

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

► **B** **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
(OJ L 198, 22.7.1991, p. 1)

Amended by:

	Official Journal		
	No	page	date
► M1 Commission Regulation (EEC) No 1535/92 of 15 June 1992	L 162	15	16.6.1992
► M2 Council Regulation (EEC) No 2083/92 of 14 July 1992	L 208	15	24.7.1992
► M3 Commission Regulation (EEC) No 207/93 of 29 January 1993	L 25	5	2.2.1993
► M4 Commission Regulation (EEC) No 2608/93 of 23 September 1993	L 239	10	24.9.1993
► M5 Commission Regulation (EC) No 468/94 of 2 March 1994	L 59	1	3.3.1994
► M6 Council Regulation (EC) No 1468/94 of 20 June 1994	L 159	11	28.6.1994
► M7 Commission Regulation (EC) No 2381/94 of 30 September 1994	L 255	84	1.10.1994
► M8 Commission Regulation (EC) No 1201/95 of 29 May 1995	L 119	9	30.5.1995
► M9 Commission Regulation (EC) No 1202/95 of 29 May 1995	L 119	11	30.5.1995
► M10 Council Regulation (EC) No 1935/95 of 22 June 1995	L 186	1	5.8.1995
► M11 Commission Regulation (EC) No 418/96 of 7 March 1996	L 59	10	8.3.1996

Amended by:

► A1 Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
(adapted by Council Decision 95/1/EC, Euratom, ECSC)	L 1	1	1.1.1995

Corrected by:

- **C1** Corrigendum, OJ L 21, 28.1.1995, p. 21 (2381/94)



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

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas demand from consumers for organically produced agricultural products and foodstuffs is increasing; whereas a new market for agricultural products is thus being created by this phenomenon;

Whereas the market price for such products is higher, while the way in which they are produced involves less intensive use of land; whereas, therefore, in the context of the reorientation of the common agricultural policy, this type of production may contribute towards the attainment of a better balance between supply of, and demand for, agricultural products, the protection of the environment and the conservation of the countryside;

Whereas, in response to the rising demand, agricultural products and foodstuffs are being placed on the market with indications stating or implying to purchasers that they have been produced organically or without the use of synthetic chemicals;

Whereas some Member States have already adopted rules and inspection arrangements for the use of such indications;

Whereas a framework of Community rules on production, labelling and inspection will enable organic farming to be protected in so far as it will ensure conditions of fair competition between the producers of products bearing such indications and give the market for organic products a more distinctive profile by ensuring transparency at all stages of production and processing, thereby improving the credibility of such products in the eyes of consumers;

Whereas organic production methods constitute a specific form of production at farm level; whereas, consequently, it should be provided that, on the labelling of processed products, indications referring to organic production methods should relate to the ingredients obtained by such methods;

Whereas, for the implementation of the arrangements concerned, provision should be made for flexible procedures whereby certain technical details or measures may be amended, amplified or further defined in order to take account of experience gained; whereas, within a suitable period, this Regulation will be supplemented by equivalent rules covering livestock production;

Whereas, in the interests of the producers and purchasers of products bearing indications referring to organic production methods, the minimum principles which must be complied with in order for products to be presented with such indications should be laid down;

Whereas organic production methods entail significant restrictions on the use of fertilizers and pesticides which may have detrimental effects on the environment or result in the presence of residues in agricultural produce; whereas, in this context, practices accepted in the Community

⁽¹⁾ OJ No C 4, 9. 1. 1990, p. 4; and
OJ No C 101, 18. 4. 1991, p. 13.

⁽²⁾ OJ No C 106, 22. 4. 1991, p. 27.

⁽³⁾ OJ No C 182, 23. 7. 1990, p. 12.

▼B

when this Regulation is adopted must be complied with in accordance with codes of practice followed in the Community when this Regulation is adopted; whereas, moreover, in the future, the principles governing the authorization of products which may be used in this type of farming must be established;

Whereas, moreover, organic farming involves varied cultivation practices and limited use of non-synthetic fertilizers and conditioners of low solubility; whereas these practices should be specified and conditions for the use of certain non-synthetic products laid down;

Whereas the procedures laid down make possible, if this appears necessary, the addition to Annex I of more specific provisions aimed at avoiding the presence of certain residues of synthetic chemicals from sources other than agriculture (environmental contamination) in the products obtained by such production methods;

Whereas, to ensure compliance with the rules on production, all stages of production and marketing should normally be subject to inspection;

Whereas all operators producing, preparing, importing or marketing products bearing indications referring to organic production methods must be subject to a regular inspection system, meeting minimum Community requirements and carried out by designated inspection authorities and/or by approved and supervised bodies; whereas provision should be made for a Community indication of inspection to appear on the labelling of the products concerned,

HAS ADOPTED THIS REGULATION:

Scope

Article 1

1. This Regulation shall apply to the following products, where such products bear, or are intended to bear, indications referring to organic production methods:

- (a) unprocessed agricultural crop products; also animals and unprocessed animal products, to the extent that principles of production and specific inspection rules for them are introduced into Annexes I and III;
- (b) products intended for human consumption composed essentially of one or more ingredients of plant origin; in addition, upon adoption of the provisions concerning livestock production referred to in (a), products intended for human consumption containing ingredients of animal origin.

2. A proposal concerning the principles and specific measures of control governing organic animal production, non-processed animal products and products intended for human consumption containing ingredients of animal origin shall be submitted by the Commission as soon as possible and before ►**M10** 30 June 1995. ◀

Article 2

For the purposes of this Regulation a product shall be regarded as bearing indications referring to organic production methods where, in the labelling, advertising material or commercial documents, such a product or its ingredients is described by the indications in use in each Member State suggesting to the purchaser that the product or its ingredients have been obtained in accordance with the rules of production laid down in ►**M10** Article 6 ◀ and in particular the following terms, unless such terms are not applied to agricultural products in foodstuffs or clearly have no connection with the method of production:

▼B

- in Spanish: ecológico,
- in Danish: økologisk,
- in German: ökologisch,
- in Greek: βιολογικό,
- in English: organic,
- in French: biologique,
- in Italian: biologico,
- in Dutch: biologisch,
- in Portuguese: biológico,

▼A1

- in Finnish: luonnonmukainen,
- in Swedish: ekologisk.

▼B*Article 3*

This Regulation shall apply without prejudice to other Community provisions governing the production, preparation, marketing, labelling and inspection of the products specified in Article 1.

Definitions*Article 4*

For the purpose of this Regulation:

1. 'labelling' shall mean any words, particulars, trade marks, brand names, pictorial matter or symbols on any packaging, document, notice, label, board or collar accompanying or referring to a product specified in Article 1;

▼M10

2. 'production' shall mean the operations on the agricultural holding involved in producing, packaging and initially labelling as products of organic production agricultural products produced on that holding;
3. 'preparation' shall mean the operations of preserving and/or processing of agricultural products, and also packaging and/or alterations made to the labelling concerning the presentation of the organic production method of the fresh, preserved and/or processed products;

▼B

4. 'marketing' shall mean holding or displaying for sale, offering for sale, selling, delivering or placing on the market in any other form;
5. 'operator' shall mean any natural or legal person who produces, prepares or imports from a third country, with a view to the subsequent marketing thereof, products as referred to in Article 1, or who markets such products;

▼M10

6. 'ingredients' shall mean the substances, including additives, used in the preparation of the products specified in Article 1 (1) (b), as defined in Article 6 (4) of Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer;

▼B

7. 'plant protection products' shall mean products as defined in Article 2 (1) of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection

▼B

products containing certain active substances ⁽¹⁾, as last amended by Directive 89/365/EEC ⁽²⁾;

8. 'detergents' shall mean substances and preparations, within the meaning of Council Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents ⁽³⁾, as last amended by Directive 86/94/EEC ⁽⁴⁾, which are intended to be used for cleaning certain products as referred to in Article 1 (1) (a).

▼M10

9. 'prepackaged foodstuff' shall mean any single item as defined in Article 1 (3) (b) of Directive 79/112/EEC;
10. 'list of ingredients' shall mean the list of ingredients referred to in Article 6 of Directive 79/112/EEC.

▼B**Labelling***Article 5*

1. The labelling and advertising of a product specified in Article 1 (1) (a) may refer to organic production methods only where:
- (a) such indications show clearly that they relate to a method of agricultural production;
- (b) the product was produced in accordance with the rules laid down in ►M10 Article 6 ◀ or imported from a third country under the arrangements laid down in Article 11;
- (c) the product was produced or imported by an operator who is subject to the inspection measures laid down in Articles 8 and 9;

▼M10

- (d) in the case of products prepared after 1 January 1997, the labelling refers to the name and/or the code number of the inspection authority or body to which the operator is subject. Member States shall decide whether to require a reference to the name and/or to the code number and shall notify the Commission accordingly.

-
3. The labelling and advertising of a product specified in Article 1 (1) (b) may bear indications referring to organic production methods in the sales description of the product only where:

- (a) at least 95 % of the ingredients of agricultural origin of the product are, or are derived from, products obtained in accordance with the rules laid down in Article 6 or imported from third countries under the arrangements laid down in Article 11;
- (b) all the other ingredients of agricultural origin of the product are included in Annex VI, Section C or have been provisionally authorized by a Member State in accordance with any implementing measures adopted where appropriate pursuant to paragraph 7;
- (c) the product contains only substances listed in Annex VI, Section A, as ingredients of non-agricultural origin;
- (d) the products or its ingredients of agricultural origin, referred to in subparagraph (a), have not been subjected to treatments involving the use of substances not listed in Annex VI, Section B;
- (e) the product or its ingredients have not been subjected to treatments involving the use of ionizing radiation;

⁽¹⁾ OJ No L 33, 8. 2. 1979, p. 36.

⁽²⁾ OJ No L 159, 10. 6. 1989, p. 58.

⁽³⁾ OJ No L 347, 17. 12. 1973, p. 51.

⁽⁴⁾ OJ No L 80, 25. 3. 1986, p. 51.

▼ M10

- (f) the product has been prepared or imported by an operator who is subject to the inspection measures laid down in Articles 8 and 9;
- (g) in the case of products prepared after 1 January 1997, the labelling refers to the name and/or the code number of the inspection authority or body to which the operator who has carried out the most recent preparation operation is subject. Member States shall decide whether to require a reference to the name and/or to the code number and shall notify the Commission accordingly.

The indications referring to organic production methods must make it clear that they relate to a method of agricultural production and must be accompanied by a reference to the ingredients of agricultural origin concerned, unless such reference is clearly given in the list of ingredients.

4. Ingredients of agricultural origin may be included in Annex VI, Section C only where it has been shown that such ingredients are of agricultural origin and are not produced in sufficient quantity in the Community in accordance with the rules laid down in Article 6, or cannot be imported from third countries in accordance with the rules laid down in Article 11.

5. Products labelled or advertised in accordance with paragraphs 1 or 3 may bear indications referring to conversion to organic production methods, provided that:

- (a) the requirements referred to in paragraph 1 or paragraph 3 respectively are fully satisfied, with the exception of that concerning the length of the conversion period referred to in paragraph 1 of Annex I;
- (b) a conversion period of at least 12 months before the harvest has been complied with;
- (c) such indications do not mislead the purchaser of the product regarding its difference from products which satisfy all the requirements of paragraphs 1 or 3. After 1 January 1996, such indications must take the form of the words 'product under conversion to organic farming', and must appear in a colour, size and style of lettering which is not more prominent than the sales description of the product; in this indication the words 'organic farming' shall not be more prominent than the words 'product under conversion to';
- (d) the product contains only one ingredient of agricultural origin;
- (e) for products prepared after 1 January 1997, the labelling refers to the name and/or the code number of the inspection authority or body to which the operator who has carried out the most recent production or preparation operation is subject. Member States shall decide whether to require a reference to the name and/or to the code number and shall notify the Commission accordingly.

5a. Without prejudice to the provisions of paragraph 3, the labelling and advertising of a product as referred to in Article 1 (1) (b) may only bear indications referring to organic production methods where:

- (a) at least 70 % of the ingredients of agricultural origin are, or are derived from, products obtained in accordance with the rules laid down in Article 6 or imported from third countries under the arrangements laid down in Article 11;
- (b) all the other ingredients of agricultural origin of the product are included in Annex VI, Section C or have been provisionally authorized by a Member State in accordance with any implementation measures adopted where appropriate, pursuant to paragraph 7;
- (c) the indications referring to organic production methods appear in the list of ingredients and only in clear relation to those ingredients obtained according to the rules laid down in Article 6 or imported from third countries under the arrangements laid down in Article 11; they appear in the same colour and with an identical size and style of lettering as the other indications in the list of ingredients. Such indications must also appear in a separate statement set in the

▼ M10

same visual field as the sales description and indicating the percentage of the ingredients of agricultural origin or derived therefrom which were obtained in accordance with the rules laid down in Article 6 or were imported from third countries under the arrangements laid down in Article 11. The statement may not appear in a colour, size and style of lettering which is more prominent than the sales description of the product. The statement shall be in the following form: 'X % of the agricultural ingredients were produced in accordance with the rules of organic production';

- (d) the product contains only substances listed in Annex VI, Section A as ingredients of non-agricultural origin;
- (e) the product or its ingredients of agricultural origin referred to in subparagraph (a) have not been subjected to treatments involving the use of substances not listed in Annex VI, Section B;
- (f) the product or its ingredients have not been subjected to treatments involving the use of ionizing radiation;
- (g) the product has been prepared or imported by an operator who is subject to the inspection measures laid down in Articles 8 and 9;
- (h) for products prepared after 1 January 1997, the labelling refers to the name and/or the code number of the inspection authority or inspecting body to which the operator who has carried out the most recent production or preparation operation is subject. Member States shall decide whether to require a reference to the name and/or to the code number and/or shall notify the Commission accordingly.

6. During a transitional period expiring on 31 December 1997, the labelling and advertising of a product as referred to in Article 1 (1) (b) prepared partly from ingredients not satisfying the requirements in paragraph 3 (a) may refer to organic production methods provided that:

- (a) at least 50 % of the ingredients of agricultural origin satisfy the requirements referred to in paragraph 3 (a);
- (b) the product satisfies the requirements referred to in paragraph 3 (c), (d), (e) and (f);
- (c) the indications referring to organic production methods:
 - appear only in the list of ingredients as provided for in Directive 79/112/EEC, as last amended by Directive 89/395/EEC,
 - clearly refer to only those ingredients obtained according to the rules referred to in Article 6 or imported under the arrangements laid down in Article 11;
- (d) the ingredients and their relative levels appear in descending order by weight in the list of ingredients;
- (e) indications in the list of ingredients appear in the same colour and with an identical size and style of lettering.

▼ B

7. Detailed rules concerning the implementation of this Article may be established according to the procedure laid down in Article 14.

▼ M10

8. Limitative lists of the substances and products referred to in paragraph 3 (b), (c) and (d) and paragraph 5a (b), (d) and (e) shall be established in Annex VI, Sections A, B and C, according to the procedure laid down in Article 14.

▼ B

Conditions of use and compositional requirements of these ingredients and substances may be specified.

Where a Member State considers that a product should be added to the abovementioned lists or that amendments should be made thereto, it shall ensure that a dossier giving the reasons for the inclusion or the amendments is sent officially to the other Member States and the Commission, which shall present it to the Committee referred to in Article 14.

▼M10

9. For the calculation of the percentages referred to in paragraphs 3 and 6, the rules provided for in Articles 6 and 7 of Directive 79/112/EEC shall be applied.

10. In a product as referred to in Article 1 (1), an ingredient obtained according to the rules laid down in Article 6 shall not be present together with the same ingredient not obtained according to those rules.

11. Before 1 January 1999, the Commission shall review the provisions of this Article and of Article 10 and submit any appropriate proposals for their revision.

▼B**Rules of production****▼M10***Article 6*

1. The organic production method implies that for the production of products referred to in Article 1 (1) (a) other than seeds and vegetative propagating material:

- (a) at least the requirements of Annex I and, where appropriate, the detailed rules relating thereto, must be satisfied;
- (b) only products composed of substances listed in Annexes I and II may be used as plant-protection products, detergents, fertilizers, soil conditioners or for another purpose where such purpose is specified in Annex II in regard to certain substances. They may be used only under the specific conditions laid down in Annexes I and II in so far as the corresponding use is authorized in general agriculture in the Member States concerned in accordance with the relevant Community provisions or national provisions in conformity with Community law;
- (c) only seed or vegetative propagating material produced by the organic production method referred to in paragraph 2 is used.

2. The organic production method implies that for seeds and vegetative reproductive material, the mother plant in the case of seeds and the parent plant(s) in the case of vegetative propagating material have been produced in accordance with the provisions of subparagraphs (a) and (b) of the previous paragraph for at least one generation or, in the case of perennial crops, two growing seasons.

3. (a) By way of derogation from paragraph 1 (c), seeds and vegetative propagating material not obtained by the organic production method may, during a transitional period expiring on 31 December 2000 and with the approval of the competent authority of the Member State, be used in so far as users of such propagating material can show to the satisfaction of the inspection body or authority of the Member State that they were unable to obtain on the market propagating material for an appropriate variety of the species in question and satisfying the requirements of paragraph 2. In that case, propagating material which is not treated with products not listed in Annex II, Section B must be used, if available on the Community market. Member States shall inform the other Member States and the Commission of any authorization granted under this paragraph.

- (b) The procedure laid down in Article 14 may be applied to decide on:
 - the introduction, before 31 December 2000, of restrictions concerning the transitional measure referred to in subparagraph (a) with regard to certain species and/or types of propagating material and/or the absence of chemical treatment,
 - the maintenance, after 31 December 2000, of the derogation provided for in subparagraph (a) with regard to certain species and/or types of propagating material and with regard to the whole Community or certain parts thereof,

▼ **M10**

- the introduction of procedural rules and criteria concerning the derogation referred to in subparagraph (a) and the information thereon communicated to the professional organizations concerned, to other Member States and the Commission.
4. Before 31 December 1999, the Commission shall review the provisions of this Article, in particular paragraph 1 (c) and paragraph 2 and submit any appropriate proposals with a view to their revision.

Article 6a

1. For the purposes of this Article, 'seedlings' shall mean whole seedlings intended for planting for plant production.
2. The organic production method implies that when producers use seedlings, they have been produced in accordance with Article 6.
3. By way of derogation from paragraph 2, seedlings not obtained by organic production methods may be used during a transitional period expiring on 31 December 1997 in so far as the following conditions are met:
 - (a) the competent authority of the Member State has authorized the use after the user or users of such material have demonstrated to the satisfaction of the inspection body or authority of the Member State that they were not able to obtain an appropriate variety of the species in question on the Community market;
 - (b) the seedlings have not been treated, since sowing, with any products other than those listed in Annex II, Sections A and B;
 - (c) the seedlings come from a producer who has accepted an inspection system equivalent to the arrangements laid down in Article 9 and has agreed to apply the restriction in subparagraph (b); this provision shall enter into force on 1 January 1996;
 - (d) after planting, the seedlings must have been cultivated in accordance with the provisions of Article 6 (1) (a) and (b) for a period of at least six weeks before harvesting;
 - (e) the labelling of any product containing ingredients derived from such seedlings may not include the indication referred to in Article 10;
 - (f) without prejudice to any restriction resulting from the procedure referred to in paragraph 4, any authorization granted under this paragraph shall be withdrawn as soon as the shortage comes to an end, and shall expire on 31 December 1997 at the latest.
4. (a) Where an authorization as referred to in paragraph 3 has been granted, the Member State shall immediately notify to the other Member State and to the Commission the following information:
 - the date of the authorization,
 - the name of the variety and species concerned,
 - the quantities that are required and the justification for those quantities,
 - the expected period of the storage,
 - any other information requested by the Commission or the Member States.
- (b) If the information submitted by any Member State of the Commission and to the Member State which granted the authorization shows that an appropriate variety is available during the period of the storage, the Member State shall consider withdrawing the authorization or reducing its period of validity, and shall inform the Commission and the other Member States of the measures it has taken, within 10 days of the date of receipt of the information.
- (c) At the request of a Member State or at the Commission's initiative, the matter shall be submitted for examination to the Committee referred to in Article 14. It may be decided, in accordance with the procedure laid down in Article 14, that the

▼M10

authorization shall be withdrawn or its period of validity amended.

▼B*Article 7*

1. Products not authorized at the date of adoption of this Regulation for a purpose indicated in Article 6 (1) (b) may be included in Annex II, provided that the following conditions are satisfied:

- (a) if they are used for the purpose of plant pest or disease control:
 - they are essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or plant breeding alternatives are not available, and
 - the conditions for their use preclude any direct contact with the seed, the crop or crop products; however, in the case of perennial crops, direct contact may take place, but only outside the growing season of the edible parts (fruits) provided that such application does not indirectly result in the presence of residues of the product in the edible parts, and
 - their use does not result in, or contribute to, unacceptable effects on, or contamination of, the environment;
- (b) if they are used for fertilization or soil-conditioning purposes:
 - they are essential for specific nutrition requirements of crops or specific soil-conditioning purposes which cannot be satisfied by the practices mentioned in Annex I, and
 - their use does not result in unacceptable effects on the environment or contribute to the contamination thereof.

▼M10

1a. The conditions provided for in paragraph 1 shall not apply to products which were in common use before the adoption of this Regulation according to the codes of practice on organic farming followed in the Community.

▼B

2. If need be, the following may be specified for any product included in Annex II:

- the detailed description of the product,
- the conditions of its use and compositional and/or solubility requirements, with regard in particular to the need to insure for these products a minimal presence of residues on edible parts of the crop and on edible crop products as well as a minimum effect on the environment,
- particular labelling requirements for products referred to in Article 1 where such products are obtained with the aid of certain products referred to in Annex II.

3. Amendments to Annex II, concerning either inclusion or cancelling of products as referred to in paragraph 1 or inclusion or amendments of specifications as referred to in paragraph 2, shall be adopted by the Commission in accordance with the procedure laid down in Article 14.

4. Where a Member State considers that a product should be added to Annex II or that amendments should be made thereto, it shall ensure that a dossier giving the reasons for the inclusion or the amendments is sent officially to the other Member States and the Commission, which shall introduce it to the committee referred to in Article 14.

Inspection system*Article 8*

1. Any operator who produces, prepares or imports from a third country products as specified in Article 1 for the purpose of marketing them shall:

▼B

- (a) notify this activity to the competent authority of the Member State in which the activity is carried out; such notification shall include the information specified in Annex IV;
- (b) submit his undertaking to the inspection system referred to in Article 9.

2. Member States shall designate an authority or body for the reception of notifications.

Member States may provide for the communication of any additional information which they consider to be necessary for effective supervision of the operators concerned.

3. The competent authority shall ensure that an updated list containing the names and addresses of operators subject to the inspection system is made available to interested parties.

Article 9

1. Member States shall set up an inspection system operated by one or more designated inspection authorities and/or by approved private bodies to which the ►**M10** operators producing, preparing or importing from third countries products as referred to in Article 1 ◀ shall be subject.

2. Member States shall adopt the measures necessary to ensure that an operator who complies with the provisions of this Regulation and pays his contribution to inspection expenses has access to the inspection system.

3. The inspection system shall comprise at least the application of the precautionary and inspection measures specified in Annex III.

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

5. For the approval of a private inspection body, the following shall be taken into account:

- (a) the standard inspection procedure to be followed, containing a detailed description of the inspection measures and precautions which the body undertakes to impose on operators subject to its inspection;
- (b) the penalties which the body intends to apply where ►**M10** irregularities and/or infringements ◀ are found;
- (c) the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability;
- (d) the objectivity of the inspection body *vis-à-vis* the operators subject to its inspection.

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

- (a) ensure that the inspections carried out by the inspection body are objective;
- (b) verify the effectiveness of its inspections;
- (c) take cognizance of any ►**M10** irregularities and/or infringements ◀ found and penalties applied;
- (d) withdraw approval of the inspection body where it fails to satisfy the requirements referred to in (a) and (b) or no longer fulfils the criteria indicated in paragraph 5 or fails to satisfy the requirements ►**M10** laid down in paragraphs 7, 8, 9 and 11. ◀

▼M10

6a. Before 1 January 1996, Member States shall issue a code number to each inspection body or authority approved or designated in accordance with the provisions of this Article. They shall inform the other Member States and the Commission thereof; the Commission shall

▼M10

publish the code numbers in the list referred to in the last subparagraph of Article 15.

▼B

7. The inspection authority and the approved inspection bodies referred to in paragraph 1 shall:

- (a) ensure that at least the inspection measures and precautions specified in Annex III are applied to undertakings subject to their inspection;
- (b) not disclose information and data they obtain in their inspection activity to persons other than the person responsible for the undertaking concerned and the competent public authorities.

8. Approved inspection bodies shall:

- (a) give the competent authority, for inspection purposes, access to their offices and facilities, together with any information and assistance deemed necessary by the competent authority for the fulfilment of its obligations pursuant to this Regulation;
- (b) send to the competent authority of the Member State by 31 January each year a list of operators subject to their inspection on 31 December of the previous year and present to the said authority a concise annual report.

9. The inspection authority and inspection bodies referred to in paragraph 1 shall:

- (a) ensure that, where an irregularity is found regarding the implementation of Articles 5 and ►M10 6 ◀ or of the measures referred to in Annex III, the indications provided for in Article 2 referring to the organic production method are removed from the entire lot or production run affected by the irregularity concerned;
- (b) where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority of the Member State.

10. The following may be adopted in accordance with the procedure laid down in Article 14:

- (a) detailed rules concerning the requirements indicated in paragraph 5 and the measures listed in paragraph 6;
- (b) implementation measures concerning the provisions of paragraph 9.

▼M10

11. As from 1 January 1998 and without prejudice to the provisions of paragraphs 5 and 6, approved inspection bodies must satisfy the requirements laid down in the conditions of standard EN 45011 of 26 June 1989.

▼B

Indication that products are covered by the inspection scheme

Article 10

▼M10

1. The indication and/or the logo shown in Annex V indicating that products are covered by the specific inspection scheme, may appear on the labeling of products as referred to in Article 1 only where such products:

- (a) satisfy the requirements of Article 5 (1) or (3);
- (b) have been subject to the inspection arrangements referred to in Article 9 throughout the production and preparation process;
- (c) are sold directly by the producer or preparer to the ultimate consumer in sealed packaging, or placed on the market as prepackaged foodstuffs; in the case of direct sales by the producer or preparer to the ultimate consumer, the sealed packaging is not

▼M10

required when the labelling enabled the product requiring this indication to be identified clearly and unambiguously;

- (d) show on the labelling the name and/or business name of the producer, preparer or vendor together with the name or code number of the inspection authority or body, and any indication required in accordance with the provisions of the regulations on the labelling of foodstuffs, in accordance with Community legislation.

▼B

2. No claim may be made on the label or advertising material that suggests to the purchaser that the indication shown in Annex V constitutes a guarantee of superior organoleptic, nutritional or salubrious quality.

3. The inspection authority and inspection bodies referred to in Article 9 (1) must:

- (a) ensure that, where an irregularity is found under ►**M10** Articles 5 and 6 ◀ or the measures referred to in Annex III, the indication shown in Annex V is removed from the entire lot or production run affected by the irregularity concerned;
- (b) where a manifest infringement, or an infringement with prolonged effects, is found, withdraw from the operator concerned the right to use the indication shown in Annex V for a period to be agreed with the competent authority of the Member State.

4. Rules on withdrawal of the indication shown in Annex V where certain infringements of Articles 5, 6 and 7 or of the requirements and measures in Annex III are detected may be adopted in accordance with the procedure laid down in Article 14.

▼M10**General enforcement measures***Article 10 a*

1. Where a Member State finds irregularities or infringements relating to the application of this Regulation in a product coming from another Member State and bearing indications as referred to in Article 2 and/or Annex V, it shall inform the Member State which designated the inspection authority or approved the inspection body and the Commission thereby.

2. Member States shall take whatever measures and action are required to prevent fraudulent use of the indications referred to in Article 2 and/or Annex V.

▼B**Imports from third countries***Article 11*

1. Without prejudice to Article 5, products as specified in Article 1 which are imported from a third country may be marketed only where:

- (a) they originate in a third country appearing in a list to be drawn up by a Commission decision in accordance with the procedure laid down in Article 14 and were produced in a region or a production unit and under the inspection of an inspection body specified, where appropriate, in the decision concerning the third country in question;
- (b) the competent authority or body in the third country has issued a certificate of inspection stating that the lot designated in the certificate:
- was obtained within a system of production applying rules equivalent to those laid down in ►**M10** Article 6 ◀, and
 - was subject to a system of inspection recognized as equivalent in accordance with paragraph 2 (b).

▼B

2. For the purpose of deciding whether, for certain products as specified in Article 1, a third country may at its request be included in the list referred to in paragraph 1 (a), the following shall be taken into account in particular:

- (a) the guarantees which the third country can offer, at least in respect of production for export to the Community, as regards the application of rules equivalent to those laid down in ►**M10** Article 6 ◀;
- (b) the effectiveness of the inspection measures applied, which, at least in respect of production for export to the Community, must be equivalent to the inspection measures referred to in Articles 8 and 9 to ensure compliance with the rules referred to in (a).

On the basis of this information, the regions or production units of origin, or the bodies whose inspections are deemed to be equivalent, may be specified in the Commission decision.

3. The certificate referred to in paragraph 1 (b) must:

- (a) accompany the goods, in the original copy, to the premises of the first consignee; thereafter the importer must keep the certificate at the disposal of the ►**M10** inspection body and/or inspection authority ◀ for not less than two years;
- (b) be drawn up in accordance with procedures and a model to be adopted in accordance with the procedure laid down in Article 14.

4. Detailed rules for the implementation of this Article may be determined according to the procedure referred to in Article 14.

5. When examining a request from a third country, the Commission shall require it to supply all the necessary information; it may also entrust experts with the task of carrying out, under its authority, an on-the-spot examination of the rules of production and inspection measures actually applied in the third country in question.

▼M2

- 6. (a) By way of derogation from paragraph 1, the importer(s) in a Member State shall be authorized by the competent authority of the Member State to market until ►**M10** 31 December 2002 ◀, products imported from a third country not included in the list referred to in paragraph 1 (a) provided the importer(s) furnish(es) the competent authority of the importing Member State with sufficient evidence that the imported products were manufactured according to production rules equivalent to those laid down in ►**M10** Article 6 ◀ and were subject to inspection measures of equivalent effectiveness to those referred to in Articles 8 and 9, and that such inspection measures will be permanently and effectively applied.

Such authorization shall be valid only as long as the abovementioned conditions are shown to be satisfied. ►**M10** It shall expire from the time of the decision to include a third country in the list referred to in paragraph 1 (a), unless it concerns a product which was produced in a region not specified in the decision referred to in paragraph 1 (a), and which was not examined in the framework of the request submitted by the third country, and only where that third country has agreed to the continuation of the authorization arrangements provided for in this paragraph. ◀

- (b) Where a Member State has received sufficient evidence from an importer, it shall forthwith notify to the Commission and the other Member States the third country from which products are imported and supply detailed information on the production and inspection arrangements and the guarantees that they will be permanently and effectively applied.
- (c) At the request of a Member State or at the Commission's initiative, the matter shall be submitted to the Committee referred to in Article 14 for examination. Should it emerge from this examination that the imported products were not manufactured according to equivalent production rules and/or inspection measures of equivalent effectiveness, the Commission shall request the Member State which granted the authorization to withdraw

▼ M2

it. It may be decided, in accordance with the procedure laid down in Article 14, that the imports in question shall be prohibited or that their continuation shall be subject to certain of the import conditions being amended within a given period.

- (d) The notification referred to in (b) shall not be required where it concerns production and inspection arrangements already notified by another Member State, pursuant to (b), unless significant new evidence is submitted justifying a review of the examination and decision referred to in (c).

Before 31 July 1994, the Commission shall re-examine the provisions of paragraph 1 and submit any appropriate proposal for its review.

▼ M10

7. The Commission may, in accordance with the procedure laid down in Article 14 at the request of a Member State, approve a third country's inspection body which has previously been assessed by the Member State concerned and add it to the list referred to in paragraph 1 (a). The Commission shall forward the request to the third country concerned.

▼ B**Free movement within the Community***Article 12*

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 products as specified in Article 1 that meet the requirements of this Regulation.

Administrative provisions and implementation*Article 13*

The following may be adopted in accordance with the procedure laid down in Article 14:

▼ M10

— detailed rules for applying this Regulation;

▼ B

— amendments to Annexes I, II, III, IV and VI,

▼ M10

— amendments to Annex V in order to define a Community logo to accompany or replace the indication that products are covered by the inspection scheme.

▼ B*Article 14*

The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by the representative of the Commission.

Where the procedure laid down in this Article is to be followed, the representative of the Commission shall submit to the committee a draft of the measures to be taken.

The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty. The votes of the representatives of the Member States within the committee shall be weighed in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measure envisaged if they are in accordance with the opinion of the committee.

▼B

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to it the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 15

Before 1 July each year, Member States shall inform the Commission of measures taken in the preceding year for the implementation of this Regulation and shall communicate in particular:

- a list of the operators who, on 31 December of the previous year, had given notification under Article 8 (1) (a) and are subject to the inspection system referred to in Article 9,
- a report on supervision pursuant to Article 9 (6).

In addition, by 31 March each year, Member States shall inform the Commission of the list of inspection bodies approved on 31 December of the previous year, their legal and operational structure, their standard inspection procedure, their penalty arrangements and, where appropriate, their mark.

The Commission shall each year publish, in the 'C' series of the *Official Journal of the European Communities*, the lists of approved bodies notified to it within the deadlines laid down in the foregoing subparagraph.

Article 16

1. This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities*.
2. Within nine months of the entry into force of this Regulation, Member States shall implement Articles 8 and 9.

▼M2

3. Article 5, Article 8 (1) and Article 11 (1) shall apply from 1 January 1993.

▼B

In accordance with the procedure laid down in Article 14, the date of application of Article 11 (1) may be deferred for a specified period for imports from a third country where, following a request by the third country, the stage reached in examining the matter does not permit a decision regarding the inclusion of the country concerned in the list provided for in Article 11 (1) (a) before expiry of the period referred to in the first subparagraph.

For the purposes of complying with the conversion period referred to in paragraph 1 of Annex I, the period which has elapsed before the entry into force of this Regulation shall be taken into account where the operator can demonstrate to the satisfaction of the inspection body that during that period he was producing in accordance with the national provisions in force or, failing that, with the recognized international standards for organic production.

4. For 12 months following the entry into force of this Regulation, Member States may, by way of derogation from Article 6 (1), authorize the use in their territory of products containing substances not listed in Annex II, where they consider that the requirements of Article 7 (1) are satisfied.

▼B

5. For a period expiring 12 months after the establishment of Annex VI in accordance with Article 5 (7), Member States may continue to authorize, in accordance with their national provisions, the use of substances not listed in the said Annex VI.

6. Each Member State shall inform the other Member States and the Commission of substances authorized pursuant to paragraphs 4 and 5.

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

▼B*ANNEX I***PRINCIPLES OF ORGANIC PRODUCTION AT FARM LEVEL****Plants and plant products**

1. The principles set out in this Annex must normally have been applied on the parcels during a conversion period of at least two years before sowing or, in the case of perennial crops other than grassland, at least three years before the first harvest of products as referred to in Article 1 (1) (a). The inspection body may, with the approval of the competent authority, decide, in certain cases, to extend or reduce that period, having regard to previous parcel use.

▼M9

In particular, the conversion period may be reduced to the strict minimum by a Member State in situations where the parcels have been treated with a product not included in Annex II, part B as part of a pest or disease control scheme made mandatory by the competent authority of the Member State on its territory or on certain parts of its territory in respect of a specific crop.

The reduction in the conversion period must take account of all the following points:

- the parcels were already converted or were undergoing conversion to organic farming,
- the degradation of the plant protection product concerned must result in an insignificant level of residue in the soil and, where the latter is a perennial crop, in the crop,
- the Member State concerned must notify the other Member States of its decision concerning the obligation of treatment and also the level of the reduction decided for the conversion period,
- products of the harvest following treatment may not be sold bearing an indication referring to organic production.

▼B

2. The fertility and the biological activity of the soil must be maintained or increased, where appropriate, by:
 - (a) cultivation of legumes, green manures or deep-rooting plants in an appropriate multiannual rotation programme;
 - (b) incorporation in the soil of organic material, composted or not, from holdings producing according to the rules of this Regulation. Pending the adoption of common technical rules concerning organic livestock production, by-products from livestock farming, such as farmyard manure, may be used if they come from livestock holdings respecting existing national rules or, in the absence thereof, internationally recognized practices concerning organic livestock production.

Other organic or mineral fertilizers, mentioned in Annex II, may be applied only to the extent that adequate nutrition of the crop being rotated or soil conditioning are not possible by the methods set out under (a) and (b) of the preceding subparagraph.

For compost activation, appropriate micro-organism or plant-based preparations ► **M4** ◀ may be used.

▼M4

So-called 'biodynamic preparations' from stone meal, farmyard manure or plants may also be used for the purposes covered by this paragraph.

▼B

3. Pests, diseases and weeds shall be controlled by a combination of the following measures:
 - choice of appropriate species and varieties,
 - appropriate rotation programme,
 - mechanical cultivation procedures,
 - protection of natural enemies of pests through provisions favourable to them (e.g. hedges, nesting sites, release of predators),
 - flame weeding.

Only in cases of immediate threat to the crop may recourse be had to products referred to in Annex II.

▼M4

4. 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:
 - those areas have received no treatments with products other than those referred to in Annex II for a period of three years before the collection;

▼ M4

— the collection does not affect the stability of the natural habitat or the maintenance of the species in the collection area.

▼ M1

Animals and animal products

Pending the adoption of the proposal referred to in Article 1 (2), and for the purpose of preparation of ingredients referred to in Article 5 (3) (a), animals shall be raised in accordance with the existing national rules, or in the absence thereof, internationally recognized practices concerning organic livestock production.

▼M7

ANNEX II

Part A

Products authorized exceptionally for use in soil conditioning and fertilization, in accordance with the dispositions of Annex I (2)

Name	Description, compositional requirements, conditions for use
Compound products or products containing only materials listed hereunder:	
— Farmyard manure	Product comprising a mixture of animal excrements and vegetable matter (animal bedding) Need recognized by the inspection body or inspection authority Indication of animal species Coming from extensive husbandry and only in the sense of ►C1 Article 6 (5) ◄ of Council Regulation (EEC) No 2328/91 (1), as last amended by Regulation (EC) No 3669/93 (2)
— Dried farmyard manure and dehydrated poultry manure	Need recognized by the inspection body or inspection authority Indication of animal species Coming from extensive husbandry and only in the sense of ►C1 Article 6 (5) ◄ of Regulation (EEC) No 2328/91
— Composted animal excrements, including poultry manure and composted farmyard manure included	Need recognized by the inspection body or inspection authority Indication of the animal species Factory farming origin forbidden
— Liquid animal excrements (slurry, urine, etc.)	Use after controlled fermentation and/or appropriate dilution Need recognized by the inspection body or inspection authority Indication of animal species Factory farming origin forbidden
— Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
— Mushroom culture wastes	The initial composition of the substrate must be limited to products of the present list
— Dejecta of worms (vermicompost) and insects	
— Guano	Need recognized by the inspection body or inspection authority
— Composted mixture of vegetable matter	Need recognized by the inspection body or inspection authority
— Products or by-products of animal origin as below: — blood meal — hoof meal — horn meal — bone meal or degelatinized bone meal — animal charcoal — fish meal — meat meal — feather, hair and ‘chiquette’ meal — wool — fur — hair — dairy products	Need recognized by the inspection body or inspection authority

▼ **M7**

Name	Description, compositional requirements, conditions for use
— Products and by-products of plant origin for fertilizers (for instance, oilseed cake meal, cocoa husks, malt culms, etc.)	
— Seaweeds and seaweed products	Only as far as obtained by: (i) physical processes including dehydration, freezing and grinding; (ii) extraction with water or aqueous acid and/or alkaline solution (iii) fermentation
— Sawdust and wood chips	Wood not chemically treated after felling
— Composted bark	Wood not chemically treated after felling
— Wood ash	From wood not chemically treated after felling
— Soft ground rock phosphate	Product as specified by Council Directive 76/116/EEC ⁽³⁾ , as last amended by Directive 89/284/EEC ⁽⁴⁾ Cadmium content less than or equal to 90 mg/kg of P205
— Aluminium calcium phosphate	Product as specified by Directive 76/116/EEC, as last amended by Directive ►C1 89/284/EEC ◄ ; Cadmium content less than or equal to 90 mg/kg of P205 Use limited to basic soils (pH > 7,5)
— Basic slag	Need recognized by the inspection body or inspection authority
— Crude potassium salt (for instance: kainit, sylvinit, etc.)	Need recognized by the inspection body or inspection authority
— Potassium sulphate containing magnesium salt	Need recognized by the inspection body or inspection authority Derived from crude potassium salt
— Stillage and stillage extract	Ammonium stillage excluded
— Calcium carbonate of natural origin (for instance: chalk, marl, ground limestone, Breton ameliorant, (maërl), phosphate chalk)	
— Magnesium and calcium carbonate of natural origin (for instance: magnesian chalk, ground magnesium limestone, etc.)	Only of natural origin Need recognized by the inspection body or inspection authority
— Magnesium sulfate (for instance: kieserite)	
— Calcium chloride solution	Foliar treatment of apple trees, after identification of deficit of calcium Need recognized by the inspection body or inspection authority
— Calcium sulphate (gypsum)	Product as specified by Directive 76/116/EEC, as amended by Directive 89/284/EEC Only of natural origin
— Elemental sulphur	Product as specified by Directive 76/446/EEC, as amended by Directive 89/284/EEC Need recognized by the inspection body or inspection authority
— Trace elements	Trace elements included in Directive 89/530/EEC ⁽⁵⁾ Need recognized by the inspection body or inspection authority
— Sodium chloride	Only mined salt Need recognized by the inspection body or inspection authority

▼ M7

Name	Description, compositional requirements, conditions for use
— Stone meal	

(¹) OJ No L 218, 6. 8. 1991, p. 1.

(²) OJ No L 338, 31. 12. 1993, p. 26.

(³) OJ No L 24, 30. 1. 1976, p. 21.

(⁴) OJ No L 111, 22. 4. 1989, p. 34.

(⁵) OJ No L 281, 30. 9. 1989, p. 116.

▼ B**B. PRODUCTS FOR PLANT PEST AND DISEASE CONTROL**

Name	Description; compositional requirements; conditions for use
Preparations on basis of pyrethrins extracted from <i>Chrysanthemum cinerariaefolium</i> , containing possibly a synergist	
Preparations from <i>Derris elliptica</i> ,	
Preparations from <i>Quassia amara</i>	
Preparations from <i>Ryania speciosa</i>	
Propolis	
Diatomaceous earth	
Stone meal	
Preparations on basis of metaldehyde containing a repellent to higher animal species and as far as applied within traps	
Sulphur	
Bordeaux mixture	
Burgundy mixture	
Sodium silicate	
Sodium bicarbonate	
Potassium soap (soft soap)	
Pheromone preparations	
<i>Bacillus thuringiensis</i> preparations	
Granulose virus preparations	
Plant and animal oils	
Paraffin oil	

C. OTHER PRODUCTS

▼B*ANNEX III***MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SCHEME REFERRED TO IN ARTICLE 8 AND 9****▼M4****A. Plants and plant products from farm production or collection****▼B**

1. Production must take place in a unit the land parcels and production and storage locations of which are clearly separate from those of any other unit not producing in accordance with the rules laid down in this Regulation; processing and/or packaging workshops may form part of the unit, where its activity is limited to processing and packaging of its own agricultural produce.

▼M4

2. When the inspection arrangements are first implemented, the producer, even where his activity is limited to the collection of wild plants, and the inspection body must draw up:
 - a full description of the unit, showing the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place,
 - all the practical measures to be taken by the producer at unit-level to ensure compliance with the provisions of this Regulation,
 - and, in case of collection of wild plants, the guarantees given by third parties, if appropriate where relevant which the producer can provide to ensure that the provisions of Annex I, point 4 are satisfied.

The description and the measures concerned must be contained in an inspection report countersigned by the producer concerned.

In addition, the report must specify:

- the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with Article 6 (1) (b),
- an undertaking by the producer to carry out operations in accordance with Articles 5 and 6 and to accept, in the event of infringement, enforcement of the measures referred to in Article 9 (9) and, where relevant, in Article 10 (3).

▼B

3. Each year, before the date indicated by the inspection body, the producer must notify the body of its schedule of production of crop products, giving a breakdown by parcel.
4. Written and/or documentary accounts must be kept which enable the inspection body to trace the origin, nature and quantities of all raw materials bought, and the use of such materials; in addition, written or documentary accounts must be kept of the nature, quantities and consignees of all agricultural products sold. Quantities sold directly to the final consumer shall be accounted on a daily basis.

▼M1

Where the unit itself processes its own agricultural produce, the accounts must contain the information as referred to in point B, 2, third hyphen of this Annex.

▼B

5. Storage, in the unit, of input products other than those the use of which is compatible with Articles 6 (1) (b) and 7 is prohibited.
6. Apart from unannounced inspection visits, the inspection body must make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorized under this Regulation may be taken. However, such samples must be taken where the use of unauthorized products is suspected. An inspection report must be drawn up after each visit, countersigned by the responsible person of the unit.
7. The producer must give the inspection body, for inspection purposes, access to the storage and production premises and to the parcels of land, as well as to the accounts and relevant supporting documents. He must provide the inspection body with any information deemed necessary for the purposes of the inspection.

▼M4

- 8.1. Products as referred to in Article 1 may be transported to other units, including wholesalers and retailers, only in appropriate packaging or containers closed in a manner preventing substitution of the content and provided with a label stating, without prejudice to any other indications required by law:
- (a) the name and address of the person responsible for the production or preparation of the product, or, where another seller is mentioned, a statement which enables the receiving unit and the inspection body to identify unequivocally the person responsible for the production of the product;
 - (b) the name of the product, including a reference to the organic production method, in accordance with Article 5.
- 8.2. However, the closing of packaging or containers is not required where:
- (a) transportation is between a producer and another operator who are both subject to the inspection system referred to in Article 9, and
 - (b) the products are accompanied by a document giving the information required under the previous subparagraph.

▼M9

9. Where an operator runs several production units in the same area, producing crops or crop products not covered by Article 1, together with storage premises for input products (such as fertilizers, plant protection products, seed) must also be subject to the inspection arrangements as regards the first subparagraph of point 2 and points 3 and 4. Crops of the same variety as those produced at the unit referred to in point 1 may not be produced at these units.

However, producers may derogate from the rule referred to in the last sentence of the preceding subparagraph:

- (a) in the case of the production of perennial crop products (fruit growing, vines and hops) provided the following conditions are met:
 - 1. the production in question forms part of a conversion plan in respect of which the producer gives a firm undertaking and which provides for the beginning of the conversion of the last part of the area concerned to organic production in the shortest possible period which may not in any event exceed a maximum of five years,
 - 2. appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned,
 - 3. the inspection body or authority is notified of the harvest of each of the products concerned at least 48 hours in advance,
 - 4. immediately upon completion of the harvest, the producer informs the inspection body or authority of the exact quantities harvested on the units concerned together with any particular distinguishing features (such as quality, colour, average weight, etc.) and confirms that the measures taken to separate the products have been applied,
 - 5. the conversion plan and the measures referred to in points 1 and 2 have been approved by the inspection body or authority. This approval must be confirmed each year after the start of the conversion plan;
- (b) in the case of areas intended for agricultural research agreed by the Member States' competent authorities, provided that conditions 2, 3 and 4 and the relevant part of condition 5 referred to in (a) are met;
- (c) in the case of production of seed, vegetative propagating material and transplants, provided that conditions 2, 3 and 4 and the relevant part of condition 5 referred to in (a) are met.

▼B

B. Processing and packaging units for plant products and foodstuffs composed essentially of plant products

1. When the inspection arrangements are first implemented, the producer and inspection body must draw up:
- a full description of the unit, showing the facilities used for the processing, packaging and storage of agricultural products before and after the operations concerning them,
 - all the practical measures to be taken at the level of the unit to ensure compliance with this Regulation.

This description and the measures concerned must be contained in an inspection report, countersigned by the responsible person of the unit.

▼M4

In addition, the report must include an undertaking by the operator to perform the operations in such a way as to comply with Article 5 and to accept, in the event of infringement, the enforcement of the measures referred to in Article 9 (9) and, where relevant, in Article 10 (3).

▼B

2. Written accounts must be kept enabling the inspection body to trace:
 - the origin, nature and quantities of agricultural products as referred to in Article 1 which have been delivered to the unit,
 - the nature, quantities and consignees of products as referred to in Article 1 which have left the unit,
 - any other information, such as the origin, nature and quantities of ingredients, additives and manufacturing aids delivered to the unit and the composition of processed products, that is required by the inspection body for the purposes of proper inspection of the operations.
3. Where products not referred to in Article 1 are also processed, packaged or stored in the unit concerned:
 - the unit must have separate areas within the premises for the storage of products as referred to in Article 1, before and after the operations,
 - operations must be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Article 1,
 - if such operations are not carried out frequently, they must be announced in advance, with a deadline agreed on with the inspection body,
 - every measure must be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the rules laid down in this Regulation.
4. Apart from unannounced inspection visits, the inspection body must make a full physical inspection, at least once a year, of the unit. Samples for testing of products not authorized under this Regulation may be taken. However, they must be taken where the use of unauthorized products is suspected. An inspection report must be drawn up after each visit countersigned by the person responsible for the unit inspected.
5. The operator must give the inspection body, for inspection purposes, access to the unit and to the written accounts and relevant supporting documents. He must provide the inspection body with any information necessary for the purposes of the inspection.

▼M4

6. Products as referred to in Article 1 may be transported to other units, including wholesalers and retailers, only in appropriate packaging or containers closed in a manner preventing substitution of the content and provided with a label stating, without prejudice to any other indications required by law:
 - (a) the name and address of the person responsible for the production or preparation of the product, or, where another seller is mentioned, a statement which enables the receiving unit and the inspection body to identify unequivocally the person responsible for the preparation of the product;
 - (b) the name of the product, including a reference to the organic production method according to the relevant provisions of Article 5.

On receipt of a product as referred to in Article 1, the operator shall check the closing of the packaging or container where it is required and the presence of the indications referred to in the previous paragraph, in point A. 8. 1 or in point C. 8. The result of this verification shall be explicitly mentioned in the accounts referred to in point B. 2. Where the check leaves any doubt that the product concerned came from an operator subject to the inspection system provided for in Article 9, it may only be put into processing or packaging after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method.

C. Importers of plant products and foodstuffs composed essentially of plant products from third countries

1. When the inspection arrangements are first implemented, the importer and inspection body must draw up:
 - a full description of the importer's premises and of his import activities, indicating as far as possible the points of entry of the products into the Community and any other facilities the importer intends to use for the storage of the imported products;

▼ **M4**

- all the practical measures to be taken by the importer to ensure compliance with this Regulation.

This description and the measures concerned must be contained in an inspection report, countersigned by the importer.

In addition, the report must include an undertaking by the importer:

- to perform the import operations in such a way as to comply with the provisions of Article 11 and to accept, in the event of infringement, the enforcement of the measures referred to in Article 9 (9);
 - to ensure that any storage facilities that the importer will use are open to inspection, to be carried out either by the inspection body or, when these storage facilities are situated in another Member State or region, by an inspection body approved for inspection in that Member State or region.
2. Written accounts must be kept enabling the inspection body to trace for each lot of products referred to in Article 1, imported from a third country:
 - the origin, nature and quantity of the lot concerned, and on request by the inspection body, any details on the transport arrangements from the exporter in the third country to the importer's premises or storage facilities;
 - the nature, quantities and consignees of the lot concerned, and on request by the inspection body, and details on the transport arrangements from the importer's premises or storage facilities to the consignees.
 3. The importer shall inform the inspection body of each imported consignment into the Community, giving any details this body or authority may require, such as a copy of the inspection certificate for the importation of organic products. When the products concerned are circulating in a Member State or region other than the one where the inspection body is approved for inspection, that body may pass the information to a body, approved for inspection in that Member State or region, for on-the-spot inspection of the imported consignment.
 4. Where imported products referred to in Article 1 are stored in storage facilities where also other agricultural products or foodstuffs are processed, packaged or stored:
 - the products as referred to in Article 1 must be kept separate from the other agricultural products and/or foodstuffs;
 - every measure must be taken to ensure identification of lots and to avoid mixtures with products not obtained in accordance with the rules laid down in this Regulation.
 5. Apart from unannounced inspection visits, the inspection body must make a full physical inspection, at least once a year, of the importer's premises and, where relevant, of a selection of the other storage facilities which the importer uses.

The inspection body shall inspect the written accounts mentioned in point C. 2 and the certificates referred to in Article 11 (1) (b) and (3). Samples for testing of substances not authorized under this Regulation may be taken. However, they must be taken where the use of unauthorized substances is suspected. An inspection report must be drawn up after each visit, countersigned by the person responsible for the unit inspected.

6. The importer must, for inspection purposes, give the inspection body access to his premises and to the written accounts and relevant supporting documents, in particular any import certificates. He must provide the inspection body with any information necessary for the purposes of the inspection.
7. Products as referred to in Article 1 shall be imported from a third country in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot with the inspection certificate.

On receipt of a product as referred to in Article 1, imported from a third country, the operator shall check the closing of the packaging or container and the correspondance of the identification of the lot with the certificate referred to in Article 11 (1) (b) or a similar certificate where required by the authorities under any arrangements adopted under Article 11 (6). The result of this verification shall be explicitly mentioned in the accounts referred to in point C. 2. Where the check leaves any doubt as to the origin of the product from a third country or from an exporter in a third country not accepted under Article 11, the product may be put on the market, or

▼ M4

processed or packaged, only after such doubt has been dispelled, unless it is placed on the market without indication of the organic production method.

8. Products referred to in Article 1 may be transported to other units, including wholesalers and retailers, only in appropriate packaging or containers closed in a manner preventing substitution of the content and provided with a label stating, without prejudice to any other indications required by law:
 - (a) the name and address of the importer of the product, or a statement which enables the receiving unit and the inspection body to identify unequivocally the importer of the product;
 - (b) the name of the product, including a reference to the organic production method under Article 5.

▼B*ANNEX IV***INFORMATION TO BE NOTIFIED AS PROVIDED IN ARTICLE 8 (1)****(a)**

- (a) Name and address of operator;
- (b) Location of premises and, where appropriate, parcels (land register data) where operations are carried out;
- (c) Nature of operations and products;
- (d) Undertaking by the operator to carry out the operations in accordance with Articles 5, 6, 7 and/or 11;
- (e) In the case of an agricultural holding, the date on which the producer ceased to apply products the use of which is not compatible with Articles 6 (1) (6) and 7 on the parcels concerned;
- (f) The name of the approved body to which the operator entrusted inspection of his undertaking, where the Member State has implemented the inspection system by approving such bodies.

▼B*ANNEX V***INDICATION THAT PRODUCTS ARE COVERED BY THE INSPECTION SCHEME**

The indication that a product is covered by the inspection scheme must be shown in the same language or languages as used for the labelling.

ES: Agricultura Biológica — Sistema de control CEE

DK: Økologisk Landbrug — EF Kontrolordning

▼A1

D: Ökologische Agrarwirtschaft — EWG-Kontrollsystem, or Biologische Landwirtschaft — EWG-Kontrollsystem

▼B

GR: Βιολογική Γεωργία — Σύστημα Ελέγχου ΕΟΚ

EN: Organic Farming — EEC Control System

F: Agriculture biologique — Système de contrôle CEE

I: Agricoltura Biologica — Regime di controllo CEE

NL: Biologische landbouw — EEG-controlesysteem

P: Agricultura Biológica — Sistema de Controllo CEE

▼A1

FI: Luonnonmukainen maataloustuotanto — ETY: n valvontajärjestelmä —
Ekologiskt jordbruk — EEG-kontrollsystem

S: Ekologiskt jordbruk — EEG-kontrollsystem

▼M3

ANNEX VI

INTRODUCTION

For the purposes of this Annex, the following definitions will apply:

1. ingredients: substances as defined in Article 4 of this Regulation under the restrictions as referred to in Article 6 (4) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer ⁽¹⁾;
2. ingredients of agricultural origin:
 - (a) single agricultural products and products derived therefrom by appropriate washing, cleaning, thermic and/or mechanical processes and/or by physical processes having the effect of reducing the moisture content of the product;
 - (b) also, products derived from the products mentioned under (a) by other processes used in food processing, unless these products are considered food additives or flavourings as defined under points 5 or 7 hereunder;
3. ingredients of non-agricultural origin: ingredients other than ingredients of agricultural origin and belonging to at least one of the following categories:
 - 3.1. food additives, including carriers for food additives, as defined under points 5 and 6 hereunder;
 - 3.2. flavourings, as defined under point 7 hereunder;
 - 3.3. water and salt;
 - 3.4. micro-organism preparations;
 - 3.5. minerals (including trace elements) and vitamins;
4. processing aids: substances as defined in Article 1 (3) (a) of Council Directive 89/107/EEC ⁽²⁾ on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption;
5. food additives: substances as defined in Article 1 (1) and (2) of Directive 89/107/EEC and covered by that Directive or by a comprehensive Directive as referred to in Article 3 (1) of Directive 89/107/EEC;
6. carriers, including carrier solvents: food additives used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its technological function in order to facilitate its handling, application or use;
7. flavouring: substances and products as defined in Article 1 (2) of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ⁽³⁾, and covered by that Directive.

GENERAL PRINCIPLES

Sections A, B and C cover the ingredients and processing aids which may be used in the preparation of foodstuffs composed essentially of one or more ingredients of plant origin, referred to in Article 1 (1) (b) of this Regulation, with the exception of wines.

Notwithstanding reference to any ingredient in Sections A and C or any processing aid in Section B, any ingredient or such processing aid shall be used only in accordance with relevant Community legislation and/or national legislation compatible with the Treaty and, in the absence thereof, in accordance with the principles of good manufacturing practice for foodstuffs. In particular, addi-

⁽¹⁾ OJ No L 33, 8. 2. 1979, p. 1.

⁽²⁾ OJ No L 40, 11. 2. 1989, p. 27.

⁽³⁾ OJ No L 184, 15. 7. 1988, p. 61.

▼ M3

tives shall be used according to the provisions of Directive 89/107/EEC and, where relevant, those of any comprehensive Directive as referred to in Article 3 (1) of Directive 89/107/EEC; flavourings shall be used according to the provisions of Directive 88/388/EEC and solvents according to the provisions of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients ⁽¹⁾.

SECTION A — INGREDIENTS OF NON-AGRICULTURAL ORIGIN
(REFERRED TO IN ARTICLE 5 (3) (B) OF REGULATION (EEC) No 2092/91):

A.1. Food additives, including carriers

	Name	Specific conditions ⁽⁵⁾
	E 170 Calciumcarbonates	—
	E 270 Lactic acid	—
	E 290 Carbondioxyde	—
	E 296 Malic acid	—
	E 300 Ascorbic acid	—
▼ <u>M5</u>	E 306 Tocopherol-rich extract	anti-oxydant in fats and oils
▼ <u>M3</u>	E 322 Lecithins	—
	E 330 Citric acid	—
▼ <u>M5</u>	E 333 Calcium citrates	—
▼ <u>M3</u>	E 334 Tartaric acid (L (+) -)	—
	E 335 Sodium tartrate	—
	E 336 Potassium tartrate	—
▼ <u>M5</u>	E 341 (i) Monocalciumphosphate	raising agent for self raising flour
▼ <u>M3</u>	E 400 Alginic acid	—
	E 401 Sodium alginate	—
	E 402 Potassium alginate	—
	E 406 Agar	—
▼ <u>M5</u>	E 407 Carrageenan	—
▼ <u>M3</u>	E 410 Locust beam gum	—
	E 412 Guar gum	—
	E 413 Tragacanth gum	—
	E 414 Arabic gum	—
	E 415 Xanthan gum	—
	E 416 Karaga gum	—
	E 440 (i) Pectin	—
	E 500 Sodiumcarbonates	—
	E 501 Potassiumcarbonates	—
	E 503 Ammoniumcarbonates	—
	E 504 Magnesiumcarbonates	—
	E 516 Calcium sulphate	CR
▼ <u>M5</u>	E 524 Sodiumhydroxyde	surface treatment of Laugengebäck
▼ <u>M3</u>	E 938 Argon	—

⁽¹⁾ OJ No L 157, 24. 6. 1988, p 28.

▼M3

	Name	Specific conditions ⁽⁵⁾
E 941	Nitrogen	—
E 948	Oxygen	—

⁽⁵⁾ CR-carrier.

A.2. Flavourings within the meaning of Directive 88/388/EEC

Substances and products as defined in Article 1 (2) (b) (i) and 1 (2) (c) of Directive 88/388/EEC labelled as natural flavouring substances or natural flavouring preparations, according to Article 9 (1) (d) and (2) of that Directive.

A.3. Water and salt

Drinking water

Salt (with sodium chloride or potassium chloride as basic components), generally used in food processing.

A.4.

Micro-organism preparations

- (i) Any preparations of micro-organisms normally used in food processing, with the exception of micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC;
- (ii) Micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC: if they have been included according to the decision procedure of Article 14.

A.5. Minerals (including trace elements) and vitamins

Only authorized as far as their use is legally required in the foodstuffs in which they are incorporated.

SECTION B — PROCESSING AIDS AND OTHER PRODUCTS WHICH MAY BE USED FOR PROCESSING OF ORGANICALLY PRODUCED INGREDIENTS OF AGRICULTURAL ORIGIN, REFERRED TO IN ARTICLE 5 (3) (C) OF REGULATION (EEC) No 2092/91

Name	Specific conditions
Water	
Calcium chloride	coagulation agent
Calcium carbonate	
Calcium hydroxide	
Calcium sulphate	coagulation agent
Magnesium chloride (or nigari)	coagulation agent
Potassium carbonate	drying of grapes
▼M5 Sodium carbonate	sugar production
Sodium hydroxyde	sugar protection, olive treatment
Sulphuric acid	sulphur production

▼M3

Carbon dioxide

▼ M3

Name	Specific conditions
Nitrogen	
Ethanol	solvent
Tannic acid	filtration aid
Egg white albumen	
Casein	
Gelatin	
Isinglass	
Vegetable oils	► <u>M5</u> greasing, releasing or antifoaming agent ◀
Silicon dioxide gel or colloidal solution	
Activated carbon	
Talc	
Bentonite	
Kaolin	
Diatomaceous earth	
Perlite	
Hazelnut shells	

▼ M5

Rice meal	—
-----------	---

▼ M3

Beeswax	releasing agent
Carnauba wax	releasing agent

Preparations of micro-organisms and enzymes:

- (i) Any preparations of micro-organisms and enzymes normally used as processing aids in food processing, with the exception of micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC;
- (ii) Micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC:
If they have been included hereunder according to the decision procedure of Article 14.

SECTION C — INGREDIENTS OF AGRICULTURAL ORIGIN WHICH HAVE NOT BEEN PRODUCED ORGANICALLY, REFERRED TO IN ARTICLE 5 (4) OF REGULATION (EEC) No 2092/91

C.1. Unprocessed vegetable products, as well as products derived therefrom by processes referred to under definition 2 (a):

C.1.1. Edible fruits, nuts and seeds

Coconuts
Brazil nuts
Cashew nuts
Dates
Pineapples
Mangoes
Papayas
Sloes
Cocoa
Maracujas (Passion fruit)
Colanuts
Peanuts
Rosehips
Sallowthorns
Blueberries

▼ M3

Maple syrup
 Quinoa
 Amaranth
 Horseradish seed

▼ M5

▼ M3

Pine kernels
 Radish seeds

▼ M5

Acorns
 Fenugreek
 Acerola
 Chicory

▼ M8

Dried banana powder (*Musa* L.)
 Gooseberries (*Ribes crista* L.)
 Dried strawberry powder (*Fragaria* L.)
 Dried raspberries (*Ribes idaeus* L.)
 Dried red currants (*Ribes rubrum* L.)

C.1.2. Edible spices and herbs

▼ M11

Lesser galanga (*Alpinia officinarum*)
 Allspice (*Pimenta dioica*)

▼ M3

C.1.3. Cereals

▼ M5

▼ M3

Wild rice (*Zizania plauspra*)

C.1.4. Oil seeds and oleaginous fruits
 Sesamum seeds

C.1.5. Miscellaneous
 Algae, including seaweed

C.2. Vegetable products, processed by processes as referred to under definition 2 (b):

C.2.1. Fats and oils, whether or not refined, but not chemically modified, derived from plants other than:

▼ M3

olive
sunflower

- C.2.2. Sugars; starch; other products from cereals and tubers
Cane and beet sugar
Starches produced from cereals and tubers, not chemically modified
Rice paper
Gluten

▼ M5

Fructose

▼ M3

- C.2.3. Miscellaneous
Lemon juice

▼ M8**▼ M3**

- C.3. Animal Products
Honey
Gelatin

▼ M5

Buttermilk powder

▼ M3

Edible aquatic organisms, not originating from aquaculture

▼ M5

Lactose