COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL REGULATION

on organic production and labelling of organic products

Proposal for a

COUNCIL REGULATION

amending Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto in agricultural products and foodstuffs

(presented by the Commission)

EXPLANATORY MEMORANDUM

POLICY FRAMEWORK

Organic production

1. In 1991 the Council created with Council Regulation (EEC) No 2092/91 the first ever Community framework for organic farming and food production. More than a decade later and having seen a strong development of organic farming, the Commission has started the process of reviewing this framework on the basis of the experience gained.

2. Organic production has seen an impressive growth since the adoption of the Regulation in 1991 and the contribution of the organic agricultural sector is still on the increase in most Member States. According to the most recent statistical data, 149 000 holdings are certified as organic or in conversion to organic production. In 2003 these holdings represent 1,4% of the total of agricultural holdings in the 25 Member States. The certified organic and in-conversion area covered 5,7 mio ha and represented 3,6% of the Utilised Agricultural Area in 2003.

3. In 2001, the Council under Swedish Presidency, taking this development and the conferences on organic food and farming in Austria in 1999 and in Denmark in 2001 into account, invited the Commission to propose a European Action Plan for Organic Food and Farming (EAP). The action plan was asked to formulate the basis for policy development for the organic sector in the coming years, thereby providing an overall strategic vision for organic farming's contribution to the common agricultural policy.

4. In the run-up to the Action Plan, extensive consultations were held including expert panel meetings, an internet consultation of the wider public and finally a public hearing in January 2004.

5. From these consultations the most important conclusions in the regulatory domain were the need to lay down more explicitly the principles and objectives of organic farming, the importance of safeguarding the integrity of the inspection system, the need to overcome dysfunctions of the internal market caused by national an private logo's and standards, the need to complete and improve standards and the need to make import provisions more efficient.

6. The Commission adopted the Communication on the EAP in June 2004. The EAP put forward 21 actions to facilitate the ongoing development of organic farming in the EU. In its conclusions of October 2004, the Council invited the Commission to advance on the implementation of the EAP on the basis of concrete measures with the view to assure simplification and overall coherence and to bring forward proposals in this regard in the course of 2005. In fact, several of the actions imply introducing amendments to Council Regulation (EEC) No 2092/91 on organic farming.

7. The proposal takes account of the wide public consultation, which took place prior to the adoption of the EAP and responds to the Council conclusions. It also takes account of subsequent responses and numerous written submissions by Member States and stakeholders on a Commission staff working paper titled "information and consultation on key ideas to reform Council Regulation (EEC) No 2092/91". This consultation took place in the framework of meetings of the standing committee and advisory group on organic farming on respectively 26 September and 5 October 2005.

Research

8. The proposal has taken into account the initial findings of the Research project "Research to support revision of the EU Regulation on organic agriculture"[1] when developing objectives and principles in current proposal. When at a later stage the Commission will draft the detailed implementation rules, the Commission will take into account the end results of Research projects "Research to support revision of the EU Regulation on organic agriculture" and "Development of criteria and procedures for the evaluation of the EAP"[2].

Sustainable development of European aquaculture

9. As regards to aquaculture the proposal achieves one of the actions of the Commission Communication to the Council and the European Parliament of 2002 on the sustainable development of European aquaculture[3], namely "harmonisation of the rules on organic aquaculture under Regulation (EEC) No 2092/91".

Simplification and better regulation

10. Defining and bringing together objectives, principles and basic labelling, control, import and production rules in a simpler, clearer and more transparent Council Regulation, represents a simplification of the current legal framework on organic production. It reduces considerably the level of detail in the Council Regulation and will allow for a further reduction of detail of the implementing rules. The proposal also replaces the current practice of 'legislation by derogation' by a transparent strictly regulated mechanism allowing less strict rules (see under flexibility).

11. The essential requirements defining organic production and labelling of organic products are laid down by the principles and production rules formulated in this proposal. The application of these principles will require further detailed rules, the management of which necessitates frequent decisions, such as on the approval of ingredients and substances that may be used in organic products. Furthermore, the recent reform of the Common Agricultural Policy (CAP) has placed the production of quality products that protect the environment and animal welfare and respond to societal concerns at its heart. This legislation thus is an important factor in the framework of the Common Agricultural Policy. It is also closely related to the developments on the agricultural markets. In order to facilitate the decision making process and to further integrate quality into the Common Agricultural Policy and its management systems, a Management Committee should replace the current 'Regulatory Committee'.

12. Finally, the control provisions are kept simple by referring to the common framework of Regulation (CE) No 882/20004 'on official food and feed controls'[4] (OFFC). Only

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1 EEC/2092/91 (Organic) Revision SSPE-CT-2004-502397: Research to support revision of the EU Regulation on organic agriculture.

2 ORGAP SSPE-CT-2005-006591: European Action Plan of Organic Food and Farming, Development of criteria and procedures for the evaluation of the EU Action Plan for Organic Agriculture

3 Communication from the Commission to the Council and the European Parliament "A strategy for the sustainable development of European aquaculture" - COM(2002) 511.

4 Regulation (EC) No 882/20004 of the European Parliament and of the Council of 29 April 2004 on official controls performed in to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

the provisions specific to organic farming are maintained in the text at hand. The application of the risk based approach of the OFFC will allow for reducing the administrative burden on operators. It is expected that this new approach will allow for a better targeting of controls to the areas presenting the highest risks. It will also allow operators that run risk based internal control systems to benefit from the risk based approach.

13. The proposal at hand thus contributes to the actions mentioned in various simplification initiatives of the Commission. It achieves the first action of the Simplification Rolling Programme for the agricultural and foodstuff industry mentioned in the Communication of the Commission on 'implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment'[5]. It is also mentioned as a policy related action in the Communication from the Commission on simplification and better regulation for the Common Agricultural Policy[6].

THE PROPOSAL

Subject matter, scope and definitions

14. The proposal explicitly covers "organic production" and not just labelling. The proposal does not cover the preparation and sale to the final consumer of meals in large scale kitchens; for example in restaurants, hotels, hospitals and canteens, or in bars and coffeeshops.

15. As regards products, the proposed scope covers unprocessed agricultural products regardless of their final use; namely livestock, unprocessed plant and livestock products and live or unprocessed aquaculture products. Processed agricultural products are proposed to be covered for as far as they are intended for human or animal consumption; namely feed, processed plant, livestock and aquaculture products. It thus provides for objectives, principles and production rules for all products including for organic wines, aquaculture products and processed foodstuffs. Detailed rules for all products may be laid down by a comitology procedure. The latter is particularly relevant for the adoption of detailed rules on organic wine production as that is excluded under the current rules. Production rules for aquaculture will also be established at a later date.

16. No extension of the scope is foreseen at this stage. It is not proposed to include products of hunting and fishing of wild animals; as they are not obtained from farming practices inclusion would not be coherent with the proposed objectives and principles. The scope will also not be extended to the following products not covered by Annex I to the Treaty establishing the European Community; namely minerals, waters, non-food processed agricultural products such as textiles, cosmetics and other industrial products.

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5 COM(2005) 535, 25.10.2005.
6 COM(2005) 509, 19.10.2005.

Objectives and principles for organic production

17. As stated in the EAP, an appropriate definition of objectives and principles is needed to strengthen the Regulation. In this regard, the proposal formulates the following objectives for organic production:

- protection of consumers' interest, ensuring consumer confidence and avoiding misleading labelling;
- the development of organic production while taking account of regional differences in climate, farming conditions and the stage of development of organic farming;
- a high level of protection of the environment, biodiversity and natural resources;
- respect of high animal welfare standards that fully meet animals' species-specific needs.

18. With regard to the underlying principles, most of them already exist in the current detailed rules in the Annexes to Regulation (EEC) No 2092/91. The proposal reformulates these principles in articles in line with the objectives.

19. Further to objectives and principles and for the sake of comprehension, the proposal establishes the basic "production rules" in the reformed Regulation. These production rules should set the parameters of the detailed rules to be laid down by Commission Regulations.

Flexibility

20. The proposal aims at providing the conditions in which the sector can develop and produce in an economically viable manner, in line with production and market developments. To this end it provides for a, certain strictly, regulated flexibility. Under this flexibility provision Member States will be allowed, by a comitology procedure, to apply less strict production rules to account for variation in local climatic, development and specific production conditions. It basically provides for transforming the current multitude of derogations into a general but strictly regulated system. But, contrary to the current system, the conditions, scope and division of competencies between the actors involved in granting exceptions is clearly laid down.

Labelling

21. In order to continue protecting the term "organic", current rules on use or references to "organic", derivatives, diminutives and translations should be maintained.

22. The EU logo should continue to be available on all products that comply with the Regulation, including for all imported products. When preparing the EAP, as a result of discussions with stakeholders and Member States, it was concluded that the EU logo should not be compulsory for the time being, as it may be viewed as an excessive EC interference in commercial freedom in other areas. However, it is proposed in those cases where the product does not bear the EU logo, to make the use of a simple standardised text fragment **EU-ORGANIC** on labels compulsory for products produced within the Community. This aims at communicating efficiently to all operators in the production chain and to the consumer that the product conforms to a single EU standard.

23. In order to maintain consumer confidence, the use of GMOs and of products produced from or by GMOs should continue to be prohibited in organic farming, as it is the case in the current Regulation. Despite this, in cases where products have been accidentally contaminated by GMOs, the current organic rules do not prohibit the simultaneous labelling as organic and GMO. As announced in the EAP, the proposal prohibits the use of the term 'organic' for GMO labelled products. Finally, the labelling thresholds for organic and non-organic produce should be identical, unless detailed rules foresee specific thresholds for example possibly for organic seeds.

24. The current provision requiring a minimum 95% of the agricultural products to be 'organic' should be maintained. However, the category allowing references to the organic production method on the list of ingredients if it contains between 70 and 95% of the agricultural ingredients from organic origin, will be suppressed. In fact, due to the development of the organic sector in recent years, this category of products is not considered to be needed anymore.

Controls

25. With regard to controls, Regulation (EC) No 882/2004 of the European Parliament and of the Council on official food and feed controls (OFFC) enters into application on 1 January 2006 which covers organic farming. The specific requirements of organic farming need to be aligned with the OFFC. In this regard, the proposal recasts the organic control provisions using the OFFC framework as far as possible to achieve the desired reforms and updates. The detailed provisions specific to organic production remain under the new organic Regulation.

26. As provided for in OFFC, Member States will have to include all production and operations covered by the new Regulation in their multi-annual national control plans and fulfil the requirements of mutual assistance. The multi-annual national control plans have to be notified to the Commission who may ask for amendments and use them to guide Community inspections. Moreover, pursuant to the OFFC private control bodies will have to be accredited. Finally, the proposal requires that competent authorities and control bodies promote and do not undermine the EC organic standard, in line with the principle of a "single concept of organic production".

27. In order to guarantee the free movement of organic products within the Community, the current provisions requiring Member States to uphold the single market will be retained. In this context the requirement of OFFC on compulsory accreditation of private control bodies, impartiality and freedom of any conflict of interest of designated control bodies is particularly relevant. One of the main purposes of the reform of the organic regulatory framework is to reduce the trade hampering impact on the internal market of multiple public and private certification. The instruments proposed for improving impartiality and reducing conflicts of interest are the integration of private control bodies in the control system, a healthy competition between control bodies and recognition of prior certification decisions for equivalent standards.

28. As regards access to national logos and marks of conformity the proposal foresees imposing full access for all products that comply with the Community rules.

29. The issuing of certificates stating that a certain operator or a specific lot of products is found to comply with the principles and rules of organic farming is a well-established

tool in trade of organic products and often conditions access to marks of conformity. Certification practices used by competent authorities or by control bodies to which the competent authority has delegated control tasks should not have, directly or indirectly, restrictive effects on the free movement of organic goods, nor on the freedom of establishment and the free provision of services in the area of issuing of certificates. In this regard certification practices should be more strictly supervised, in particular where mutual recognition of certificates and the collection of fees are concerned. Such supervision should be undertaken without prejudice to the application of Articles 43 and 49 of the Treaty. As regards access to private logos and marks of conformity it foresees rules facilitating access for products that comply with equivalent standards, by placing the burden of proof for not complying with equivalent standards on the control body which logo the operator wishes to use. Finally it provides for ensuring that the fees for control and certification tasks are reasonable.

30. Furthermore, promoting a "single concept" of what constitutes organic production will contribute to consumer recognition and confidence, which in turn is expected to improve the free movement of organic produce. To this end general claims that a certain set of standards will guarantee a "better, stricter or higher standard organic", directly on organic products or in their advertising or in publicity material should be prohibited. However, non-misleading and true claims of fact will be allowed.

31. A high harmonisation level further reduces the room for private logos and marks of conformity. The proposal therefore maintains the ambition for a high harmonisation level expressed in the EAP. This should be facilitated by the already discussed flexibility mechanism and the adoption of detailed rules by a management committee (see also flexibility).

32. Finally, the guarantees provided by the control system are based on verification of documentary checks, inspections of organic farms and businesses, reconciliation of trade flows and testing of products for absence of prohibited substances. No tests are commercially available to verify the innate characteristics of organic products in an unequivocal and reproducible manner. The Institute for Reference Materials and Measurements in Geel of the Directorate General Joint Research Centre is conducting Research into the development of such tests.

Imports

33. With regard to trade with third countries, it is proposed to grant access to the EU market either on the basis of compliance with the EU rules or on equivalent guarantees provided by Third Country authorities or certified EU approved control bodies. The equivalency assessments for the purpose of import will be based on the international standard (*Codex Alimentarius*) or on the Community regulation. Third countries may add their own arrangements where needed. The current system of 'community list of third countries' will be maintained. Annual reporting and follow-up control visits with Member States involvement are foreseen. Single product access to the EU market will be granted either on the basis of compliance with the EU standards and submission to the EU system of controls, or on the basis of equivalent guarantees certified by control bodies that have been approved by the Community for that purpose.

Entry into force and application of the new rules

34. The proposal does not contain the detailed rules currently laid down in the Annexes to Regulation (EEC) No 2092/91. In order to permit a smooth change over to the new system, it is therefore necessary to allow for a sufficiently long period before it will apply. This period is proposed to be set at 1 January 2009 allowing for the reworking and transposing of the existing detailed rules to the new Regulation.

35. Part of the import provisions of the current Regulation (EEC) No 2092/91 run out on 31 December 2006. The new import scheme should thus apply as from 1 January 2007. However, this will leave little time for its implementation, in particular as regards the recognition of control bodies competent to carry out control in those countries which are not on the list of recognised third countries. In order not to disrupt international trade, it is considered necessary to extend the possibility for Member States to continue to grant import authorisations for individual products until the measures necessary for the functioning of the new import scheme have been put in place To this end a second proposal amending Regulation (EEC) No 2092/91 is included.

Budgetary implications

36. The present proposal does not entail any direct financial implications for the Community budget.

2005/0278 (CNS)

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on organic production and labelling of organic products

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[7],

Whereas:

(1) Organic production is an overall system of farm management and food production that combines best environmental practices, a high level of biodiversity, preservation of natural resources, application of high animal welfare standards and production 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 contribution of the organic agricultural sector is on the increase in most Member States. Growth in consumer demand in recent years is particularly notable. 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 the developments on 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.

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[7] OJ C […], p. […].

(4) The Communication from the Commission to the Council and the European Parliament on a European Action Plan for Organic Food and Farming[8] 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 ensuring simplification and overall coherence and in particular to establishing principles encouraging harmonisation of standards and, where possible, a reducing 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 a harmonised perception of the concept of organic production.

(6) To that end, Council regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs[9] 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 and livestock production, including rules on conversion, as well as on production of processed food and of feed. Competence to determine the details of those general rules and to adopt Community production rules for aquaculture should be conferred on the Commission.

(8) The development of organic production should further be facilitated 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 deliberately used in organic farming or in the processing of organic products.

(10) Organic farming should primarily rely on renewable resources within locally organised agricultural systems. In order to minimise the use of non-renewable resources, wastes of plant and animal origin should be recycled to return nutrients to the land and for energy production.

(11) 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.

(12) The essential elements of the organic plant production management system are soil fertility management, choice of species and varieties, multi-annual 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.

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[8] COM(2004) 415, 10.6.2004.

[9] OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Regulation (EC) No 1567/2005 (OJ L 252, 28.9.2005, p. 1).

(13) 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.

(14) 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 multi-annual rotation systems and the feeding of livestock with organic-farming crop products produced on the holding itself or on neighbouring organic holdings.

(15) As organic stock farming is a land-related activity, animals should have, where possible, access to open air or grazing areas.

(16) Organic stock farming should respect high animal welfare standards and meet animals' species–specific behavioural needs and 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 favour slow growing strains and take account of their capacity to adapt to local conditions. The implementing rules for livestock production and aquaculture production shall ensure compliance with at least the provisions of the European Convention to the Protection of Animals kept for Farming purposes (T-AP) and its subsequent recommendations.

(17) The organic livestock production system should aim at completing the production cycles of the different livestock species with organically reared animals. It shall therefore encourage the increase of the gene pool of organic animals, improve self reliance and thus ensure the development of the sector.

(18) Pending the adoption of Community production rules for aquaculture, 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. However, to prevent disturbances on the internal market, Member States should be required to recognise each other's production standards in this field.

(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) The commercial availability of organic agricultural ingredients has increased over the past years and therefore the use of non-organic ingredients in organic processed food and feed can be further restricted.

(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 less restrictive standards, 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 less restrictive rules is deemed to be justified.

(23) For consumer protection and fair competition, the terms used to indicate organic products should, throughout the Community and independently of the language used, be protected from being used on non-organic products. The protection should also apply to the usual derivatives or diminutives of those terms, whether they are used alone or combined.

(24) It is also necessary to prevent other forms of misleading general labelling and advertising claims.

(25) In order to create clarity throughout the Community market, a simple standardised reference should be made obligatory for all organic products produced within the Community, at least where such products do not bear the Community organic production logo. The possibility to use this reference should also apply to organic products imported from third countries, but without any obligation to do so.

(26) The Community rules should promote a harmonised concept of organic production recognised, defined and defended by all stakeholders. It is therefore necessary to prevent the use of general label claims referring to higher, better, more or stricter organic, since claims of this nature are confusing and undermine the harmonised approach. Indications referring to specific elements of the production method should however be allowed, provided that they are true statements of fact that comply with the general labelling requirements set out in 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[10].

(27) The deliberate 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 is labelled as containing GMOs, consisting of GMOs or produced from GMOs.

(28) In order to ensure that organic products are produced in accordance with the requirements laid down under the Community legal framework on organic production, all activities falling under the scope of this legislation should be controlled throughout the production chain and be 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[11].

(29) It might in some cases appear disproportionate to apply notification and control requirements to certain types of retail operators. It is therefore appropriate to allow Member States to exempt such operators from these requirements.

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[10] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

[11] OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 25.5.2004, p. 1.

(30) The issuing of certificates stating that a certain operator or a specific lot of products is found to comply with the principles and rules of organic farming is a well-established tool in trade of organic products and often conditions access to marks of conformity. Certification practices used by competent authorities or by control bodies to which the competent authority has delegated control tasks should not have, directly or indirectly, restrictive effects on the free movement of organic goods. Certification practices should therefore be subject to certain conditions, requiring in particular mutual recognition of conformity assessment decisions as regards equivalent standards as well as limitations on the collection of fees, in order to avoid hindering the smooth functioning of the internal market.

(31) Organic products imported into the European Community should be allowed to be placed on the Community market labelled 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, meaning that they should be capable of meeting the same objectives and principles. In addition, the products imported under an equivalent system should be covered by a certificate issued by the competent authority or recognised control body of the third country concerned.

(32) The assessment of equivalency with regard to imported products should take into account the international standards laid down in *Codex Alimentarius*.

(33) 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 bodies recognised as being competent for the task of ensuring controls and certification in those countries.

(34) Relevant statistical information should be collected in order to obtain reliable data needed for the implementation and follow-up of this Regulation and as tools for producers, market operators and policy makers. The statistical information needed should be defined within the context of the Community Statistical Programme.

(35) This Regulation should apply from a date defined in order to give the Commission sufficient time to adopt the measures necessary for the implementation of the Regulation.

(36) 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[12]. Considering that the legislation on organic production is an important factor in the framework of the Common Agricultural Policy, as it is closely related to the developments on the agricultural markets, it is appropriate to bring it in line with existing legislative procedures used to manage the this policy. The powers conferred on the Commission under this Regulation should therefore be exercised in accordance with the management procedure provided for in Article 4 of Decision 1999/468/EC,

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[12] OJ L 184, 17.7.1999, p. 23.

HAS ADOPTED THIS REGULATION:

TITLE I
SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1
Subject matter and scope

1. This Regulation establishes objectives, principles and rules concerning:

   (a) the production, placing on the market, import, export and controls of organic products;

   (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 or aquaculture, where such products are intended to be marketed as organic:

   (a) unprocessed plant and livestock products and livestock;

   (b) processed plant and livestock products which are intended for human consumption (hereinafter referred to as "processed food");

   (c) live or unprocessed products of aquaculture;

   (d) processed products of aquaculture which are intended for human consumption;

   (e) feed.

   However, it shall not apply to products of hunting and fishing of wild animals.

3. This Regulation shall apply within the territory of the European Community to any operator involved in the following activities:

   (a) primary production;

   (b) processing of food and feed;

   (c) packaging, labelling and advertising;

   (d) warehousing, transport and distribution;

   (e) imports to and exports from the Community;

   (f) placing on the market.

   However, it shall not apply to catering operations, factory canteens, institutional catering, restaurants or other similar food service operations.

Article 2
Definitions

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

(a) ‘organic production’ means the use of organic production methods on the farm holding, as well as activities involved in the further processing, packaging and labelling of a product, in compliance with the objectives, principles and rules established in this Regulation;

(b) ‘organic product’ means an agricultural product coming from organic production;

(c) ‘plant production’ means production of agricultural crop products and harvesting of wild plant products for commercial purposes;

(d) ‘livestock production’ means the production of domestic or domesticated terrestrial animals (including insects);

(e) ‘aquaculture’ means the rearing or cultivation of aquatic organisms using techniques designed to increase the production beyond the natural capacity of the environment, where the organisms remain the property of a natural or legal person throughout the rearing or cultivation stage, up to and including harvesting;

(f) ‘conversion’ means the transition from non organic to organic farming;

(g) ‘preparation’ means the operations of preserving and/or processing of organic products (including slaughter and cutting for livestock products), and also packaging and/or alterations made to the labelling concerning the organic production method;

(h) ‘placing on the market’ has the meaning given by Article 3, point 8 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[13];

(i) ‘labelling’ means any words, particulars, trade marks, brand name, pictorial matter or symbol placed on any packaging, document, notice, label, ring or collar accompanying or referring to a product referred to in the first subparagraph of Article 1(2);

(j) ‘competent authority’ means the central authority of a Member State competent for the organisation of official controls in the field of organic production or any other authority on which that competence has been conferred and, where appropriate, the corresponding authority of a third country;

(k) ‘control body’ means an independent third party to which the competent authority has delegated certain control tasks;

(l) ‘certificate’ means a written confirmation issued by a competent authority or a control body that an operator or a specific lot of products is found to comply with the principles and rules applicable to organic production;

(m) ‘mark of conformity’ means the assertion of conformity to a particular set of standards or other normative documents in the form of a mark;

(n) ‘ingredients’ has the meaning given by Article 6(4) of Directive 2000/13/EC of the European Parliament and of the Council[14];

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[13] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

[14] OJ L 109, 6.5.2000, p. 29.

(o) 'plant protection products' means products as defined in Article 2, point 1 of Council Directive 91/414/EEC[15];

(p) 'genetically modified organism (GMO)' means an organism as defined in Article 2 of Directive 2000/18/EC of the European Parliament and of the Council[16];

(q) 'produced from GMOs' means derived, in whole or in part, from GMOs but not containing or consisting of GMOs;

(r) 'products produced by GMOs' means food and feed additives, flavourings, vitamins, enzymes, processing aids, certain products used in animal nutrition (under Directive 82/471/EEC[17]), plant protection products, fertilisers and soil conditioners, produced by nourishing an organism with materials that are in whole or in part GMOs;

(s) 'food' has the meaning given by Article 2 of Regulation (EC) No 178/2002;

(t) 'feed' has the meaning given by Article 3, point 4 of Regulation (EC) No 178/2002;

(u) 'feed additives' means products as defined in Article 2(a) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council[18];

(v) 'equivalent' in describing different systems or measures, means that they are capable of meeting the same objectives and principles.

TITLE II
OBJECTIVES AND PRINCIPLES FOR ORGANIC PRODUCTION

Article 3
Objectives

The organic production system shall pursue the following objectives:

(a) It shall establish, in a practical, economically viable management system for agriculture, a production of a wide variety of products by methods that:

  (i) minimise the negative effects on the environment;

  (ii) maintain and enhance a high level of biological diversity on farms and their surrounding areas;

  (iii) preserve as far as possible the natural resources, such as water, soil, organic matter and air;

  (iv) respect high animal welfare standards and in particular meet animals' species-specific behavioural needs.

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15 OJ L 230, 19.8.1991, p. 1.
16 OJ L 106, 17.4.2001, p. 1.
17 OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).
18 OJ L 268, 18.10.2003, p. 29.

(b) It shall establish a production of food and other agricultural products that responds to a consumer demand for goods produced by use of natural processes, or processes that are comparable to natural processes, and naturally occurring substances.

Article 4
Overall principles

The following principles shall apply to all organic production:

(a) the use of living organisms and mechanical production methods shall be preferred to the use of synthetic materials;

(b) natural substances shall be used in preference to chemically synthesised substances, which may be used only where natural substances are not commercially available;

(c) GMOs and products produced from or by GMOs may not be used, with the exception of veterinary medicinal products;

(d) rules of organic production shall be adapted to local conditions, stages of development and specific husbandry practices, while maintaining the common concept of organic production.

Article 5
Principles applicable to farming

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

(a) farming shall maintain and enhance soil fertility, prevent and combat soil erosion, and minimise pollution;

(b) farming shall aim at producing products of high quality instead of maximising production;

(c) the use of non-renewable resources and off-farm inputs shall be minimized;

(d) wastes and by-products of plant and animal origin shall be recycled as input in plant and livestock production and for energy production;

(e) production decisions shall take account of the local or regional ecological balance;

(f) plants shall be primarily fed through the soil ecosystem;

(g) maintenance of animal and plant health shall be based on preventative techniques including selection of appropriate breeds and varieties;

(h) feed for livestock shall come primarily from the holding where the animals are kept or shall be produced in cooperation with other organic farms in the same region;

(i) the highest level of animal welfare shall be observed;

(j) products of organic livestock production shall come from animals that since birth or hatching and throughout their life have been raised on organic holdings;

(k) breeds shall be chosen favouring slow growing strains and having regard to the capacity of animals to adapt to local conditions, their vitality and their resistance to disease or health problems;

(l) organic livestock feed shall be composed essentially of agricultural ingredients from organic farming and of natural non-agricultural substances;

(m) husbandry practices which enhance the immune system and strengthen the natural defence against diseases shall be used;

(n) aquaculture production shall minimise the negative effect on the aquatic environment;

(o) feed used in aquaculture shall be from sustainable fisheries or composed essentially of agricultural ingredients from organic farming and of natural non-agricultural substances;

(p) polyploid animals may not be used.

Article 6
Principles applicable to processing

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

(a) organic food and feed shall be produced essentially from agricultural ingredients which shall be organic, except where an organic ingredient is not commercially available;

(b) additives and processing aids shall be used to a minimum extent and only in case of essential technological need;

(c) ionising radiation may not be used.

TITLE III
PRODUCTION RULES

CHAPTER 1
FARM PRODUCTION

Article 7
General farm production rules

1. The entire commercial part of a holding shall be managed in compliance with the requirements applicable to organic production or conversion to organic production.

However, in accordance with specific conditions to be laid down in accordance with the procedure referred to in Article 31(2), a holding may be split up into clearly separated units which are not all managed under organic production.

Where, in accordance with the second subparagraph, not all of a farm is used for organic production, the farmer shall keep the land, animals, and products used for

organic production separate from the rest and keep adequate records to show the separation.

2. Farmers are required not to use GMOs or products produced from GMOs where they should have knowledge of their presence due to information on any label accompanying the product or from any other accompanying document.

Where farmers use products purchased from third parties to produce organic food or feedstuffs, they shall require the vendor to confirm that the products supplied have not been produced by GMOs.

Article 8
Plant production rules

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

(a) organic plant production shall be based on tillage and cultivation practices that maintain or increase soil organic matter, enhance soil stability and soil biodiversity, and prevent soil compaction and soil erosion;

(b) fertility and biological activity of the soil shall be maintained and increased by multi-annual crop rotation including green manure, application of manure and organic material from organic farms;

(c) in addition, fertilisers and soil conditioners compatible with the objectives and principles of organic production may be used if they have been approved under Article 11;

(d) mineral nitrogen fertilisers shall not be used;

(e) all plant production techniques used shall prevent or minimise any contribution to contamination of the environment;

(f) prevention of damage caused by pests, diseases and weeds shall rely primarily on the choice of species and varieties, crop rotation and cultivation techniques;

(g) in the case of threat to a crop, plant protection products compatible with the objectives and principles of organic production may be used if they have been approved under Article 11;

(h) the use of any approved synthetic substances shall be subject to conditions and limits as regards the crops that they can be applied to, the application method, the dosage, the time limits for use and the contact with crop;

(i) only organically produced seed and propagating material may be used. To this end, the mother plant in the case of seeds and the parent plant in the case of vegetative propagating material shall have been produced in accordance with the rules laid down in this Regulation for at least one generation, or, in the case of perennial crops, two growing seasons.

2. The collection of edible plants and parts thereof, growing naturally in natural areas, forests and agricultural areas, is considered an organic production method provided that:

(a) those areas have not, for a period of three years before the collection, received treatments with products other than those approved under Article 11;

(b) the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

Article 9
Livestock production rules

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

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

(i) organic livestock shall be born and raised on organic holdings;

(ii) for breeding purposes, non-organically raised animals may be brought onto a holding under specific conditions to be established in accordance with the procedure referred to in Article 31(2);

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

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

(ii) husbandry practices, including stocking densities, and housing conditions shall ensure that developmental, physiological and ethological needs of animals are met;

(iii) the livestock shall have permanent access to a free-range area, preferably pasture, whenever weather conditions and the state of the ground allow this;

(iv) the number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, or pollution caused by animals or by the spreading of their manure;

(v) organic livestock shall be kept separate or readily separable from other livestock;

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

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

(viii) any suffering, including mutilation, shall be kept to a minimum;

(ix) apiaries must be placed in areas which ensure nectar and pollen sources consisting essentially of organically produced crops and/or spontaneous vegetation and must keep enough distance from sources leading to contamination of products from beekeeping;

(x) hives and materials used in beekeeping must be 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 not be induced by hormone treatment, unless in order to treat reproduction disorders;

(ii) cloning and embryo transfer shall not be used;

(iii) an appropriate choice of breed shall contribute to the prevention of any suffering and to avoiding the need for mutilation of animals;

(d) with regard to feed:

(i) livestock shall be fed with organic feed, which may include proportions of feed from farm units which are in conversion to organic farming, that meet the animal's nutritional requirements at the various stages of its development;

(ii) animals shall have permanent access to pasture or roughage;

(iii) feed additives may be used only if they have been approved under Article 11;

(iv) growth promoters and synthetic amino-acids may not be used;

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

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

(i) disease prevention shall be based on breed and strain selection, husbandry management practices, high quality feed and exercise, appropriate stocking density and adequate and appropriate housing maintained in hygienic conditions;

(ii) disease outbreaks shall be treated immediately to avoid suffering to the animal; allopathic products including antibiotics may be used where necessary, when the use of phytotherapeutic, homeopathic and other products is inappropriate.

Article 10

Production rules for aquaculture

1. The Commission shall in accordance with the procedure referred to in Article 31(2), and subject to the objectives and principles laid down in Title II, establish production rules, including rules on conversion, applicable to organic aquaculture.

2. Pending the adoption of the rules referred to in paragraph 1, national rules, or in the absence thereof private standards accepted or recognised by the Member States, shall apply, provided that they pursue the same objectives and principles as those laid down in Title II.

Article 11

Use of certain products and substances in farming

1. The Commission shall in accordance with the procedure referred to in Article 31(2), and subject to the objectives and principles laid down in Title II, establish specific criteria for the approval of products and substances that may be used in organic farming as follows:

   (a) plant protection products;

   (b) fertilisers and soil conditioners;

   (c) plant, animal and mineral feed material;

   (d) feed additives;

   (e) cleaning materials;

   (f) other substances.

2. The Commission shall, in accordance with the procedure referred to in Article 31(2), decide on approval of the products and substances referred to in paragraph 1 and fix the conditions and limits for their use.

Article 12

Conversion

The following rules shall apply to a farm on which organic production is commenced:

(a) prior to the first growing season of crops which are to be grown according to organic production methods, products not permitted to be used in organic farming shall not have been applied for a period to be defined in accordance with the procedure referred to in Article 31(2);

(b) livestock existing on the holding may be deemed organic after a transitional period to be defined in accordance with the procedure referred to in Article 31(2);

(c) milk and milk products from formerly non organic dairy animals may be sold as organic after a period to be defined in accordance with the procedure referred to in Article 31(2);

(d) on single farm units partly under organic production and partly in conversion to organic production, the farmer shall keep the land, animals, and products separate and keep adequate records to show the separation.

CHAPTER 2
FEED PRODUCTION

Article 13
Production rules for feed

1. Production of organic feed shall be kept separate from production of non organic feed.

2. Organic feed materials, and/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. Hexane and other organic solvents may not be used.

4. Feed manufacturers are required not to use GMOs or products produced from GMOs where they should have knowledge of their presence due to information on any label accompanying the product or from other accompanying documents.

   Where feed manufacturers use ingredients and additives purchased from third parties to produce feedstuffs for organic livestock, they shall require the vendor to confirm that the products supplied have not been produced by GMOs.

CHAPTER 3
PRODUCTION OF PROCESSED PRODUCTS

Article 14
General rules on the production of processed food

1. The following criteria shall apply to the composition of organic processed food:

   (a) at least 95%, by weight, of the ingredients of agricultural origin of the product shall be organic;

   (b) ingredients of non-agricultural origin and processing aids may be used only if they have been approved under Article 15;

   (c) non-organic agricultural ingredients may be used only if they have been approved under Article 15.

2. The extraction, processing and storage of organic food shall be conducted with care to avoid losing the properties of the ingredients. Substances and techniques that reconstitute these properties or correct the results of negligence in the processing of these products shall not be used.

3. Processors are required not to use GMOs or products produced from GMOs where they should have knowledge of their presence due to information on the label accompanying the product or from any other accompanying document.

Where processors use ingredients and processing aids purchased from third parties to produce organic food or feedstuffs, they shall require the vendor to confirm that the products supplied have not been produced by GMOs.

Article 15
Use of certain products and substances in processing

1. The Commission shall in accordance with the procedure referred to in Article 31(2), and subject to the objectives and principles laid down in Title II, establish specific criteria for the approval of ingredients of non-agricultural origin and processing aids that may be used in the production of organic processed food.

2. The Commission shall in accordance with the procedure referred to in Article 31(2), and subject to the objectives and principles laid down in Title II, establish specific criteria for the approval of agricultural ingredients which are not organic but which may be used in the production of organic processed food where organic agricultural ingredients are not commercially available.

3. The Commission shall, in accordance with the procedure referred to in Article 31(2), decide on approval of the products and substances referred to in paragraphs 1 and 2 and, where necessary, fix the conditions and limits for their use.

CHAPTER 4
FLEXIBILITY

Article 16
Less restrictive production rules

1. The Commission may, in accordance with the procedure referred to in Article 31(2) and the conditions set out in paragraph 2 and subject to the objectives and principles laid down in Title II, provide for the granting of exceptions from the production rules laid down in Chapters 1 to 3.

2. Exceptions as referred to in paragraph 1 shall be kept to a minimum and may only be provided for in the following cases:

   (a) where they are necessary in order to enable farm units initiating organic production to become viable, in particular for holdings located in areas in the early stages of development of organic production;

   (b) where they are necessary in order to ensure that organic production can be maintained on holdings confronted with climatic, geographical or structural constraints;

   (c) where it is necessary in order to ensure access to feed, seed and vegetative propagating material, live animals and other farm inputs, where such inputs are not commercially available in organic form;

   (d) where it is necessary in order to ensure access to ingredients of agricultural origin, where such ingredients are not commercially available in organic form;

(e) where they are necessary in order to solve specific problems related to the management of organic livestock;

(f) where they are necessary in order to ensure continued production of traditional food products well known for at least a generation;

(g) where temporary measures are necessary in order to allow organic production to continue or recommence in the case of catastrophic circumstances;

(h) where restrictions and obligations related to the protection of human and animal health are imposed on the basis of Community legislation.

3. The Commission may in accordance with the procedure referred to in Article 31(2) lay down specific conditions for the application of exceptions provided for under paragraph 1.

TITLE IV
LABELLING

Article 17
Use of terms referring to organic production

1. The terms listed in Annex I, their derivatives or diminutives, alone or combined, may be used throughout the Community and in any Community language for the labelling and advertising of a product which is produced and controlled, or imported, in accordance with this Regulation.

2. The terms listed in Annex I, their derivatives or diminutives, alone or combined, may not be used anywhere in the Community and in any Community language for the labelling and advertising of a product which has not been produced and controlled, or imported, in accordance with this Regulation, unless these terms clearly cannot be associated with agricultural production.

3. The terms listed in Annex I, their derivatives or diminutives, alone or combined, may not be used for a product which bears a label indicating that it contains GMOs, consists of GMOs or is produced from GMOs.

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

5. The Commission may in accordance with the procedure referred to in Article 31(2) adapt the list of terms set out in Annex I.

Article 18
Compulsory indications

1. Where a term referred to in Article 17, or its derivative or diminutive, is used in labelling of products produced within the Community, the following indications shall also appear on the label:

(a) the code number referred to in Article 22(7) of the body competent for the controls to which the operator is subject;

(b) where the logo referred to in Article 19 is not used, at least one of the indications listed in Annex II in capital lettering.

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

In addition, the Commission shall in accordance with the procedure referred to in Article 31(2) lay down specific criteria as regards the presentation and size of the indications referred to in paragraph 1.

3. The Commission may in accordance with the procedure referred to in Article 31(2) adapt the list of indications set out in Annex II.

4. For products imported from third countries, the use of the indications referred to in paragraph 1 shall be optional.

Article 19
Community organic production logo

The Commission shall, in accordance with the procedure referred to in Article 31(2), define a Community logo which may be used in the labelling, presentation and advertising of products produced and controlled, or imported, in accordance with this Regulation.

Article 20
Label and advertising claims

1. General claims that a particular set of private or national organic standards is stricter, more organic or otherwise superior to the rules laid down in this Regulation, or to any other set of organic standards, may not be used on labels or in advertising.

However, indications referring to specific elements of the production method used for a certain product may only be used on labels or in advertising on condition that they are true statements of fact and otherwise in conformity with the general labelling requirements set out in Directive 2000/13/EC.

2. Member States shall take the measures necessary to ensure compliance with the conditions set out in this Article.

3. The Commission may in accordance with the procedure referred to in Article 31(2) adopt measures in order to ensure compliance with this Article.

Article 21
Specific labelling requirements

The Commission shall in accordance with the procedure referred to in Article 31(2) establish specific labelling requirements applicable to organic feed and to products originating from holdings in conversion.

TITLE V
CONTROLS

Article 22
Control system

1. Member States shall in accordance with the provisions laid down in Regulation (EC) No 882/2004 set up a system of controls applicable to the activities referred to in Article 1(3) of this Regulation.

2. In applying Article 3 of Regulation (EC) No 882/2004, the nature and frequency of the controls shall be determined on the basis of an analysis of the risk of irregularity in the field of each of the activities referred to in Article 1(3) of this Regulation.

3. Member States shall in accordance with Article 4 of Regulation (EC) No 882/2004 designate the competent authority responsible for the controls to be carried out under the control system.

4. The competent authority may in accordance with Article 5 of Regulation (EC) No 882/2004 delegate certain control tasks to one or more control bodies.

   The control bodies shall fulfil the requirements set out in European Standard EN 45011 or ISO Guide 65 'General requirements for bodies operating product certification systems' of the version as most recently notified by a publication in the *Official Journal of the European Union,* C series.

5. Approved control bodies shall give the competent authority access to their offices and facilities and provide any information and assistance deemed necessary by the competent authority for the fulfilment of its obligations according to this Article.

6. The competent authority 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 16, unless this is provided for in the specific conditions laid down by the Commission in accordance with Article 16(3).

7. Member States shall attribute a code number to each body competent to carry out controls under this Regulation.

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

Article 23
Adherence to the control system

1. Any operator who produces, prepares, stores or imports from or exports to a third country products as specified in the first subparagraph of Article 1(2) with a view to the subsequent marketing thereof, or who markets such products, shall:

(a) notify this activity to a competent authority of the Member State where the activity is carried out;

(b) submit his undertaking to the control system.

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

3. Member States shall ensure that any operator who complies with the rules of this Regulation, and who pays a reasonable fee as a contribution to the control expenses, is entitled to be covered by the control system.

4. The competent authority shall keep an updated list containing the names and addresses of operators subject to the control system.

Article 24
Certification

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

2. A competent authority may not refuse to grant certificates or the use of its mark of conformity for any product that meets the requirements laid down in this Regulation.

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

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

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

Article 25
Measures in case of infringements and irregularities

1. The competent authority shall:

(a) where an irregularity is found as regards compliance with the requirements laid down in this Regulation, ensure that the indications and the logo provided for in Articles 17, 18 and 19 are not used on the entire lot or production run affected by this irregularity;

(b) where a manifest infringement or an infringement with prolonged effect is found, prohibit the operator concerned from marketing products with

indications referring to the organic production method for a period to be determined by the competent authority.

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

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

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

Article 26
Exchange of information

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

TITLE VI
TRADE WITH THIRD COUNTRIES

Article 27
Imports from third countries

1. A product imported from a third country may be placed on the Community market labelled as organic where it complies with the provisions set out in Titles II, III and IV of this Regulation.

2. A third country operator who wishes to place his products labelled as organic on the Community market, under the conditions provided for in paragraph 1, shall submit his activities to any competent authority or control body as referred to in Title V, provided that the authority or body concerned perform controls in the third country of production, or to a control body approved in accordance with paragraph 5.

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

(a) the product has been produced in accordance with production standards equivalent to those applied to organic production in the Community, or in accordance with the internationally recognised standards set out in the *Codex Alimentarius* guidelines;

(b) the producer has been subject to control arrangements which are equivalent to those of the Community control system, or which comply with the *Codex Alimentarius* guidelines;

(c) the third country operator who wishes to place his products labelled as organic on the Community market under the conditions of this paragraph has submitted

his activities to a control system recognised in accordance with paragraph 4 or a control body recognised in accordance with paragraph 5;

(d) the product is covered by a certificate issued by the competent authorities or control bodies of a third country recognised in accordance with paragraph 4, or by a control body recognised in accordance with paragraph 5, which confirms that the product satisfies the conditions set out in this paragraph.

4. The Commission shall in accordance with the procedure referred to in Article 31(2) recognise the third countries whose production standards and control arrangements are equivalent to those applied in the Community, or are in accordance with the internationally recognised standards set out in the *Codex Alimentarius* guidelines, and establish a list of these countries.

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

5. For products imported from a third country which is not recognised under paragraph 4, and where the operator has not submitted his activities to a competent authority or control body as referred to in Title V, the Commission shall in accordance with the procedure referred to in Article 31(2) recognise the control bodies competent to carry out controls and issue certificates in that third country for the purpose of paragraph 3, and establish a list of these control bodies.

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

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

TITLE VII
FINAL AND TRANSITIONAL RULES

Article 28
Free movement of organic products

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

Article 29
Transmission of information to the Commission

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

(a) the names and addresses of the competent authorities;

(b) lists of control bodies and their code numbers and, where appropriate, their marks of conformity with standards.

Article 30
Statistical information

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

Article 31
Management Committee on organic production

1. The Commission shall be assisted by the Management Committee on organic production (hereinafter "the Committee").

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC[19] shall apply.

3. The period provided for in Article 4(3) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its rules of procedure.

Article 32
Implementing rules

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

(a) detailed rules as regards the production rules laid down in Title III, in particular as regards the specific requirements and conditions to be respected by farmers and other producers of organic products;

(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 the specific criteria for delegation of tasks to private control bodies and the criteria for approval of such bodies;

(d) detailed rules as regards the rules on imports from third countries laid down in Title VI, in particular as regards the criteria and procedures to be followed with regard to the recognition under Article 27 of third countries and control bodies, including the publication of lists of recognised third countries and control bodies, and as regards the certificate referred to in Article 27(3), point (d).

[19] OJ L 184, 17.7.1999, p. 23.

Article 33

Repeal of Regulation (EEC) No 2092/91

1. Regulation (EEC) No 2092/91 is hereby repealed from 1 January 2009.

2. References to the repealed Regulation (EEC) No 2092/91 shall be construed as references to this Regulation.

Article 34

Transitional measures

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

Article 35

Entry into force and application

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

It shall apply as from 1 January 2009.

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

Done at Brussels,

For the Council
The President

ANNEX I

Terms referred to in Article 17(1)

– ES: ecológico,

– CS: ekologické,

– DA: økologisk,

– DE: ökologisch, biologisch,

– ET: mahe, ökoloogiline,

– EL: βιολογικό,

– EN: organic,

– FR: biologique,

– GA: orgánach,

– IT: biologico,

– LV: bioloģiskā,

– LT: ekologiškas,

– HU: ökológiai,

– MT: organiku,

– NL: biologisch,

– PL: ekologiczne,

– PT: biológico,

– SK: ekologické,

– SL: ekološki,

– FI: luonnonmukainen,

– SV: ekologisk.

ANNEX II

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

– UE-ECOLÓGICO,

– EU-EKOLOGICKÉ,

– EU-ØKOLOGISK,

– EU-ÖKOLOGISCH,

– EL-MAHE,

– EL-ÖKOLOOGILINE,

– ΕΕ-ΒΙΟΛΟΓΙΚΌ,

– EU-ORGANIC,

– UE-BIOLOGIQUE,

– AE-ORGÁNACH,

– UE-BIOLOGICO,

– ES-BIOLOĢISKĀ,

– ES-EKOLOGIŠKAS,

– EU-ÖKOLÓGIAI,

– EU-ORGANIKU,

– EU-BIOLOGISCH,

– UE-EKOLOGICZNE

– EU-EKOLOGICKE,

– EU-EKOLOSKI,

– EU-LUONNONMUKAINEN,

– EU-EKOLOGISK.

2005/0279 (CNS)

Proposal for a

COUNCIL REGULATION

amending Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto in agricultural products and foodstuffs

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[20],

Whereas:

(1) Given the need to advance on the implementation of the European Action Plan for Organic Food and Farming[21] on the basis of concrete measures with a view to assuring simplification and overall coherence, Council Regulation (EEC) No 2092/91[22] will be repealed on [1 January 2009] and replaced by Council Regulation (EC) No …./2006 of […] on organic production and labelling of organic products[23].

(2) Under the new scheme established by Regulation (EC) No …./2006 for imports of organic produce from third countries, organic products imported into the Community should be allowed to be placed on the Community market labelled 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 Community legislation.

(3) To this end, third countries whose production standards and control arrangements are equivalent to those applied in the Community should be recognised and a list thereof should be published. The control bodies competent to carry out control in countries which are not on the list of recognised third countries should also be recognised and listed. Third country operators who produce in direct compliance with Community rules should be allowed to choose to submit their activities to the competent authorities and control bodies designated by the Member States.

(4) Article 11(6) of Regulation (EEC) No 2092/91 provides for the possibility for Member States to grant until 31 December 2006 import authorisations for individual products under certain conditions. It is thus appropriate to amend that Article, so as to allow for

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20 OJ C […], p. […].
21 COM(2004) 415.
22 OJ L 198, 22.7.1991, p. 1. Regulation as last amended by ….
23 OJ L […, ….2006, p. …].

a replacement of the current import scheme by the new import scheme as from that date.

(5) The new import scheme should thus apply as from 1 January 2007. However, this will leave little time for its implementation, in particular as regards the recognition of control bodies competent to carry out control in those countries which are not on the list of recognised third countries. In order not to disrupt international trade, it is considered necessary to extend the possibility for Member States to continue to grant import authorisations for individual products until the measures necessary for the functioning of the new import scheme have been put in place.

(6) Regulation (EEC) No 2092/91 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2092/91 is amended as follows:

(1) In Article 10(1), point (b) is replaced by the following:

"(b) have been subject to the inspection system referred to in Article 9 or, in the case of products imported under Article 11(3) and (6), to equivalent measures;"

(2) Article 11 is replaced by the following:

"Article 11

1. A product imported from a third country may be placed on the Community market labelled as organic where it complies with the production rules laid down in this Regulation.

2. A third country operator who wishes to place his products labelled as organic on the Community market, under paragraph 1, shall submit his activities to any inspection authority or inspection body as referred to in Article 9, provided that the authority or body concerned perform controls in the third country of production, or to a control body approved in accordance with paragraph 5 of this Article.

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

(a) the product has been produced in accordance with production standards equivalent to those applied to organic production in the Community, or in accordance with the internationally recognised standards set out in the *Codex Alimentarius* guidelines;

(b) the producer has been subject to control arrangements which are equivalent to those of the Community control system, or which comply with the *Codex Alimentarius* guidelines;

(c) the third country operator who wishes to place his products labelled as organic on the Community market under the conditions of this paragraph has submitted his activities to a control system recognised in accordance with paragraph 4 or a control body recognised in accordance with paragraph 5;

(d) the product is covered by a certificate issued by the competent authorities or control bodies of a third country recognised in accordance with paragraph 4, or by a control body recognised in accordance with paragraph 5, which confirms that the product satisfies the conditions set out in this paragraph.

4. The Commission shall, in accordance with the procedure referred to in Article 14(2), recognise the third countries whose production standards and control arrangements are equivalent to those applied in the Community, or are in accordance with the internationally recognised standards set out in the *Codex Alimentarius* guidelines, and publish a list of these countries.

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

5. For products imported from a third country which is not recognised under paragraph 4, and where the operator has not submitted his activities to an inspection authority or inspection body as referred to in Article 9, the Commission shall, in accordance with the procedure referred to in Article 14(2), recognise the control bodies competent to carry out controls and issue certificates in that third country for the purpose of paragraphs 2 or 3 of this Article, and publish a list of these control bodies.

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

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

6. For a period ending six months after the publication of the first list of control bodies recognised pursuant to paragraph 5, the competent authority of a Member State may authorise importers in that Member State to place on the market products imported from third countries which are not included in the list referred to in paragraph 4, provided that the importer provides sufficient evidence showing that the conditions referred to in points (a) and (b) of paragraph 3 are satisfied. If those conditions are no longer satisfied, the authorisation shall be immediately withdrawn.

The imported product shall be covered by a certificate issued by the competent authority of the authorising Member State or by a control body recognised in accordance with paragraph 5, which confirms that the product satisfies the conditions set out in this paragraph.

Each Member State shall inform the other Member States and the Commission of each authorisation granted pursuant to this paragraph, including information on the production standards and control arrangements concerned.

At the request of a Member State or at the Commission's initiative, an authorisation granted pursuant to this paragraph shall be examined by the Committee set in Article 14. If it emerges from this examination that the conditions referred to in points (a) and (b) of paragraph 3 of this Article are not satisfied, the Commission shall request the Member State which granted the authorisation to withdraw it.

7. The Commission may, in accordance with the procedure referred to in Article 14(2), adopt detailed rules for the application of this Article, and in particular:

(a) as regards the criteria and procedures to be followed with regard to the recognition of third countries and control bodies under paragraphs 4 and 5 of this Article, including the publication of lists of recognised third countries and control bodies,

(b) as regards the certificate referred to in paragraphs 3(d) and 6 of this Article."

(3) The second subparagraph of Article 16(3) is deleted.

(4) Point C of Annex III is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 January 2007.

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

Done at Brussels,

For the Council
The President

ANNEX

Point C of the Specific Conditions in Annex III to Regulation (EEC) No 2092/91 is amended as follows:

(1) In the first paragraph, the second indent is replaced by the following:

"– the first consignee shall mean the natural or legal person to whom the consignment is delivered and who will receive it for further preparation and/or marketing."

(2) In point 5, the first subparagraph is replaced by the following:

"The inspection body or authority shall inspect the stock and financial records mentioned in section C, point 2 and the certificate referred to in Article 11(3)(d) or Article 11(6)."