision 2006/970/Euratom <sup>(8)</sup>, Council Regulation (Euratom) No 1908/2006 <sup>(9)</sup> and Council Decisions 2006/976/Euratom <sup>(10)</sup> and 2006/977/Euratom <sup>(11)</sup> (hereinafter referred to as the 'Seventh EC and Euratom Framework Programmes');

WHEREAS without prejudice to the provisions of the Treaties establishing the Communities, this Agreement and any activities entered into under it will in no way affect the powers vested in the Member States to undertake bilateral activities with Switzerland in the fields of science, technology, research and development, and to conclude, where appropriate, agreements to that end,

HAVE AGREED AS FOLLOWS:

#### Article 1

##### Subject matter

place of establishment or under Community law, having legal personality and being entitled to have rights and obligations of any kind in its own name. This shall include, *inter alia*, universities, research organisations, industrial companies, including small and medium-sized enterprises, and individuals.

1. The form and conditions of Swiss participation in the implementation of the whole of the Seventh EC and Euratom Framework Programmes shall be as laid down in this Agreement, without prejudice to the terms of the Fusion Agreement.

#### Article 2

Legal entities established in Switzerland may participate in all the specific programmes of the Seventh EC and Euratom Framework Programmes.

##### Forms and means of cooperation

Cooperation shall take the following forms:

2. Swiss legal entities may participate in the activities of the Joint Research Centre of the Communities, as far as this participation is not covered by paragraph 1.

3. Legal entities established in the Communities, including the Joint Research Centre, may participate in research programmes and/or projects in Switzerland on themes equivalent to those of the programmes of the Seventh EC and Euratom Framework Programmes.

1. Participation of legal entities established in Switzerland in all specific programmes adopted under the Seventh EC and Euratom Framework Programmes, in accordance with the terms and conditions laid down in the rules for the participation of undertakings, research centres and universities both in research, technological development and demonstration activities of the European Community and in research and training activities of the European Atomic Energy Community.

4. For the purposes of this Agreement 'legal entity' means any natural or any legal person created under the national law at its

In case the Community makes provisions for the implementation of Articles 169 and 171 of the Treaty establishing the European Community Switzerland shall be allowed to participate in the

<sup>(1)</sup> OJ L 412, 30.12.2006, p. 1.

<sup>(2)</sup> OJ L 391, 30.12.2006, p. 1.

<sup>(3)</sup> OJ L 400, 30.12.2006, p. 86. Corrected version published in OJ L 54, 22.2.2007, p. 30.

<sup>(4)</sup> OJ L 400, 30.12.2006, p. 243. Corrected version published in OJ L 54, 22.2.2007, p. 81.

<sup>(5)</sup> OJ L 400, 30.12.2006, p. 272. Corrected version published in OJ L 54, 22.2.2007, p. 91.

<sup>(6)</sup> OJ L 400, 30.12.2006, p. 299. Corrected version published in OJ L 54, 22.2.2007, p. 101.

<sup>(7)</sup> OJ L 400, 30.12.2006, p. 368. Corrected version published in OJ L 54, 22.2.2007, p. 126.

<sup>(8)</sup> OJ L 400, 30.12.2006, p. 60. Corrected version published in OJ L 54, 22.2.2007, p. 21.

<sup>(9)</sup> OJ L 400, 30.12.2006, p. 1. Corrected version published in OJ L 54, 22.2.2007, p. 4.

<sup>(10)</sup> OJ L 400, 30.12.2006, p. 404. Corrected version published in OJ L 54, 22.2.2007, p. 139.

<sup>(11)</sup> OJ L 400, 30.12.2006, p. 434. Corrected version published in OJ L 54, 22.2.2007, p. 149.



legal structures created under these provisions subject to the rules that will be adopted for the establishment of these legal structures and provided that these rules will become applicable in Switzerland. The Switzerland/Communities Research Committee shall decide on the applicability of these rules in Switzerland.

Legal entities established in Switzerland shall be eligible for participation in indirect actions based on Articles 169 and 171 of the Treaty establishing the European Community.

2. Financial contribution by Switzerland to the budgets of the programmes adopted for the implementation of the Seventh EC and Euratom Framework Programmes, as defined in Article 5(2).

3. Participation of legal entities established in the Communities in Swiss research programmes and/or projects decided by the Federal Council on themes equivalent to those of the Seventh EC and Euratom Framework Programmes, in accordance with the terms and conditions laid down in the relevant Swiss regulations and with the agreement of the partners in the specific project and the management of the corresponding Swiss programme. Legal entities established in the Communities participating in Swiss research programmes and/or projects shall cover their own costs, including their relative share of the project's general management and administrative costs.

4. In addition to timely provision of information and documentation concerning the implementation of the Seventh EC and Euratom Framework Programmes and of the Swiss programmes and/or projects, the cooperation between the Parties may include the following forms and means:

- (a) regular exchanges of views on research policy guidelines and priorities and plans in Switzerland and in the Communities;
- (b) exchanges of views on the prospects and development of cooperation;
- (c) timely exchanges of information on the implementation of the research programmes and projects in Switzerland and in the Communities and on the results of the work undertaken under this Agreement;
- (d) joint meetings;
- (e) visits and exchanges of researchers, engineers and technicians;
- (f) regular contacts and follow-up between programme or project leaders in Switzerland and in the Communities;
- (g) participation by experts in seminars, symposia and workshops.

## Article 3

### Adaptation

Cooperation may be adapted and developed at any time by mutual agreement between the Parties.

## Article 4

### Intellectual property rights and obligations

1. Subject to Annex A and applicable law, legal entities established in Switzerland participating in the Communities' research programmes shall, as regards ownership, exploitation and dissemination of information and intellectual property arising from such participation, have the same rights and obligations as legal entities established in the Communities. This provision shall not apply to the results obtained from projects started before the provisional application of this Agreement.

2. Subject to Annex A and applicable law, legal entities established in the Communities taking part in Swiss research programmes and/or projects, as provided for in Article 2(3), shall, as regards ownership, exploitation and dissemination of information and intellectual property arising from such participation, have the same rights and obligations as legal entities established in Switzerland participating in the programmes and/or projects in question.

## Article 5

### Financial provisions

1. Commitments entered into by the Communities under the Seventh EC and Euratom Framework Programmes prior to the provisional application of this Agreement — as well as the payments which result from these — shall give rise to no contribution on the part of Switzerland. Switzerland's financial contribution deriving from participation in the implementation of the Seventh EC and Euratom Framework Programmes shall be established in proportion to and in addition to the amount available each year in the general budget of the European Union for commitment appropriations to meet the Commission's financial obligations stemming from work to be carried out in the forms necessary for the implementation, management and operation of the programmes and activities covered by this Agreement.

2. The proportionality factor governing Switzerland's contribution to the Seventh EC and Euratom Framework Programmes, except the Fusion Programme, shall be obtained by establishing the ratio between Switzerland's gross domestic product, at market prices, and the sum of gross domestic products, at market prices, of the Member States of the European Union. The Swiss contribution to the Fusion Programme shall continue to be calculated on the basis of the corresponding agreement. These

ratios shall be calculated on the basis of the latest statistical data from Eurostat, available at the time of publication of the preliminary draft budget of the European Union for the same year.

3. The rules governing Switzerland's financial contribution are set out in Annex B.

#### Article 6

##### Switzerland/Communities Research Committee

1. The Switzerland/Communities Research Committee set up in the Framework Agreement shall review, evaluate and ensure the proper implementation of this Agreement. Any issues arising from the implementation or interpretation of this Agreement shall be referred to this Committee.

2. The Committee may identify on request of Switzerland regions of Switzerland that fulfil the criteria set out in Article 5(1) of Council Regulation (EC) No 1083/2006 <sup>(1)</sup> and may therefore be eligible regions benefiting from research actions under the Work Programme 'Research Potential' under the specific 'Capacities' programme.

3. The Committee may decide to amend the references to Community acts in Annex C.

#### Article 7

##### Participation

1. Without prejudice to the provisions of Article 4, legal entities established in Switzerland participating in the Seventh EC and Euratom Framework Programmes shall have the same contractual rights and obligations as entities established in the Communities.

2. For legal entities established in Switzerland, the terms and conditions applicable for the submission and evaluation of proposals and those for the granting and conclusion of grant agreements and/or contracts under the Communities' programmes shall be the same as those applicable for grant agreements and/or contracts concluded under the same programmes with legal entities established in the Communities.

3. Legal entities established in Switzerland shall be eligible for loans the EIB makes in support of research objectives set out under the Seventh EC Framework Programme.

4. An adequate number of Swiss experts shall be taken into consideration in the selection of evaluators or referees under the Communities' research and technological development programmes taking into account the skills and knowledge appropriate to the tasks assigned to them.

5. Without prejudice to the provisions of Article 1(3), Article 2(3) and Article 4(2) and to existing regulations and rules of procedure, legal entities established in the Communities may participate under equivalent terms and conditions to Swiss partners in programmes and/or projects of the Swiss research programmes mentioned in Article 2(3). The Swiss authorities may make participation in a project by one or more legal entities established in the Communities subject to joint participation by at least one Swiss entity.

#### Article 8

##### Mobility

Each Party shall undertake, in accordance with existing regulations and agreements in force, to guarantee the entry and stay — as far as indispensable for successful accomplishment of the activity concerned — of a limited number of their researchers participating, in Switzerland and in the Communities, in the activities covered by this Agreement.

#### Article 9

##### Revision and future collaboration

1. Should the Communities revise or extend their research programmes, this Agreement may be revised or extended under mutually agreed conditions. The Parties shall exchange information and views concerning any such revision or extension, as well as on any matters which affect directly or indirectly Switzerland's cooperation in the fields covered by the Seventh EC and Euratom Framework Programmes. Switzerland shall be notified of the exact content of the revised or extended programmes within two weeks of their adoption by the Communities. In case of such revision or extension of the research programmes, Switzerland may terminate this Agreement by giving six months' notice. The Parties shall give notice of any intention to terminate or to extend this Agreement within three months after the adoption of the Communities' decision.

2. Should the Communities adopt new multi-annual Framework Programmes for research and technological development, this Agreement may be renewed or renegotiated under conditions agreed mutually between the Parties. The Parties shall exchange information and views on the preparation of such programmes or other current and future research activities through the Switzerland/Communities Research Committee.

#### Article 10

##### Relation to other international agreements

1. The provisions of this Agreement shall apply without prejudice to the advantages envisaged by other international agreements binding one of the Parties and reserved only for legal entities established on the territory of that Party.

<sup>(1)</sup> OJ L 210, 31.7.2006, p. 25.

2. A legal entity established in another country associated to the Seventh EC Framework Programme (Associated Country) enjoys the same rights and obligations under this Agreement as legal entities that are established in a Member State provided that the Associated Country in which the entity is established has agreed to award legal entities from Switzerland the same rights and obligations.

#### *Article 11*

##### **Territorial application**

This Agreement shall apply, on the one hand, to the territories in which the Treaties establishing the Communities are applied and under the conditions laid down in those Treaties and, on the other, to the territory of Switzerland.

#### *Article 12*

##### **Annexes**

Annexes A, B and C shall form an integral part of this Agreement.

#### *Article 13*

##### **Amendment and termination**

1. This Agreement shall apply for the duration of the Seventh EC and Euratom Framework Programmes.

2. This Agreement may be amended only in writing by common consent between the Parties. This procedure for entry into force of the amendments shall be the same as the procedure applicable to this Agreement.

3. Each Party may terminate this Agreement at any time, subject to six months' written notice.

4. Projects and activities in progress at the time of termination and/or expiry of this Agreement shall continue until their completion under the conditions laid down in this Agreement. The Parties shall settle by common consent any other consequences of termination.

#### *Article 14*

##### **Entry into force and provisional application**

1. This Agreement shall be ratified or concluded by the Parties in accordance with their respective rules. It shall enter into force on the dates of the final notification of completion of the procedures necessary to this end. It shall be provisionally applied as of 1 January 2007.

2. Should one of the Parties inform the other that it will not conclude this Agreement, it is hereby agreed that:

- the Communities shall reimburse to Switzerland its contribution to the general budget of the European Union, as provided for in Article 2(2),
- however, the funds committed by the Communities for participation by legal entities established in Switzerland in indirect actions, including the reimbursements provided for in Article 2(1), shall be deducted by the Communities from the abovementioned reimbursement,
- projects and activities started during this provisional application and still in progress at the time of the abovementioned notification shall continue until their completion under the conditions laid down in this Agreement.

This Agreement shall be drawn up in duplicate in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish and Swedish languages, each of those texts being equally authentic.

Съставено в Люксембург на двадесет и пети юни две хиляди и седма година.

Hecho en Luxemburgo, el veinticinco de junio de dos mil siete.

V Lucemburku dne dvacátého pátého června dva tisíce sedm.

Udfærdiget i Luxembourg den femogtyvende juni to tusind og syv.

Geschehen zu Luxemburg am fünfundzwanzigsten Juni zweitausendsieben.

Kahe tuhande seitsmenda aasta juunikuu kahekümne viiendal päeval Luxembourgis.

Έγινε στο Λουξεμβούργο, στις είκοσι πέντε Ιουνίου δύο χιλιάδες επτά.

Done at Luxembourg, on the twenty-fifth day of June in the year two thousand and seven.

Fait à Luxembourg, le vingt-cinq juin deux mille sept.

Fatto a Lussemburgo, addì venticinque giugno duemilasette.

Luksemburgā, divtūkstoš septītā gada divdesmit piektajā jūnijā.

Priimta du tūkstančiai septintųjų metų birželio dvidešimt penktą dieną Liuksemburge.

Kelt Luxembourgban, a kettőezer-hetedik év június havának huszonötödik napján.

Magħmul fil-Lussemburgu, fil-hamsa u ghoxrin jum ta' Ġunju tas-sena elfejn u sebgha.

Gedaan te Luxemburg, de vijfentwintigste juni tweeduizend zeven.

Sporządzono w Luksemburgu dnia dwudziestego piątego czerwca roku dwa tysiące siódmego.

Feito no Luxemburgo, em vinte e cinco de Junho de dois mil e sete.

Adoptat la Luxemburg, douăzeci și cinci iunie două mii șapte.

V Luxemburgu dňa dvadsiateho plateho júna dvetisícšedem.

V Luxembourggu, petindvajsetega junija leta dva tisoč sedem.

Tehty Luxemburgissa kahdentenakymmenentenäviidentenä päivänä kesäkuuta vuonna kaksi-tuhattaseitsemän.

Som skedde i Luxemburg den tjugofemte juni tjugohundrasju.

За Европейската общност  
 Por la Comunidad Europea  
 Za Evropské společenství  
 For Det Europæiske Fællesskab  
 Für die Europäische Gemeinschaft  
 Euroopa Ühenduse nimel  
 Για την Ευρωπαϊκή Κοινότητα  
 For the European Community  
 Pour la Communauté européenne  
 Per la Comunità europea  
 Eiropas Kopienas vārdā  
 Europos bendrijos vardu  
 Az Európai Közösség részéről  
 Ghall-Komunità Ewropea  
 Voor de Europese Gemeenschap  
 W imieniu Wspólnoty Europejskiej  
 Pela Comunidade Europeia  
 Pentru Comunitatea Europeană  
 Za Európske spoločenstvo  
 Za Evropsko skupnost  
 Euroopan yhteisön puolesta  
 För Europeiska gemenskapen

За Европейската общност за атомна енергия  
 Por la Comunidad Europea de la Energía Atómica  
 Za Evropské společenství pro atomovou energii  
 For Det Europæiske Atomenergifællesskab  
 Für die Europäische Atomgemeinschaft  
 Euroopa Aatomienergiaühenduse nimel  
 Για την Ευρωπαϊκή Κοινότητα Ατομικής Ενέργειας  
 For the European Atomic Energy Community  
 Pour la Communauté européenne de l'énergie atomique  
 Per la Comunità europea dell'energia atomica  
 Eiropas Atomenerģijas kopienas vārdā  
 Europos atominės energijos bendrijos vardu  
 Az Európai Atomenergia-közösség részéről  
 Ghall-Komunità Ewropea ta' l-Energija Atomika  
 W imieniu Europejskiej Wspólnoty Energii Atomowej  
 Voor de Europese Gemeenschap voor Atoomenergie  
 Pela Comunidade Europeia da Energia Atómica  
 Pentru Comunitatea Europeană a Energiei Atomice  
 Za Európske spoločenstvo pre atómovú energiu  
 Za Evropsko skupnost za atomsko energijo  
 Euroopan atominieneryayhteisön puolesta  
 För Europeiska atomenergigemenskapen




За Конфедерация Швейцария  
 Por la confederación Suiza  
 Za Švýcarskou konfederaci  
 For Det Schweiziske Forbund  
 Für die Schweizerische Eidgenossenschaft  
 Šveitsi Konföderatsiooni nimel  
 Για την Ελβετική Συνομοσπονδία  
 For the Swiss Confederation  
 Pour la Confédération suisse  
 Per la Confederazione svizzera  
 Šveices Konfederācijas vārdā  
 Šveicarijos Konfederacijos vardu  
 A Svájci Államszövetség részéről  
 Ghall-Konfederazzjoni Żvizzera  
 Voor de Zwitserse Bondsstaat  
 W imieniu Konfederacji Szwajcarskiej  
 Pela Confederação Suíça  
 Pentru Confederația Elvețiană  
 Za Švajčiarsku konfederáciu  
 Za Švicarsko konfederacijo  
 Sveitsin valaliiton puolesta  
 På Schweiziska edsförbundets vägnar





## ANNEX A

**PRINCIPLES ON THE ALLOCATION OF INTELLECTUAL PROPERTY RIGHTS****I. Scope**

For the purposes of this Agreement, 'intellectual property' shall have the meaning defined in Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 14 July 1967.

For the purposes of this Agreement, 'knowledge' means the results, including information, whether or not they can be protected, as well as copyrights or rights pertaining to such information, following applications for, or the issue of, patents, designs, plant varieties, supplementary protection certificates or similar forms of protection.

**II. Intellectual property rights of the legal entities of the Parties**

1. Each Party shall ensure that the intellectual property rights of the legal entities of the other Party participating in the activities undertaken under this Agreement and the rights and obligations resulting from such participation are treated in a manner compatible with the relevant international conventions applicable to the Parties, notably the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights administered by the World Trade Organisation), the Berne Convention (Paris Act 1971) and the Paris Convention (Stockholm Act 1967).
2. Legal entities established in Switzerland participating in indirect actions under the Seventh EC and Euratom Framework Programmes shall have intellectual property rights and obligations under the conditions set out in Regulation (EC) No 2321/2002 of the European Parliament and of the Council <sup>(1)</sup> modified by Regulation (EC) No 1906/2006, in Council Regulation (Euratom) No 2322/2002 <sup>(2)</sup>, modified by Council Regulation (Euratom) No 1908/2006 of 18 December 2006 and in the grant agreement and/or contract concluded with the European Community, in accordance with point 1. Where Switzerland participates in indirect actions under the Seventh EC Framework Programme, implemented in accordance with Article 169 and Article 171 of the Treaty establishing the European Community, Switzerland shall have the same intellectual property rights and obligations as the Member States participating therein, as set out in the relevant provisions.
3. Legal entities established in a European Union Member State participating in Swiss research programmes and/or projects shall have the same intellectual property rights and obligations as legal entities established in Switzerland participating in these research programmes or projects, in accordance with point 1.

**III. Intellectual property rights of the Parties**

1. Unless otherwise agreed between the Parties, the following rules shall apply to the knowledge generated by the Parties in the course of the activities undertaken in accordance with Article 2(4) of this Agreement:
  - (a) the Party generating the knowledge shall have ownership thereof. Where their respective shares in the work cannot be determined, the Parties shall co-own the knowledge;
  - (b) the Party holding ownership shall grant the other Party rights of access to the knowledge with a view to the activities referred to in Article 2(4) of this Agreement. No charge shall be made for granting rights of access to the knowledge.
2. Unless otherwise agreed between the Parties, the following rules shall apply to scientific literature from the Parties:
  - (a) where a Party publishes data, information and technical or scientific results arising from the activities undertaken under this Agreement in journals, articles, reports and books, including audiovisual works and software, a worldwide, non-exclusive, irrevocable royalty-free licence to translate, adapt, transmit and publicly distribute the works in question shall be granted to the other Party;

<sup>(1)</sup> OJ L 355, 30.12.2002, p. 23.

<sup>(2)</sup> OJ L 355, 30.12.2002, p. 35.

- (b) all copies of copyrighted data and information to be publicly distributed and prepared under this section shall indicate the names of the author or authors, unless an author expressly declines to be named. Copies shall also bear a clearly visible acknowledgement of the cooperative support of the Parties.
3. Unless otherwise agreed between the Parties, the following rules shall apply to undisclosed information of the Parties:
- (a) at the time of submission to the other Party of information relating to the activities undertaken under this Agreement, each Party shall identify the information which it wishes to remain undisclosed;
  - (b) for the specific purposes of application of this Agreement, the receiving Party may, on its own responsibility, communicate undisclosed information to bodies or persons under its authority;
  - (c) with the prior written consent of the Party providing undisclosed information, the receiving Party may disseminate such information more widely than otherwise permitted by subparagraph (b). The Parties shall cooperate in developing procedures for requesting and obtaining prior written consent for wider dissemination, and each Party shall grant such approval to the extent permitted by its domestic policies, regulations and laws;
  - (d) non-documentary undisclosed or other confidential information provided in seminars or other meetings of the representatives of the Parties arranged under this Agreement, or information arising from the attachment of staff, use of facilities or indirect actions must remain confidential, where the recipient of such undisclosed or other confidential or privileged information was made aware of the confidential character of the information before it was communicated, in accordance with subparagraph (a);
  - (e) each Party shall ensure that undisclosed information which it acquires in accordance with subparagraphs (a) and (d) shall be controlled as provided for in this Agreement. If one of the Parties becomes aware that it will be, or may be expected to become, unable to meet the non-dissemination provisions of subparagraphs (a) and (d), it shall immediately inform the other Party. The Parties shall thereafter consult to define an appropriate course of action.
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## ANNEX B

**FINANCIAL RULES GOVERNING THE CONTRIBUTION OF SWITZERLAND REFERRED TO IN ARTICLE 5 OF THIS AGREEMENT****I. Determination of financial participation**

1. The Commission shall communicate to Switzerland together with relevant background material as soon as possible and at the latest on 1 September of each year:
  - (a) the amounts in commitment appropriations in the statement of expenditure of the preliminary draft budget of the European Union corresponding to the two Framework Programmes;
  - (b) the estimated amount of the contributions derived from the preliminary draft budget, corresponding to the participation of Switzerland in the two Framework Programmes. Nonetheless, in order to facilitate internal budgetary procedures, the Commission services shall provide corresponding indicative figures at the latest on 31 May of each year.
2. As soon as the general budget has been finally adopted, the Commission shall communicate to Switzerland the above mentioned amounts in the statement of expenditure corresponding to the participation of Switzerland.

**II. Payment procedures**

1. The Commission shall issue, in June and November of each financial year, a call for funds to Switzerland corresponding to its contribution under this Agreement. These calls for funds shall provide respectively for the payment of six twelfths of Switzerland's contribution for each call for funds and not later than 30 days after receipt of the corresponding call for funds. However, in the last year of the two Framework Programmes, the full amount of Switzerland's contribution shall be paid not later than 30 days after the receipt of the call for funds.
2. The contributions of Switzerland shall be expressed and paid in euro.
3. Switzerland shall pay its contribution under this Agreement according to the schedule in paragraph 1. Any delay in payment shall give rise to the payment of interest at a rate equal to the one-month inter-bank offered rate (EURIBOR) as on page 248 of Telerate. This rate shall be increased by 1,5 percentage point for each month of delay. The increased rate shall be applied to the entire period of delay. However, the interest shall be due only if the contribution is paid more than 30 days after the scheduled payment dates mentioned in paragraph 1.
4. Travel costs incurred by Swiss representatives and experts for the purposes of taking part in the work of the research committees and those involved in the implementation of the two Framework Programmes shall be reimbursed by the Commission on the same basis as, and in accordance with, the procedures currently in force for the representatives and experts of the Member States of the Communities.

**III. Conditions for implementation**

1. The financial contribution of Switzerland to the two Framework Programmes in accordance with Article 5 of this Agreement shall normally remain unchanged for the financial year in question.
2. The Commission, at the time of the closure of the accounts relating to each financial year (n), within the framework of the establishment of the revenue and expenditure account, shall proceed to the regularisation of the accounts with respect to the participation of Switzerland, taking into consideration modifications which have taken place, either by transfer, cancellations, carry-overs, or by supplementary and amending budgets during the financial year.

This regularisation shall occur at the time of the first payment for the year  $n + 1$ . However, the final such regularisation shall occur not later than July of the fourth year following the end of the two Framework Programmes. Payment by Switzerland shall be credited to the European Communities' programmes as budget receipts allocated to the appropriate budget heading in the statement of revenue of the general budget of the European Union.

**IV. Information**

1. At the latest on 31 May of each financial year ( $n + 1$ ), the statement of appropriations for the two Framework Programmes, related to the previous financial year (n), shall be prepared and transmitted to Switzerland for information, according to the format of the Commission's revenue and expenditure account.
2. The Commission shall communicate to Switzerland statistics and all other general financial data relating to the implementation of the two Framework Programmes which is made available to the Member States.

## ANNEX C

**FINANCIAL CONTROL OF SWISS PARTICIPANTS IN THE COMMUNITY PROGRAMMES COVERED BY THIS AGREEMENT****I. Direct communication**

The Commission shall communicate directly with the participants in the Seventh EC and Euratom Framework Programmes established in Switzerland and with their subcontractors. They may submit directly to the Commission all relevant information and documentation which they are required to submit on the basis of the instruments referred to in this Agreement and of the grant agreements and/or contracts concluded to implement them.

**II. Audits**

1. In accordance with Council Regulation (EC, Euratom) No 1605/2002 <sup>(1)</sup>, amended by Council Regulation (EC, Euratom) No 1995/2006 <sup>(2)</sup> and Commission Regulation (EC, Euratom) No 2342/2002 <sup>(3)</sup> amended by Regulation (EC Euratom) No 1248/2006 <sup>(4)</sup> of 7 August 2006 and with the other rules referred to in this Agreement, the grant agreements and/or contracts concluded with participants in the programme established in Switzerland may provide for scientific, financial, technological or other audits to be conducted at any time on the premises of the participants and of their subcontractors by Commission agents or by other persons mandated by the Commission.
2. Commission agents and other persons mandated by the Commission shall have appropriate access to sites, works and documents and to all the information required in order to carry out such audits, including in electronic form. This right of access shall be stated explicitly in the grant agreements and/or contracts concluded to implement the instruments referred to in this Agreement.
3. The European Court of Auditors shall have the same rights as the Commission.
4. The audits may be conducted after the Seventh EC and Euratom Framework Programmes or this Agreement expire, on the terms laid down in the grant agreements and/or contracts in question.
5. The Swiss Federal Audit Office shall be informed in advance of the audits conducted on Swiss territory. Such notification shall not be a legal precondition for carrying out such audits.

**III. On-the-spot checks**

1. Within the framework of this Agreement, the Commission (OLAF) shall be authorised to carry out on-the-spot checks and inspections on Swiss territory, in accordance with the terms and conditions laid down in Council Regulation (Euratom, EC) No 2185/96 <sup>(5)</sup> and Regulation (EC) No 1073/1999 <sup>(6)</sup> of the European Parliament and the Council.
2. On-the-spot checks and inspections shall be prepared and conducted by the Commission in close collaboration with the Swiss Federal Audit Office or with the other competent Swiss authorities designated by the Swiss Federal Audit Office, which shall be notified in good time of the object, purpose and legal basis of the checks and inspections, so that they can provide all the requisite help. To that end, the officials of the competent Swiss authorities may participate in the on-the-spot checks and inspections.
3. If the Swiss authorities concerned so wish, the on-the-spot checks and inspections may be carried out jointly by the Commission and them.
4. Where the participants in the Seventh EC and Euratom Framework Programmes resist an on-the-spot check or inspection, the Swiss authorities, acting in accordance with national rules, shall give Commission inspectors such assistance as they need to allow them to discharge their duty in carrying out an on-the-spot check or inspection.

<sup>(1)</sup> OJ L 248, 16.9.2002, p. 1.

<sup>(2)</sup> OJ L 390, 30.12.2006, p. 1.

<sup>(3)</sup> OJ L 357, 31.12.2002, p. 1.

<sup>(4)</sup> OJ L 227, 19.8.2006, p. 3.

<sup>(5)</sup> OJ L 292, 15.11.1996, p. 2.

<sup>(6)</sup> OJ L 136, 31.5.1999, p. 1.

5. The Commission shall report as soon as possible to the Swiss Federal Audit Office any fact or suspicion relating to an irregularity which has come to its notice in the course of the on-the-spot check or inspection. In any event the Commission shall be required to inform the abovementioned authority of the result of such checks and inspections.

#### IV. Information and consultation

1. For the purposes of proper implementation of this Annex, the competent Swiss and Community authorities shall regularly exchange information and, at the request of one of the Parties, shall conduct consultations.
2. The competent Swiss authorities shall inform the Commission without delay of any fact or suspicion which has come to their notice relating to an irregularity in connection with the conclusion and implementation of the grant agreements and/or contracts concluded in application of the instruments referred to in this Agreement.

#### V. Confidentiality

Information communicated or acquired in any form under this Annex shall be covered by professional secrecy and protected in the same way as similar information is protected by Swiss law and by the corresponding provisions applicable to the Community institutions. Such information may not be communicated to persons other than those within the Community institutions or in the Member States or Switzerland whose functions require them to know it nor may it be used for purposes other than to ensure effective protection of the Parties' financial interests.

#### VI. Administrative measures and penalties

Without prejudice to application of Swiss criminal law, administrative measures and penalties may be imposed by the Commission in accordance with Regulations (EC, Euratom) No 1605/2002, amended by Regulation (EC, Euratom) No 1995/2006, and (EC, Euratom) No 2342/2002, amended by Regulation (EC, Euratom) No 1248/2006, and with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests <sup>(1)</sup>.

#### VII. Recovery and enforcement

Decisions taken by the Commission under the Seventh EC Framework Programme within the scope of this Agreement which impose a pecuniary obligation on persons other than States shall be enforceable in Switzerland. The enforcement order shall be issued, without any further control than verification of the authenticity of the act, by the authorities designated by the Swiss government, which shall inform the Commission thereof. Enforcement shall take place in accordance with the Swiss rules of procedure. The legality of the enforcement decision shall be subject to control by the Court of Justice of the European Communities. Judgments given by the Court of Justice of the European Communities pursuant to an arbitration clause in a contract under the Seventh EC and Euratom Framework Programmes shall be enforceable on the same terms.

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<sup>(1)</sup> OJ L 312, 23.12.1995, p. 1.



**FINAL ACT**

The Plenipotentiaries

of the EUROPEAN COMMUNITY

and

of the SWISS CONFEDERATION,

meeting at Luxembourg on the twenty fifth day of June in the year two thousand and seven, for the signature of the Agreement on Scientific and Technological Cooperation between the European Community and the European Atomic Energy Community on the one hand, and the Swiss Confederation on the other hand, have adopted the following Joint Declaration, which is attached to this Final Act:

Joint Declaration of the Contracting Parties on a close dialogue in view of new structures implementing Articles 169 and 171 of the EC Treaty.

They have also noted the following Declarations, which are attached to this Final Act:

Declaration of the Council on Swiss attendance of committees.

Declaration of the Communities on the treatment of EU researchers under this agreement in Switzerland.

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**Joint Declaration of the contracting Parties on a close dialogue in view of new structures implementing  
Articles 169 and 171 of the EC Treaty**

The two Parties declare that, with a view to ensuring the proper implementation of Article 2.1 of this Agreement, the Swiss Confederation will be timely informed as appropriate about preparatory works regarding structures based on Articles 169 and/or 171 of the EC Treaty to be implemented under the Seventh Framework Programmes.

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**Declaration of the Council on Swiss attendance of Committees**

The Council agrees that Switzerland's representatives may, insofar as the items concern them, attend meetings as observers of:

- all Committees set up under the Seventh EC and Euratom Framework programmes including the Scientific and Technical Research Committee (CREST),
- the Board of Governors of the Joint Research Centre.

Switzerland's representatives shall not be present when these committees vote.

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**Declaration of the Communities on treatment of EU researchers in Switzerland under this Agreement**

The Communities expect that Switzerland to the extent that it applies a maximum threshold to the number of residence permits available for nationals of any of the Member States of the European Union, the residence permits issued for participating researchers shall not count for the calculation of this maximum threshold. The Communities further expect that researchers participating in projects, and employed by the Joint Research Centres of the Communities, may equally benefit from Article 12(3) of the Cooperation agreement between the Euratom and the Swiss Confederation in the field of controlled thermonuclear fusion and plasma physics (OJ L 242/1, 4.9.1978).

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**Declaration of the Government of Switzerland**

The Government of Switzerland considers that the declaration of the Communities on treatment of EU researchers in Switzerland under this agreement shall be without prejudice to the rights and obligations of the Contracting Parties under the Agreement and under the Swiss legal order.

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