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► **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
► M12 Commission Regulation (EC) No 1488/97 of 29 July 1997	L 202	12	30.7.1997
► M13 Commission Regulation (EC) No 1900/98 of 4 September 1998	L 247	6	5.9.1998
► M14 Commission Regulation (EC) No 330/1999 of 12 February 1999	L 40	23	13.2.1999
► M15 Council Regulation (EC) No 1804/1999 of 19 July 1999	L 222	1	24.8.1999
► M16 Commission Regulation (EC) No 331/2000 of 17 December 1999	L 48	1	19.2.2000
► M17 Commission Regulation (EC) No 1073/2000 of 19 May 2000	L 119	27	20.5.2000
► M18 Commission Regulation (EC) No 1437/2000 of 30 June 2000	L 161	62	1.7.2000
► M19 Commission Regulation (EC) No 2020/2000 of 25 September 2000	L 241	39	26.9.2000
► M20 Commission Regulation (EC) No 436/2001 of 2 March 2001	L 63	16	3.3.2001
► M21 Commission Regulation (EC) No 2491/2001 of 19 December 2001	L 337	9	20.12.2001
► M22 Commission Regulation (EC) No 473/2002 of 15 March 2002	L 75	21	16.3.2002
► M23 Commission Regulation (EC) No 223/2003 of 5 February 2003	L 31	3	6.2.2003
► M24 Commission Regulation (EC) No 599/2003 of 1 April 2003	L 85	15	2.4.2003
► M25 Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
► M26 Commission Regulation (EC) No 2277/2003 of 22 December 2003	L 336	68	23.12.2003

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.

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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

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Article 1

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

- (a) unprocessed agricultural crop products; also livestock and unprocessed livestock products, to the extent that principles of production and specific inspection rules for them are introduced in Annexes I and III;
- (b) processed agricultural crop and livestock products intended for human consumption prepared essentially from one or more ingredients of plant and/or animal origin;
- (c) feedingstuffs, compound feedingstuffs and feed materials not covered under subparagraph (a) as from the entry into force of this Regulation referred to in paragraph 3.

2. By way of derogation from paragraph 1, where the detailed production rules are not laid down in Annex I for certain animal species, the rules provided for labelling in Article 5 and for the inspections in Articles 8 and 9 shall apply for these species and the products therefrom, with the exception of aquaculture and aquaculture products. Pending the inclusion of detailed production rules, national rules or in the absence thereof private standards accepted or recognised by the Member States shall apply.

3. The Commission shall, not later than 24 August 2001, propose a regulation in accordance with the procedure in Article 14 providing for labelling requirements as well as inspection requirements and precautionary measures for products mentioned in paragraph (1)(c), as far as these requirements are related to the organic production method.

Pending the adoption of the Regulation referred to in the first subparagraph for the products mentioned in paragraph (1)(c), national rules in conformity with Community law or, in the absence thereof, private standards accepted or recognised by the Member States shall apply.

▼M15*Article 2*

For the purpose of this Regulation, a product shall be regarded as bearing indications referring to the organic production method, where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials are described by the indication in use in each Member State, suggesting to the purchaser that the product, its ingredients or feed materials have been obtained in accordance with the rules of production laid down in Article 6 and in particular the following terms or their usual derivatives (such as bio, eco etc.) or diminutives, alone or combined, unless such terms are not applied to agricultural products in foodstuffs or feedingstuffs or clearly have no connection with the method of production:

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

Article 3

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

▼B**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;

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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;

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3. 'preparation' shall mean the operations of preserving and/or processing of agricultural products (including slaughter and cutting for livestock 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;

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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;

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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;

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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 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).

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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;

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11. ‘livestock production’ shall mean the production of domestic or domesticated terrestrial animals (including insects) and aquatic species farmed in fresh, salt or brackish water. The products of hunting and fishing of wild animals shall not be considered as organic production;
12. ‘genetically modified organism (GMO)’ shall mean any organism as defined in Article 2 of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ⁽⁵⁾;
13. ‘GMO derivative’ shall mean any substance which is either produced from or produced by GMOs, but does not contain them;
14. ‘use of GMOs and GMO derivatives’ shall mean use thereof as foodstuffs, food ingredients (including additives and flavourings), processing aids (including extraction solvents), feedingstuffs, compound feedingstuffs, feed materials, feed additives, processing aids for feedingstuffs, certain products used in animal nutrition (under Directive 82/471/EEC) ⁽⁶⁾, plant protection products, veterinary medicinal products, fertilisers, soil conditioners, seeds, vegetative reproductive material and livestock;
15. ‘veterinary medicinal products’ shall mean products as defined in Article 1(2) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽⁷⁾;

⁽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.

⁽⁵⁾ OJ L 117, 8.5.1990, p. 15. Directive as last amended by Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

⁽⁶⁾ 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).

⁽⁷⁾ OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

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16. 'homeopathic veterinary medicinal products' shall mean products as defined in Article 1(1) of Council Directive 92/74/EEC of 22 September 1992, widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products ⁽¹⁾;
17. 'feedingstuffs' shall mean products as defined in Article 2(a) of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs ⁽²⁾;
18. 'feed materials' shall mean products as defined in Article 2(a) of Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC ⁽³⁾;
19. 'compound feedingstuffs' shall mean products as defined in Article 2(b) of Directive 79/373/EEC;
20. 'feed additives' shall mean products as defined in Article 2(a) of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽⁴⁾;
21. 'certain products used in animal nutrition' shall mean nutritional products within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition;
22. 'organic-production unit/holding/stockfarm' shall mean a unit, holding or stockfarm complying with the rules of this Regulation;
23. 'organically-produced feedingstuffs/feed materials' shall mean feedingstuffs/feed materials produced in accordance with the rules of production laid down in Article 6;
24. 'in-conversion feedingstuffs/feed materials' shall mean feedingstuffs/feed materials complying with the rules of production laid down in Article 6, except for the conversion period where those rules apply for at least one year before the harvest;
25. 'conventional feedingstuffs/feed materials' shall mean feedingstuffs/feed materials not covered by the categories mentioned in paragraphs 23 and 24.

▼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;

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- (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

⁽¹⁾ OJ L 297, 13.10.1992, p. 12.

⁽²⁾ OJ L 86, 6.4.1979, p. 30. Directive as last amended by Directive 98/87/EC (OJ L 318, 27.11.1998, p. 43).

⁽³⁾ OJ L 125, 23.5.1996, p. 35. Directive as amended by Directive 98/67/EC (OJ L 261, 24.9.1998, p. 10).

⁽⁴⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 45/1999 (OJ L 6, 21.1.1999, p. 3).

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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;
- (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;

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(h) the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms.

3a. By way of derogation from paragraphs 1 to 3, trade marks which bear an indication referred to in Article 2, may continue to be used until 1 July 2006 in the labelling and advertising of products which do not comply with this Regulation provided that:

- registration of the trade mark was applied for before 22 July 1991 — and in Finland, Austria, and Sweden before 1 January 1995 — and is in conformity with the First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks ⁽¹⁾, and
- the trade mark is already reproduced with a clear, prominent, and easily readable indication that the products are not produced according to the organic production method as prescribed in this Regulation.

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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.

⁽¹⁾ OJ L 40, 11.2.1989, p. 1. Directive as amended by Decision 92/10/EEC (OJ L 6, 11.1.1992, p. 35).

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5. Crop products labelled or advertised in accordance with paragraphs 1 or 3 may bear indications referring to conversion to the organic production method, provided that:

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- (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';

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- (d) the product contains only one crop ingredient of agricultural origin;

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- (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;

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- (f) the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms.

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- 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 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;

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- (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;

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- (i) the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms.

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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.

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

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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.

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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.

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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.

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10. In a product as referred to in Article 1(1), paragraphs (a) and (b), 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.

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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***▼M15**

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 mentioned in Annex I or listed in Annex II may be used as plant protection products, fertilisers, soil conditioners, feedingstuffs, feed materials, compound feedingstuffs, feed additives, substances used in animal nutrition under Directive 82/471/EEC, cleaning and disinfecting products for livestock buildings and installations, products for pest and disease control of livestock buildings and installations or for another purpose where such purpose is specified in Annex II in regard to certain products. They may be used only under the specific conditions laid down in Annexes I and II in so far as the corresponding use is authorised in general agriculture in the Member States concerned in accordance with the relevant Community provisions or national provisions in conformity with Community law;
- (c) only seed or vegetative propagating material produced by the organic production method referred to in paragraph 2 is used;
- (d) genetically modified organisms and/or any product derived from such organisms must not be used, with the exception of veterinary medicinal products.

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:

- (a) without the use of genetically modified organisms and/or any products derived from such organisms, and
- (b) in accordance with subparagraphs (a) and (b) of paragraph 1 for at least one generation or, in the case of perennial crops, two growing seasons.

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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 ►M15 31 December 2003 ◀ 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

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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 ►**M15** 31 December 2003 ◀, 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 ►**M15** 31 December 2003 ◀, 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,
 - 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 ►**M15** 31 December 2002 ◀, 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,

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- 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 authorization shall be withdrawn or its period of validity amended.

▼B*Article 7***▼M15**

1. Products not authorised 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 or for cleaning and disinfecting livestock buildings and installations:
 - they are essential for the control of a harmful organism or a particular disease for which other biological, cultural, physical or breeding alternatives are not available, and
 - the conditions for their use preclude any direct contact with the seed, the crop, crop products or livestock and livestock 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;

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- (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.

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1b. With regard to minerals and trace elements used in animal nutrition, additional sources for these products may be included in Annex II provided that they are of natural origin or failing that, synthetic in the same form as natural products.

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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

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- 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:
 - (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;

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- (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. ◀

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

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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.

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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 **► M15** ◀.

▼ M15

12. (a) For livestock meat production Member States shall ensure, without prejudice to the provisions of Annex III, that the inspections relate to all stages of production, slaughter, cutting and any other preparation up to the sale to the consumer to ensure as far as technically possible the traceability of livestock products through the production, processing and any other preparation chain from the unit of production of the livestock until the unit of final packaging and/or labelling. They shall inform the Commission together with the report on supervision referred to in Article 15, on the measures taken and their follow-up.
- (b) For other livestock products different from meat, further provisions to ensure, as far as technically possible, traceability will be set out in Annex III.
- (c) In any event the measures taken under Article 9 shall ensure that consumers are given guarantees that the products have been produced in accordance with this Regulation.

▼ 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 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.

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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.

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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).

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.

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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 ►**M15** 31 December 2005 ◀, 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 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.

▼M15

However, with regard to the rules referred to in Annex I, part B, concerning livestock production, Member States may apply more stringent rules to livestock and livestock products produced within their territory, provided that these rules are in compliance with Community law and do not prohibit or restrict the marketing of other livestock and livestock products that meet the requirements of this Regulation.

▼B**Administrative provisions and implementation**▼M15*Article 13*

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

- detailed rules for applying this Regulation;
- amendments to Annexes I to IV, VI, VII and VIII;
- 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;
- restrictions and implementation measures for applying the derogation as referred to in Article 6, (1) (d) for veterinary medicinal products;
- implementation measures according to scientific evidence or technical progress to apply the prohibition on the use of GMOs and GMOs derivatives with regard, in particular, to a *de minimis* threshold for unavoidable contamination which shall not be exceeded.

▼M25*Article 14*

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ⁽¹⁾ shall apply.

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

3. The Committee shall adopt its Rules of Procedure.

▼B*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

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

▼B

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.

▼M15*Article 15a*

In respect of the measures set out in this Regulation, particularly those to be implemented by the Commission, with a view to meeting the objectives laid down in Articles 9 and 11 and the technical annexes, the necessary appropriations shall be set aside each year during the budgetary procedure.

▼B*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.

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

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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.

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▼ **M15**

A. PLANT AND PLANT PRODUCTS

▼ **M22**

- 1.1. The principles laid down in Article 6(1)(a), (b) and (d) and set out in particular 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 grassland, at least two years before its exploitation as feedingstuff from organic farming, 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 conversion period shall commence at the earliest on the date on which the producer notified his activity in accordance with Article 8 and submitted his holding to the inspection system provided for in Article 9.
- 1.2. However, the inspection authority or body may decide, in agreement with the competent authority, to recognise retroactively as being part of the conversion period any previous period in which:
 - (a) the land parcels were part of a programme implemented pursuant to Council Regulation (EEC) No 2078/92 of 30 June 1992 on agricultural production methods compatible with the requirements of the protection of the environment and the maintenance of the countryside ⁽¹⁾ or Chapter VI of Council Regulation (EC) No 1257/1999 of 17 May 1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) and amending and repealing certain Regulations ⁽²⁾, or as part of another official programme, provided that the programmes concerned guarantee that products not listed in parts A and B of Annex II have not been used on those parcels; or
 - (b) the parcels were natural or agricultural areas which were not treated with products not listed in parts A and B of Annex II. This period can be taken into consideration retroactively only under the condition that satisfactory proof has been furnished to the inspection authority or body allowing it to satisfy itself that the conditions were met for a period of at least three years.
- 1.3. The inspection authority or body may, with the approval of the competent authority, decide, in certain cases, to extend the conversion period beyond the period laid down in paragraph 1.1 having regard to previous parcel use.
- 1.4. In the case of parcels which have already been converted to or were in the process of conversion to organic farming, and which are treated with a product not listed in Annex II, the Member State may reduce the length of the conversion period to less than the period laid down in paragraph 1.1 in the following two cases:
 - (a) parcels treated with a product not listed in part B of Annex II as part of a compulsory disease or pest control measure imposed by the competent authority of the Member State within its own territory or in certain parts thereof for a specific crop production;
 - (b) parcels treated with a product not listed in parts A or B of Annex II as part of scientific tests approved by the competent authority of the Member State.

In these cases the length of the conversion period shall be fixed taking into account all of the following points:

- the process of degradation of the plant protection product concerned must guarantee, at the end of the conversion period, an insignificant level of residues in the soil and, in the case of a perennial crop, in the plant,
- the harvest following the treatment may not be sold with reference to organic production methods,
- the Member State concerned must inform the other Member States and the Commission of its decision to require compulsory treatment.

⁽¹⁾ OJ L 215, 30.7.1992, p. 85.

⁽²⁾ OJ L 160, 26.6.1999, p. 80.

▼M17

- 2.1. The fertility and the biological activity of the soil must be maintained or increased, in the first instance, by:
 - (a) cultivation of legumes, green manures or deep-rooting plants in an appropriate multi-annual rotation programme;
 - (b) incorporation of livestock manure from organic livestock production in accordance with the provisions and within the restrictions of part B, point 7.1, of this Annex;
 - (c) incorporation of other organic material, composted or not, from holdings producing according to the rules of this Regulation.
- 2.2. Other organic or mineral fertilisers, mentioned in Annex II, may, exceptionally, be applied, as a complement to the extent that:
 - adequate nutrition of the crop being rotated or soil conditioning are not possible by the methods set out under (a), (b) and (c) of the preceding subparagraph,
 - with regard to the products in Annex II referring to manure and/or animal excrements: these products may only be used to the extent that, in combination with the livestock manure referred to in point 2(1)(b) above, the restrictions as referred to in part B, section 7.1, of this Annex are satisfied.
- 2.3. For compost activation appropriate plant-based preparations or preparations of micro-organisms, not genetically modified in the meaning of point 12 of Article 4 may be used. So-called 'biodynamic preparations' from stone meal, farmyard manure or plants may also be used for the purposes covered by this paragraph and by paragraph 2.1.
- 2.4. Appropriate preparations of micro-organisms, not genetically modified in the meaning of point 12 of Article 4 and permitted in general agriculture in the Member State concerned, may be used to improve the overall condition of the soil or the availability of nutrients in the soil or in the crops, where the need for such use has been recognised by the inspection body or inspection authority.

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

▼M13

5. For production of mushrooms, substrates may be used, if they are composed only of the following components:
 - 5.1. farmyard manure and animal excrements (including the products referred to in indents 1 to 4 of Annex II, Part A to Regulation (EEC) No 2092/91):
 - (a) either from holdings producing according to the organic production method;
 - (b) or satisfying the requirements referred to in Annex II, Part A, indents 1 to 4, of Regulation (EEC) No 2092/91, only up to 25 % ⁽¹⁾, and only when the product under 5.1(a) is not available;

⁽¹⁾ This percentage is calculated on weight of total components of the substrate (excluding the covering material and any added water) before composting.

▼ **M13**

- 5.2. products of agricultural origin, other than those covered under point 5.1 (e.g. straw), from holdings producing according to organic production method;
- 5.3. peat not chemically treated;
- 5.4. wood, not treated with chemical products after felling;
- 5.5. mineral products of Annex II, Part A to Regulation (EEC) No 2092/91, water and soil.

▼ **M15**

B. LIVESTOCK AND LIVESTOCK PRODUCTS FROM THE FOLLOWING SPECIES: BOVINE (INCLUDING *BUBALUS* AND BISON SPECIES), PORCINE, OVINE, CAPRINE, EQUIDAE, POULTRY.

1. General principles

- 1.1. Livestock production forms an integral part of many agricultural holdings practising organic farming.
- 1.2. Livestock production must contribute to the equilibrium of agricultural production systems by providing for the nutrient requirements of crops and by improving the soil's organic matter. It can thus help establish and maintain soil-plant, plant-animal and animal-soil interdependence. As part of this concept, landless production ('production hors sol') is not in conformity with the rules of this Regulation.
- 1.3. By utilising renewable natural resources (livestock manure, legumes and fodder crops), the cropping/stockfarming system and the pasturage systems allow soil fertility to be maintained and improved in the long term and contributes to the development of sustainable agriculture.
- 1.4. Organic stockfarming is a land-related activity. Except where authorised by way of exception in this Annex, livestock must have access to a free-range area and the number of animals per unit of area must be limited to ensure integrated management of livestock and crop production on the production unit, so minimising any form of pollution, in particular of the soil and of surface and ground water. The number of livestock must be closely related to the area available in order to avoid problems of over-grazing and erosion and to allow for the preading of livestock manure so that any adverse effect on the environment can be avoided. Detailed rules on the use of livestock manure are set out in Section 7.
- 1.5. In organic stockfarming, all livestock on one and the same production unit must be reared in accordance with the rules laid down in this Regulation.
- 1.6. However, livestock not reared in accordance with the provisions of this Regulation may be present on the holding provided they are reared on units where the buildings and parcels are separated clearly from the units producing in accordance with the rules of this Regulation, and a different species is involved.
- 1.7. By derogation from this principle, livestock not reared in accordance with the provisions of this Regulation can use, for a limited period of time each year, the pasturage of units complying with this Regulation, provided that such animals come from extensive husbandry (as defined in Article 6(5) of Regulation (EC) No 950/97⁽¹⁾ or, for other species not mentioned in that Regulation, the number of animals per ha corresponding to 170 kg of Nitrogen per year/hectare as defined in Annex VII of this Regulation) and provided that other animals which are subject to the requirements of this Regulation are not present on this pasturage at the same time. This derogation must be authorised beforehand by the inspection authority or body.
- 1.8. By way of a second derogation from this principle, animals reared in accordance with the provisions of this Regulation may be grazed on common land, providing that:
 - (a) the land has not been treated with products other than those allowed for in Annex II of this Regulation, for at least three years;

⁽¹⁾ OJ L 142, 2.6.1997, p. 1. Regulation as amended by Regulation (EC) No 2331/98 (OJ L 291, 30.10.1998, p. 10).

▼M15

- (b) any animals which use the land concerned, which are not subject to the requirements of this Regulation, are derived from extensive production, as defined in Article 6(5) of Regulation (EC) No 950/97; or, for other species not mentioned in that Regulation, the number of animals per ha corresponding to 170 kg of Nitrogen per year/hectare as defined in Annex VII of this Regulation;
- (c) any livestock products produced by animals reared in accordance with the provisions of this Regulation, whilst using this land, shall not be regarded as being from organic-production, unless adequate segregation from other animals not complying with the requirements of this Regulation, can be proved to the satisfaction of the inspection authority or body.

2. Conversion

2.1. Conversion of land associated with organic livestock production

- 2.1.1. Where a production unit is converted, the whole area of the unit used for animal feed must comply with the rules on organic farming, using the conversion periods established in part A of this Annex relating to plants and plant products.
- 2.1.2. By derogation from this principle, the conversion period may be reduced to one year for pasturages, open air runs and exercise areas used by non-herbivore species. This period may be reduced to six months where the land concerned has not, in the recent past, received treatments with products other than those referred to in Annex II of this Regulation. This derogation must be authorised by the inspection authority or body.

2.2. Conversion of livestock and livestock products

- 2.2.1. If livestock products are to be sold as organic products, the livestock must be reared according to the rules laid down in this Regulation for at least:
 - 12 months in the case of equidae and bovines (including *bubalus* and bison species) for meat production, and in any case at least three quarters of their lifetime,
 - six months in the case of small ruminant and pigs; however, during a transitional period of three years expiring on 24 August 2003, the period for pigs shall be four months,
 - six months in the case of animals for milk production; however, during a transitional period of three years expiring on 24 August 2003, the period shall be three months,
 - 10 weeks for poultry for meat production, brought in before they are three days old,
 - six weeks in the case of poultry for egg production.
- 2.2.2. By derogation from paragraph 2.2.1 and for the constitution of a herd or flock, calves and small ruminants for meat production can be sold as organically reared during a transitional period expiring 31 December 2003, provided that:
 - they come from extensive husbandry,
 - they are reared in the organic-production unit until the time of sale or slaughter, for a minimum period of six months for calves and two months for small ruminants,
 - the origin of the animals complies with the conditions expressed in the fourth and fifth indents of paragraph 3.4.

2.3. Simultaneous conversion

- 2.3.1. By derogation from paragraphs 2.2.1, 4.2 and 4.4 if there is simultaneous conversion of the complete production unit, including livestock, pasturage and/or any land used for animal feed, the total combined conversion period for both livestock, pasturage and/or any land used for animal feed, shall be reduced to 24 months subject to the following conditions:
 - (a) the derogation applies only to the existing animals and their offspring and at the same time also to the land used for animal feed/pasturage before starting the conversion;
 - (b) the animals are mainly fed with products from the production unit.

▼ **M15****3. Origin of the animals**

- 3.1. In the choice of breeds or strains, account must be taken of the capacity of animals to adapt to local conditions; their vitality, and their resistance to disease. In addition, breeds or strains of animals shall be selected to avoid specific diseases or health problems associated with some breeds or strains used in intensive production (e.g. porcine stress syndrome, PSE Syndrome, sudden death, spontaneous abortion, difficult births requiring caesarean operations, etc.). Preference is to be given to indigenous breeds and strains.
- 3.2. Livestock must come from production units which comply with the rules on the various types of livestock production laid down in Article 6 and in this Annex. Throughout their life, this system of production must be applied.
- 3.3. By way of a first derogation, subject to the prior approval by the inspection authority or body, livestock existing on the livestock production unit, not complying with the rules of this Regulation can be converted.
- 3.4. ► **M26** By way of a second derogation, when a herd or flock is constituted for the first time and organically reared animals are not available in sufficient numbers, non-organically reared livestock may be brought into an organic livestock production unit, subject to the following conditions:
- pullets for the production of eggs must not be more than 18 weeks old,
 - poultry for meat production must be less than three days old,
 - young buffalo for breeding purposes must be less than six months old,
 - calves and foals for breeding purposes must be reared according to the rules of this Regulation as soon as they are weaned and in any case they must be less than six months old,
 - lambs and kids for breeding purposes must be reared according to the rules of this Regulation as soon as they are weaned and in any case must be less than 60 days old,
 - piglets for breeding purposes must be reared according to the rules of this Regulation as soon as they are weaned and they must weigh less than 35 kg. ◀
- 3.5. ► **M26** This derogation, which must be authorised beforehand by the inspection authority or body, applies for a transitional period expiring on 31 December 2004. ◀
- 3.6. ► **M26** By way of a third derogation, the renewal or reconstitution of the herd or flock shall be authorised by the control authority or body when organically reared animals are not available, and in the following cases:
- (a) high mortality of animals caused by health or catastrophic circumstances;
 - (b) pullets for egg production no more than 18 weeks old;
 - (c) poultry for meat production less than three days old;
 - (d) piglets for breeding purposes, as soon as they are weaned, of a weight less than 35 kg.
- Cases (b), (c) and (d) are authorised for a transitional period expiring on 31 December 2004. ◀
- 3.7. In the case of pigs, pullets and poultry for meat production, this transitional derogation will be re-examined before the date of expiry to see if there are grounds for an extension to this deadline.
- 3.8. By way of a fourth derogation, subject to a maximum of 10 % of adult equine or bovine (including *bubalus* and bison species) livestock and 20 % of the adult porcine, ovine and caprine livestock, livestock may be brought in, as female (nulliparous) animals, from non organic-production stockfarms per year, for supplementing natural growth and for the renewal of the herd or flock, when organically reared animals are not available, and only when authorised by the control authority or body.
- 3.9. The percentages laid down in the above derogation shall not apply to production units with less than 10 equine or bovine animals, or with less than five porcine, ovine or caprine animals. For these units, any renewal as mentioned above shall be limited to a maximum of one animal per year.

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- 3.10. ► **M26** These percentages may be increased, up to 40 % following the opinion and agreement of the inspection authority or body, in the following special cases:
- when a major extension to the stockfarm is undertaken,
 - when a breed is changed,
 - when a new livestock specialisation is developed,
 - when breeds are in danger of being lost to farming. Animals of those breeds must not necessarily be nulliparous. ◀
- 3.11. By way of a fifth derogation, males for breeding may be brought in from non organic-production stockfarms provided that the animals are subsequently reared and always fed in accordance with the rules laid down in this Regulation.
- 3.12. Where livestock comes from units not complying with the present Regulation, in accordance with the conditions and restrictions set out in paragraphs 3.3 to 3.11 above, the periods laid down in paragraph 2.2.1 must be observed if the products are to be sold as being from organic production and during these periods all the rules set out in this Regulation must be complied with.
- 3.13. Where livestock is obtained from units not complying with this Regulation, special attention must be paid to animal health measures. The inspection authority or body may apply, depending on local circumstances, special measures, such as screening tests, and quarantine periods.
- 3.14. The Commission will present a report by 31 December 2003 concerning the availability of originally reared livestock with a view to presenting a proposal, if appropriate, to the Standing Committee aimed at ensuring that all organic meat production should come from animals that were born and raised on organic-production holdings.

4. **Feed**

- 4.1. Feed is intended to ensure quality production rather than maximising production, while meeting the nutritional requirements of the livestock at various stages of their development. Fattening practices are authorised in so far as they are reversible at any stage of the rearing process. Force-feeding is forbidden.
- 4.2. Livestock must be fed on organically produced feedingstuffs.
- 4.3. ► **M26** Furthermore, livestock must be reared in accordance with the rules set out in this Annex, using feed from the unit or, when this is not possible, using feed from other units or enterprises subject to the provisions of this Regulation. Moreover, in the case of herbivores, except during the period each year when the animals are under transhumance, at least 50 % of the feed shall come from the farm unit itself or in case this is not feasible, be produced in cooperation with other organic farms. ◀
- 4.4. Up to 30 % of the feed formula of rations on average may comprise in-conversion feedingstuffs. When the in-conversion feedingstuffs come from a unit of the own holding, this percentage can be increased to 60 %. ► **M23** These figures shall be expressed as a percentage of the dry matter of feedingstuffs of agricultural origin. ◀
- 4.5. The feeding of young mammals must be based on natural milk, preferably maternal milk. All mammals must be fed on natural milk for a minimum period, depending on the species concerned, which shall be three months for bovines (including *bubalus* and bison species) and equidae, 45 days for sheep and goats and 40 days for pigs.
- 4.6. Where relevant, Member States shall designate areas or regions where transhumance (including movements of animals to grazing areas in mountains) is practicable, without prejudice to the provisions on the feeding of livestock laid down in this Annex.
- 4.7. Rearing systems for herbivores are to be based on maximum use of pasturage according to the availability of pastures in the different periods of the year. At least 60 % of the dry matter in daily rations is to consist of roughage, fresh or dried fodder, or silage. Nevertheless, the inspection authority or body can permit a reduction to 50 % for animals in dairy production for a maximum period of three months in early lactation.
- 4.8. ► **M26** By way of a derogation from paragraph 4.2, for a transitional period expiring on 24 August 2005, the use of a limited proportion of

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conventional feedingstuffs is authorised where farmers can show to the satisfaction of the inspection body or authority of the Member State that they are unable to obtain feed exclusively from organic production. The maximum percentage of conventional feedingstuffs authorised per year is 10 % in the case of herbivores and 20 % for other species. These figures shall be calculated annually as a percentage of the dry matter of feedingstuffs from agricultural origin. The maximum percentage authorised of conventional feedingstuffs in the daily ration, except during the period each year when the animals are under transhumance, must be 25 % calculated as a percentage of the dry matter. ◀

- 4.9. ► **M22** By derogation from paragraph 4.8. when forage production is lost or when restrictions are imposed, in particular as a result of exceptional meteorological conditions, the outbreak of infectious diseases, the contamination with toxic substances, or as a consequence of fires, the competent authorities of the Member States can authorise for a limited period and in relation to a specific area, a higher percentage of conventional feedingstuffs where such authorisation is warranted. Upon approval by the competent authority, the inspection authority or body shall apply this derogation to individual operators. Member States will inform each other and the Commission on the derogations they have granted. ◀

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- 4.11. Roughage, fresh or dried fodder, or silage must be added to the daily ration for pigs and poultry.
- 4.12. Only products listed in Annex II, Part D, sections 1.5 and 3.1 can be used as additives and processing aids, respectively, in silage.
- 4.13. Conventional feed materials of agricultural origin can be used for animal feeding only if listed in Annex II, Part C, section 1 (feed materials from plant origin), subject to the quantitative restrictions imposed in this Annex, and only if they are produced or prepared without the use of chemical solvents.
- 4.14. Feed materials from animal origin (whether conventional or organically produced) can only be used if listed in Annex II, Part C, section 2, and subject to the quantitative restrictions imposed in this Annex.
- 4.15. No later than 24 August 2003, Part C, sections 1, 2, 3 and Part D of Annex II will be reviewed with the aim of removing, in particular, conventional feed materials of agricultural origin produced organically in sufficient quantity in the Community.
- 4.16. In order to satisfy nutritional requirements of livestock, only products listed in Annex II, Part C, section 3 (feed materials from mineral origin), and part D, sections 1.1 (trace elements) and 1.2 (vitamins, pro-vitamins and chemically well-defined substances having a similar effect), can be used for animal feeding.
- 4.17. ► **M26** Only products listed in Annex II, part D, sections 1.3 (enzymes), 1.4 (microorganisms), 1.5 (preservatives), 1.6 (binders, anti-caking agents and coagulants), 1.7 (antioxidant substances), 1.8 (silage additives), 2 (certain products used in animal nutrition) and 3 (processing aids in feedingstuffs) can be used in animal feeding for the purposes indicated in respect to the abovementioned categories. Antibiotics, coccidiostatics, medicinal substances, growth promoters or any other substance intended to stimulate growth or production shall not be used in animal feeding. ◀
- 4.18. Feedingstuffs, feed materials, compound feedingstuffs feed additives, processing aids for feedingstuffs and certain products used in animal nutrition must not have been produced with the use of genetically modified organisms or products derived therefrom.
5. **Disease prevention and veterinary treatment**
- 5.1. Disease prevention in organic livestock production shall be based on the following principles:
- (a) the selection of appropriate breeds or strains of animals as detailed in Section 3;
 - (b) the application of animal husbandry practices appropriate to the requirements of each species, encouraging strong resistance to disease and the prevention of infections;

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- (c) the use of high quality feed, together, with regular exercise and access to pasturage, having the effect of encouraging the natural immunological defence of the animal;
 - (d) ensuring an appropriate density of livestock, thus avoiding overstocking and any resulting animal health problems.
- 5.2. The principles set out above, should limit animal-health problems so that they can be controlled mainly by prevention.
- 5.3. If, despite all of the above preventive measures, an animal becomes sick or injured, it must be treated immediately, if necessary in isolation, and in suitable housing.
- 5.4. The use of veterinary medicinal products in organic farming shall comply with the following principles:
- (a) Phytotherapeutic (e.g. plant extracts (excluding antibiotics), essences, etc.), homeopathic products (e.g. plant, animal or mineral substances) and trace elements and products listed in Part C, section 3 of Annex II, shall be used in preference to chemically-synthesised allopathic veterinary medicinal products or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended;
 - (b) If the use of the above products should not prove, or is unlikely to be, effective in combating illness or injury, and treatment is essential to avoid suffering or distress to the animal, chemically-synthesised allopathic veterinary medicinal products or antibiotics may be used under the responsibility of a veterinarian;
 - (c) The use of chemically synthesised allopathic veterinary medicinal products or antibiotics for preventive treatments is prohibited;
- 5.5. In addition to the above principles, the following rules shall apply:
- (a) the use of substances to promote growth or production, (including antibiotics, coccidiostats and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction (e.g. induction or synchronisation of oestrus), or for other purposes, is prohibited. Nevertheless, hormones may be administered to an individual animal, as a form of therapeutic veterinary treatment;
 - (b) veterinary treatments to animals, or treatments to buildings, equipment and facilities, which are compulsory under national or Community legislation shall be authorised, including the use of immunological veterinary medicinal products when a disease has been recognised as present in a specific area in which the production unit is located.
- 5.6. Whenever veterinary medicinal products are to be used the type of product must be recorded clearly, (including an indication of the active pharmacological substances involved) together with details of the diagnosis; the posology; the method of administration; the duration of the treatment, and the legal withdrawal period. This information is to be declared to the inspection authority or body before the livestock or livestock products are marketed as organically produced. Livestock treated must be clearly identified, individually in the case of large animals; individually or by batch, in the case of poultry and small animals.
- 5.7. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the legal withdrawal period or, in a case in which this period is not specified, 48 hours.
- 5.8. With the exception of vaccinations, treatments for parasites and any compulsory eradication schemes established by Member States, where an animal or group of animals receive more than two or a maximum of three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within one year (or more than one course of treatment if their productive lifecycle is less than one year) the livestock concerned, or produce derived from them, may not be sold as being products produced in accordance with this Regulation, and the livestock must undergo the conversion periods laid down in Section 2 of this Annex, subject to the agreement of the inspection authority or body.

▼ **M15****6. Husbandry management practices, transport and identification of livestock products**6.1. *Husbandry practices*

- 6.1.1. In principle, the reproduction of organically reared livestock should be based on natural methods. Nevertheless artificial insemination is permitted. Other forms of artificial or assisted reproduction (for example embryo transfers) are prohibited.
- 6.1.2. Operations such as attaching elastic bands to the tails of sheep, tail-docking, cutting of teeth, trimming of beaks and dehorning must not be carried out systematically in organic farming. Some of these operations may, however, be authorised by the inspection authority or body, for reasons of safety (for example dehorning in young animals) or if they are intended to improve the health, welfare or hygiene of the livestock. Such operations must be carried out at the most appropriate age by qualified personnel and any suffering to the animals must be reduced to a minimum.
- 6.1.3. Physical castration is allowed in order to maintain the quality of products and traditional production practices (meat-type pigs, bullocks, capons, etc.) but only under the conditions set out in the last sentence of the paragraph 6.1.2.
- 6.1.4. Keeping livestock tethered is forbidden. Nevertheless, by derogation from this principle, the inspection authority or body, can authorise this practice for individual animals upon justification by the operator, that this is necessary for safety or welfare reasons, and that such tethering is only for a limited period of time.
- 6.1.5. By derogation from the provisions laid down in paragraph 6.1.4, cattle can be tethered in buildings already existing before 24 August 2000, provided that regular exercise is provided and rearing takes place in line with animal welfare requirements with comfortably littered areas as well as individual management. This derogation which must be authorised by the inspection authority or body shall apply for a transitional period expiring on 31 December 2010.
- 6.1.6. By a further derogation, cattle in small holdings can be tethered if it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have at least twice a week access to pastures, open air runs or exercise areas. This derogation, which must be authorised by the inspection authority or body, shall apply to holdings which meet the requirements of natural rules concerning organic production of livestock effective until 24 August 2000, or in the absence thereof of private standards accepted or recognised by the Member States.
- 6.1.7. Before 31 December 2006, the Commission will present a report on the implementation of the provisions of paragraph 6.1.5.
- 6.1.8. Where livestock are reared in groups, the size of the group must depend upon their stage of development and the behavioural needs of the species concerned. The keeping of livestock in conditions, or on a diet, which may encourage anaemia, is prohibited.
- 6.1.9. For poultry, the minimum age at slaughter shall be:
- 81 days for chickens,
 - 150 days for capons,
 - 49 days for Peking ducks,
 - 70 days for female Muscovy ducks,
 - 84 days for male Muscovy ducks,
 - 92 days for Mallard ducks,
 - 94 days for guineafowl,
 - 140 days for turkeys and roasting geese.

Where producers do not apply these minimum slaughter ages, they must use slow-growing strains.

6.2. *Transport*

- 6.2.1. Transport of livestock must be carried out so as to limit the stress suffered by the animals in accordance with the relevant national or Community legislation in force. Loading and unloading must be carried out with caution and without the use of any type of electrical stimulation to coerce the animals. The use of any allopathic tranquiliser, prior to and during transport, is prohibited.

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6.2.2. During the period leading up to and at the time of slaughter, livestock must be handled in such a way that stress to the animals is reduced to a minimum.

6.3. *Identification of livestock products*

6.3.1. Livestock and livestock products are to be identified at all stages of their production, preparation, transport and marketing.

7. Livestock manure

7.1. The total amount of manure, as defined in Directive 91/676/EEC ⁽¹⁾, applied on the holding may not exceed 170 kg of Nitrogen per year/hectare of agricultural area used, the amount specified in Annex III of the abovementioned Directive. Where necessary, the total stocking density shall be reduced to avoid exceeding the limit expressed above.

7.2. To determine the appropriate density of livestock referred to above, the livestock units equivalent to 170 kg of Nitrogen per year/hectare of agricultural area used for the various categories of animals shall be set out by the competent authorities of the Member States, taking, as a guideline, the figures laid down in Annex VII.

7.3. Member States shall communicate to the Commission and to the other Member States, any deviation from these figures and provide the reasons justifying such changes. This requirement relates only to the calculation of the maximum number of livestock for the purposes of ensuring that the limit of 170 kg of Nitrogen from manure per year/hectare is not exceeded. It is without prejudice to the stocking densities for animal health and welfare purposes laid down in Section 8 and in Annex VIII.

7.4. Organic-production holdings may establish cooperation ► **M22** exclusively ◀ with other holdings and enterprises, which comply with the provisions of this Regulation, with the intention of spreading surplus manure from organic production. The maximum limit of 170 kg of Nitrogen from manure per year/hectare of agricultural area used, will be calculated on the basis of all of the organic-production units involved in such a cooperation.

7.5. Member States may establish lower limits than those specified in paragraphs 7.1 to 7.4, taking into account the characteristics of the area concerned, the application of other nitrogen fertilisers to the land and the nitrogen supply to the crops from the soil.

7.6. Storage facilities for livestock manure must be of a capacity to preclude the pollution of water by direct discharge, or by run-off and infiltration of the soil.

7.7. To ensure sound fertiliser management, the capacity of such storage facilities for livestock manure must exceed the storage capacity required for the longest period of the year in which any application of fertiliser to the land is either inappropriate (in accordance with the codes of good agricultural practice established by Member States) or when such application is prohibited, in cases where the production unit is located within a designated nitrate vulnerable zone.

8. Free range areas and livestock housing

8.1. *General principles*

8.1.1. Housing conditions for livestock must meet the livestock's biological and ethological needs (e.g. behavioural needs as regards appropriate freedom of movement and comfort). The livestock must have easy access to feeding and watering. Insulation, heating and ventilation of the building must ensure that air circulation, dust level, temperature, relative air humidity and gas concentration, are kept within limits which are not harmful to the animals. The building must permit plentiful natural ventilation and light to enter.

8.1.2. Free-range, open-air exercise areas, or open-air runs must, if necessary, provide sufficient protection against rain, wind, sun and extreme temperatures, depending on the local weather conditions and the breed concerned.

⁽¹⁾ OJ L 375, 31.12.1991, p. 1.

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- 8.2. *Stocking densities and the avoidance of over grazing*
- 8.2.1. Housing for livestock will not be mandatory in areas with appropriate climatic conditions to enable animals to live outdoors.
- 8.2.2. The stocking density in buildings shall provide for the comfort and well being of the animals which, in particular, shall depend on the species, the breed and the age of the animals. It shall also take account of the behavioural needs of the animals, which depend in particular on the size of the group and the animals' sex. The optimum density will seek to ensure the animals' welfare by providing them with sufficient space to stand naturally, lie down easily, turn round, groom themselves, assume all natural postures and make all natural movements such as stretching and wing flapping.
- 8.2.3. The minimum surface areas for indoor housing and outdoor exercise areas, and other characteristics of housing for different species and categories of animals, are laid down in Annex VIII.
- 8.2.4. The outdoor stocking density of livestock kept on pasturage, other grassland, heathland, wetland, heather, and other natural or semi-natural habitats, must be low enough to prevent poaching of the soil and over grazing of vegetation.
- 8.2.5. Housing, pens, equipment and utensils must be properly cleaned and disinfected to prevent cross-infection and the build-up of disease carrying organisms. Only the products listed in Part E of Annex II can be used for such cleaning and disinfection of livestock buildings and installations. Faeces, urine and uneaten or spilt food must be removed as often as necessary to minimise smell and to avoid attracting insects or rodents. Only the products listed in part B, section 2, of Annex II can be used for the elimination of insects and other pests in buildings and other installations where livestock is kept.
- 8.3. *Mammals*
- 8.3.1. Subject to the provisions in paragraph 5.3, all mammals must have access to pasturage or an open-air exercise area or an open-air run which may be partially covered, and they must be able to use those areas whenever the physiological condition of the animal, the weather conditions and the state of the ground permit, unless there are Community or national requirements relating to specific animal health problems that prevent this. Herbivores, must have access to pasturage whenever conditions allow.
- 8.3.2. In cases where herbivores have access to pasturage during the grazing period and where the winter-housing system gives freedom of movement to the animals, the obligation to provide open-air exercise areas or open-air runs during the winter months may be waived.
- 8.3.3. Notwithstanding the last sentence of paragraph 8.3.1, bulls over one year old must have access to pasturage or an open-air exercise area or an open-air run.
- 8.3.4. By way of derogation from paragraph 8.3.1, the final fattening phase of cattle pigs and sheep for meat production may take place indoors, provided that this indoors period does not exceed one fifth of their lifetime and in any case for a maximum period of three months.
- 8.3.5. Livestock housing must have smooth, but not slippery floors. At least half of the total floor area must be solid, that is, not of slatted or of grid construction.
- 8.3.6. The housing must be provided with a comfortable, clean and dry laying/rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material must be provided in the rest area. The litter must comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised for use as a fertiliser in organic farming in accordance with Part A of Annex II.
- 8.3.7. As regards the rearing of calves, from 24 August 2000, all holdings, without derogation, must comply with Directive 91/629/EEC⁽¹⁾ laying down minimum standards for the protection of calves. The housing of calves in individual boxes is forbidden after the age of one week.

⁽¹⁾ OJ L 340, 11.12.1991, p. 28. Directive as last amended by Directive 97/2/EC (OJ L 25, 28.1.1997, p. 24).

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- 8.3.8. As regards the rearing of pigs, from 24 August 2000, all holdings must comply with Council Directive 91/630/EEC ⁽¹⁾ laying down minimum standards for the protection of pigs. However, sows must be kept in groups, except in the last stages of pregnancy and during the suckling period. Piglets may not be kept on flat decks or in piglet cages. Exercise areas must permit dunging and rooting by the animals. For the purposes of rooting different substrates can be used.
- 8.4. *Poultry*
- 8.4.1. Poultry must be reared in open-range conditions and cannot be kept in cages.
- 8.4.2. Water fowl must have access to a stream, pond or lake whenever the weather conditions permit in order to respect animal welfare requirements or hygienic conditions.
- 8.4.3. Buildings for all poultry must meet the following minimum conditions:
- at least one third shall be solid, that is, not of slatted or of grid construction, and covered with a litter material such as straw, wood shavings, sand or turf;
 - in poultry houses for laying hens, a sufficiently large part of the floor area available to the hens must be available for the collection of bird droppings;
 - they must have perches of a size and number commensurate with the size of the group and of the birds as laid down in Annex VIII;
 - they must have exit/entry pop-holes of a size adequate for the birds, and these pop-holes must have a combined length of at least 4 m per 100 m² area of the house available to the birds;
 - each poultry house must not contain more than:
 - 4 800 chickens,
 - 3 000 laying hens,
 - 5 200 guinea fowl,
 - 4 000 female Muscovy or Peking ducks or 3 200 male Muscovy or Peking ducks or other ducks,
 - 2 500 capons, geese or turkeys;
 - the total usable area of poultry houses for meat production on any single production unit, must not exceed 1 600 m².
- 8.4.4. In the case of laying hens natural light may be supplemented by artificial means to provide a maximum of 16 hours light per day with a continuous nocturnal rest period without artificial light of at least eight hours.
- 8.4.5. Poultry, must have access to an open-air run whenever the weather conditions permit and, whenever possible, must have such access for at least one third of their life. These open-air runs must be mainly covered with vegetation be provided with protective facilities, and permit animals to have easy access to adequate numbers of drinking and feeding troughs.
- 8.4.6. For health reasons, buildings must be emptied of livestock between each batch of poultry reared. The buildings and fittings are to be cleaned and disinfected during this time. In addition, when the rearing of each batch of poultry has been completed, runs must be left empty to allow vegetation to grow back, and for health reasons. Member States will establish the period in which runs must be empty and they will communicate their decision to the Commission and the other Member States. These requirements shall not apply to small numbers of poultry which are not kept in runs and which are free to roam, throughout the day.
- 8.5. *General derogation on the housing of livestock*
- 8.5.1. By way of derogation from the requirements set out in paragraphs 8.3.1, 8.4.2, 8.4.3 and 8.4.5 and the stocking densities laid down in Annex VIII, the competent authorities of the Member States may authorise derogations from the requirements of these paragraphs and of Annex VIII for a transitional period expiring on 31 December 2010. This derogation can only be applied to livestock producing holdings with existing buildings, constructed before 24 August 1999 and in so far as these livestock buildings comply with national rules

(1) OJ L 340, 11.12.1991, p. 33.

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concerning organic livestock production, in force prior to that date, or in the absence thereof with private standards accepted or recognised by the Member States.

- 8.5.2. The operators benefiting from this derogation shall present a plan to the inspection authority or body, containing the arrangements which ensure, at the end of the derogation, compliance with the provisions of this Regulation.
- 8.5.3. Before 31 December 2006, the Commission shall present a report on the implementation of the provision of paragraph 8.5.1.

C. BEEKEEPING AND BEEKEEPING PRODUCTS**1. General principles**

- 1.1. Beekeeping is an important activity that contributes to the protection of the environment and agricultural and forestry production through the pollination action of bees.
- 1.2. The qualification of beekeeping products as being from organic production is closely bound up both with the characteristic of the hives' treatments and the quality of the environment. This qualification also depends on the conditions for extraction, processing and storage of beekeeping products.
- 1.3. When an operator runs several beekeeping units in the same area all the units must comply with the requirements of this Regulation. By derogation from this principle, an operator can run units not complying with this Regulation provided that all the requirements of this Regulation are fulfilled with the exception of the provisions laid down in paragraph 4.2 for the siting of the apiaries. In that case, the product cannot be sold with references to organic production methods.

2. Conversion period

- 2.1. Beekeeping products can be sold with references to the organic production method only when the provisions laid down in this Regulation have been complied with for at least one year. During the conversion period the wax has to be replaced according to the requirements laid down in paragraph 8.3.

3. Origin of the bees

- 3.1. In the choice of breeds, account must be taken of the capacity of animals to adapt to local conditions, their vitality and their resistance to disease. Preference shall be given to the use of European breeds of *Apis mellifera* and their local ecotypes.
- 3.2. Apiaries must be constituted by means of the division of colonies or the acquisition of swarms or hives from units complying with the provisions laid down in this Regulation.
- 3.3. By way of a first derogation, subject to the prior approval by the inspection authority or body, apiaries existing in the production unit not complying with the rules of this Regulation can be converted.
- 3.4. By way of a second derogation, swarms on their own may be acquired from beekeepers not producing in accordance with this Regulation during a transitional period expiring on 24 August 2002 subject to the conversion period.
- 3.5. By way of a third derogation, the reconstitution of the apiaries shall be authorised by the control authority or body, when apiaries complying with this Regulation are not available, in case of high mortality of animals caused by health or catastrophic circumstances, subject to the conversion period.
- 3.6. By way of a fourth derogation, for the renovation of the apiaries 10 % per year of the queen bees and swarms not complying with this Regulation can be incorporated into the organic-production unit provided that the queen bees and swarms are placed in hives with combs or comb foundations coming from organic-production units. In the case, the conversion period does not apply.

4. Siting of the apiaries

- 4.1. The Member States may designate regions or areas where beekeeping complying with this Regulation is not practicable. A map on an appropriate scale listing the location of hives as provided for in Annex III,

▼ **M15**

Part A1, section 2, first indent shall be provided to the inspection authority or body by the beekeeper. Where no such areas are identified, the beekeeper must provide the inspection authority or body with appropriate documentation and evidence, including suitable analyses if necessary, that the areas accessible to his colonies meet the conditions required in this Regulation.

4.2. The siting of the apiaries must:

- (a) ensure enough natural nectar, honeydew and pollen sources for bees and access to water;
- (b) be such that, within a radius of 3 km from the apiary site, nectar and pollen sources consist essentially of organically produced crops and/or spontaneous vegetation, according to the requirements of Article 6 and Annex I of this Regulation, and crops not subject to the provisions of this Regulation but treated with low environmental impact methods such as, for example, those described in programs developed under Regulation (EEC) No 2078/92 ⁽¹⁾ which cannot significantly affect the qualification of beekeeping production as being organic;
- (c) maintain enough distance from any non-agricultural production sources possibly leading to contamination, for example: urban centres, motorways, industrial areas, waste dumps, waste incinerators, etc. The inspection authorities or bodies shall establish measures to ensure this requirement.

The above requirements do not apply to areas where flowering is not taking place, or when the hives are dormant.

5. **Feed**

- 5.1. At the end of the production season hives must be left with reserves of honey and pollen sufficiently abundant to survive the winter.
- 5.2. The artificial feeding of colonies is authorised where the survival of the hives is endangered due to extreme climatic conditions. Artificial feeding shall be made with organically produced honey, preferably from the same organic-production unit.
- 5.3. By way of a first derogation from paragraph 5.2, the competent authorities of the Member States can authorise the use of organically-produced sugar syrup, or organic sugar molasses instead of organically-produced honey in artificial feeding, in particular, when it is required by climatic conditions that provoke crystallisation of honey.
- 5.4. By way of a second derogation, sugar syrup, sugar molasses and honey not covered by this Regulation may be authorised by the inspection authority or body for artificial feeding during a transitional period expiring on 24 August 2002.
- 5.5. The following information shall be entered in the register of the apiaries with regard to the use of artificial feeding: type of product, dates, quantities and hives where it is used.
- 5.6. Other products different from those indicated in paragraphs 5.1 to 5.4 cannot be used in beekeeping which complies with this Regulation.
- 5.7. Artificial feeding may be carried out only between the last honey harvest and 15 days before the start of the next nectar or honeydew flow period.

6. **Disease prevention and veterinary treatments**

- 6.1. Disease prevention in beekeeping shall be based on the following principles:
 - (a) the selection of appropriate hardy breeds;
 - (b) the application of certain practices encouraging strong resistance to disease and the prevention of infections, such as: regular renewal of queen bees, systematic inspection of hives to detect any health anomalies, control of male broods in the hives, disinfecting of materials and equipment at regular intervals, destruction of contaminated material or sources, regular renewal of beeswax and sufficient reserves of pollen and honey in hives.

⁽¹⁾ OJ L 215, 30.7.1992, p. 85. Regulation as last amended by Regulation (EC) No 2772/95 (OJ L 288, 1.12.1995, p. 35).

▼ **M15**

- 6.2. If despite all the above preventive measures, the colonies become sick or infested, they must be treated immediately and, if necessary, the colonies can be placed in isolation apiaries.
- 6.3. The use of veterinary medicinal products in beekeeping which complies with this Regulation shall respect the following principles:
- (a) they can be used in so far as the corresponding use is authorised in the Member State in accordance with the relevant Community provisions or national provisions in conformity with Community law;
 - (b) phytotherapeutic and homeopathic products shall be used in preference to allopathic products chemically synthesised, provided that their therapeutic effect is effective for the condition for which the treatment is intended;
 - (c) if the use of the abovementioned products should prove or is unlikely to be effective to eradicate a disease or infestation which risks destroying colonies, allopathic chemically synthesised medicinal products may be used under the responsibility of a veterinarian, or other persons authorised by the Member State, without prejudice to the principles laid down in paragraphs (a) and (b) above;
 - (d) the use of allopathic chemically synthesised medicinal products for preventive treatments is prohibited;
 - (e) without prejudice to the principle in (a) above formic acid, lactic acid, acetic acid and oxalic acid and the following substances: menthol, thymol, eucalyptol or camphor can be used in cases of infestation with *Varroa jacobsoni*.
- 6.4. In addition to the above principles, veterinary treatments or treatments to hives, combs etc., which are compulsory under national or Community legislation shall be authorised.
- 6.5. If a treatment is applied with chemically synthesised allopathic products, during such a period, the colonies treated must be placed in isolation apiaries and all the wax must be replaced with wax complying with the conditions laid down in this Regulation. Subsequently, the conversion period of one year will apply to those colonies.
- 6.6. The requirements laid down in the previous paragraph do not apply to products mentioned in paragraph 6.3(e).
- 6.7. Whenever veterinary medicinal products are to be used, the type of product (including the indication of the active pharmacological substance) together with details of the diagnosis, the posology, the method of administration, the duration of the treatment and the legal withdrawal period must be recorded clearly and declared to the inspection body or authority before the products are marketed as organically produced.
- 7. Husbandry management practices and identification**
- 7.1. The destruction of bees in the combs as a method associated with the harvesting of beekeeping products is prohibited.
- 7.2. Mutilation such as clipping the wings of queen bees is prohibited.
- 7.3. The replacement of the queen bees involving the killing of the old queen is permitted.
- 7.4. The practice of destroying the male brood is permitted only to contain the infestation with *Varroa jacobsoni*.
- 7.5. The use of chemical synthetic repellents is prohibited during honey extractions operations.
- 7.6. The zone where the apiary is situated must be registered together with the identification of the hives. The inspection body or authority must be informed of the moving of apiaries with a deadline agreed on with the inspection authority or body.
- 7.7. Particular care shall be taken to ensure adequate extraction, processing and storage of beekeeping products. All the measures to comply with these requirements shall be recorded.
- 7.8. The removals of the supers and the honey extraction operations must be entered in the register of the apiary.

▼M15**8. Characteristics of hives and materials used in beekeeping**

- 8.1. The hives must be made basically of natural materials presenting no risk of contamination to the environment or the apiculture products.
- 8.2. With the exception of products mentioned in paragraph 6.3(e) in the hives can be used only natural products such as propolis, wax and plant oils.
- 8.3. The beeswax for new foundations must come from organic production units. By way of derogation, in particular in the case of new installations or during the conversion period, bees wax not coming from such units may be authorised by the inspection authority or body in exceptional circumstances where organically produced beeswax is not available on the market and provided that it comes from the cap.
- 8.4. The use of combs, which contain broods, is prohibited for honey extraction.
- 8.5. For the purposes of protecting materials (frames, hives and combs), in particular from pests, only appropriate products listed in part B, Section 2, of Annex II are permitted.
- 8.6. Physical treatments such as steam or direct flame are permitted.
- 8.7. For cleaning and disinfecting materials, buildings, equipment, utensils or products used in beekeeping only the appropriate substances listed in Annex II Part E are permitted.

▼ M7

ANNEX II

Part A

▼ M12

Fertilizers and soil conditioners

▼ M17

General conditions for all the products:

- use only in accordance with provisions of Annex I,
- use only in accordance with the provisions of the legislation on placing on the market and use of the products concerned applicable in general agriculture in the Member State where the product is used.

▼ M7

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
▼ <u>M20</u> — Composted or fermented household waste	Product obtained from source separated household waste, which has been submitted to composting or to anaerobic fermentation for biogas production Only vegetable and animal household waste Only when produced in a closed and monitored collection system, accepted by the Member State Maximum concentrations in mg/kg of dry matter: cadmium: 0,7; copper: 70; nickel: 25; lead: 45; zinc: 200; mercury: 0,4; chromium (total): 70; chromium (VI): 0 ⁽³⁾ Need recognised by the inspection body or inspection authority Only during a period expiring on ► <u>M22</u> 31 March 2006 ◀

▼ M7

Name	Description, compositional requirements, conditions for use
— Peat	Use limited to horticulture (market gardening, floriculture, arboriculture, nursery)
▼ <u>M12</u>	
— Clays (e.g. perlite, vermiculite, etc.)	
▼ <u>M7</u>	
— 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
▼ <u>M20</u>	
— Composted or fermented mixture of vegetable matter	Product obtained from mixtures of vegetable matter, which have been submitted to composting or to anaerobic fermentation for biogas production
	Need recognised by the inspection body or inspection authority
▼ <u>M7</u>	
— Products or by-products of animal origin as below:	Need recognized by the inspection body or inspection authority
— blood meal	
— hoof meal	
— horn meal	
— bone meal or degelatinized bone meal	
▶ <u>M17</u> ————— ◀	
— fish meal	
— meat meal	
— feather, hair and 'chiquette' meal	
— wool	
— fur	
— hair	
— dairy products	▶ <u>M12</u> Maximum concentration in mg/kg of dry matter of Chromium (VI): 0 (°) ◀
— Products and by-products of plant origin for fertilizers	
(for instance, oilseed cake meal, cocoa husks, malt culms, etc.)	
▼ <u>M12</u>	
— Seaweeds and seaweed products	As far as directly obtained by:
	(i) physical processes including dehydration, freezing and grinding;
	(ii) extraction with water or aqueous acid and/or alkaline solution;
	(iii) fermentation;
	need recognized by the inspection body or inspection authority
▼ <u>M7</u>	
— 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 (°), as last amended by Directive 89/284/EEC (°)
	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 ▶ <u>C1</u> 89/284/EEC ◀;
	Cadmium content less than or equal to 90 mg/kg of P205

▼ **M7**

Name	Description, compositional requirements, conditions for use
— Basic slag	Use limited to basic soils (pH > 7,5)
— Crude potassium salt (for instance: kainit, sylvinit, etc.)	Need recognized by the inspection body or inspection authority

▼ **M17**

— Potassium sulphate, possibly containing magnesium salt	Product obtained from crude potassium salt by a physical extraction process, and containing possibly also magnesium salts Need recognised by the inspection body or inspection authority
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▼ **M7**

— Stillage and stillage extract	Ammonium stillage excluded
— Calcium carbonate of natural origin (for instance: chalk, marl, ground limestone, Breton ameliorant, (maërl), phosphate chalk)	Only of natural origin
— Magnesium and calcium carbonate of natural origin (for instance: magnesian chalk, ground magnesium limestone, etc.)	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

▼ **M20**

— Industrial lime from sugar production	Need recognised by the inspection body or inspection authority
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▼ **M7**

— 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 ⁽⁴⁾ Need recognized by the inspection body or inspection authority
— Sodium chloride	Only mined salt Need recognized by the inspection body or inspection authority
— Stone meal	

⁽¹⁾ OJ No L 218, 6. 8. 1991, p. 1.

⁽²⁾ OJ No L 338, 31. 12. 1993, p. 26.

► **M12** ⁽³⁾ Limit of determination. ◀

⁽⁴⁾ OJ No L 24, 30. 1. 1976, p. 21.

⁽⁵⁾ OJ No L 111, 22. 4. 1989, p. 34.

⁽⁶⁾ OJ No L 281, 30. 9. 1989, p. 116.

▼ **M15**

B. PESTICIDES

1. Products for plant protection

▼ **M12**

General conditions applicable for all the products composed or containing the following active substances:

- use in accordance with provisions of Annex I,
- only in accordance with the specific provisions of the plant protection product legislation applicable within the Member State where the product is used (where relevant (*)).

I. Substances of crop or animal origin

Name	Description; compositional requirements; conditions for use
▼ M17 Azadirachtin extracted from <i>Azadirachta indica</i> (Neem tree)	Insecticide Need recognised by the inspection body or inspection authority
▼ M12 (*) Beeswax	Pruning agent
Gelatine	Insecticide
(*) Hydrolysed proteins	Attractant; only in authorized applications in combination with other appropriate products of this Annex II, part B.
Lecithin	Fungicide
Extract (aqueous solution) from <i>Nicotiana tabacum</i>	Insecticide; only against aphids in subtropical fruit trees (e.g. oranges, lemons) and tropical crops (e.g. bananas); use only at the start of the vegetation period; need recognized by the inspection body or inspection authority; only during a period expiring 31 March 2002.
Plant oils (e.g. mint oil, pine oil, caraway oil).	Insecticide, acaricide, fungicide and sprout inhibitor.
▼ M20 Pyrethrins extracted from <i>Chrysanthemum cinerariaefolium</i>	Insecticide Need recognised by the inspection body or inspection authority
▼ M12 Quassia extracted from <i>Quassia amara</i> .	Insecticide, repellent
Rotenone extracted from <i>Derris spp.</i> and <i>Lonchocarpus spp.</i> and <i>Terphrosia spp.</i>	Insecticide; need recognized by the inspection body or inspection authority.
(*) In certain Member States the products market with (*) are not considered as plant protection products and are not subject to the provisions of the plant protection products legislation.	

(*) In certain Member States the products market with (*) are not considered as plant protection products and are not subject to the provisions of the plant protection products legislation.

▼ M12

II. Microorganisms used for biological pest control

Name	Description; compositional requirements; conditions for use
Microorganisms (bacteria, viruses and fungi) e.g. <i>Bacillus thuringiensis</i> , <i>Granulosis virus</i> , etc.	Only products not genetically modified in the meaning of Directive 90/220/EEC ⁽¹⁾ .
⁽¹⁾ OJ No L 117, 8. 5. 1990, p. 15.	

III. Substances to be used in traps and/or dispensers

General conditions:

- the traps and/or dispensers must prevent the penetration of the substances in the environment and prevent contact of the substances with the crops under cultivation.
- the traps must be collected after use and disposed of safely

Name	Description; composition requirements; conditions for use
(*) Diammonium phosphate	Attractant; only in traps
Metaldehyde	Molluscicide; only in traps containing a repellent to higher animal species; only during a period expiring ► <u>M22</u> 31 March 2006 ◀.
▼ <u>M17</u> Pheromones	Attractant; sexual behaviour disrupter; only in traps and dispensers.
▼ <u>M12</u> Pyrethroids (only deltamethrin or lambda-cyhalothrin)	Insecticide; only in traps with specific attractants; only against <i>Batrocera oleae</i> and <i>Ceratitis capitata</i> wied; need recognized by the inspection body or inspection authority.
▼ <u>M22</u>	_____
▼ <u>M12</u>	

(*) In certain Member States the products market with (*) are not considered as plant protection products and are not subject to the provisions of the plant protection products legislation.

▼ M22

IIIa Preparations to be surface-spread between cultivated plants

Name	Description; compositional requirements; conditions for use
Iron (III) orthophosphate	Molluscicide

▼ M12

IV. Other substances from traditional use in organic farming

▼ M22

Name	Description; compositional requirements; conditions for use
Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulphate, cuprous oxide	<p>Fungicide</p> <p>Until 31 December 2005 up to a maximum of 8 kg copper per hectare per year, and from 1 January 2006 up to 6 kg copper per ha per year, without prejudice to a more limited quantity if laid down under the specific terms of the general legislation on plant protection products in the Member State where the product is to be used</p> <p>For perennial crops, Member States may, by derogation to the previous paragraph, provide that the maximum levels apply as follows:</p> <ul style="list-style-type: none"> — the total maximum quantity used from 23 March 2002 until 31 December 2006 shall not exceed 38 kg copper per ha — from 1 January 2007, the maximum quantity which may be used each year per ha shall be calculated by subtracting the quantities actually used in the 4 preceding years from, respectively, 36, 34, 32 and 30 kg copper for the years 2007, 2008, 2009 and 2010 and following years <p>Need recognised by the inspection body or inspection authority</p>
(*) Ethylene	Degreening bananas
Fatty acid potassium salt (soft soap)	Insecticide
(*) Potassium alum (Kalinite)	Prevention of ripening of bananas
▼ <u>M17</u>	
Lime sulphur (calcium polysulphide)	Fungicide, insecticide, acaricide; need recognised by the inspection body or inspection authority.
▼ <u>M12</u>	
Paraffin oil	Insecticide, acaricide
Mineral oils	Insecticide, fungicide; only in fruit trees, vines, olive trees and tropical crops (e.g. bananas);
▼ <u>M22</u>	
▼ <u>M12</u>	
Potassium permanganate	need recognized by the inspection body or inspection authority.
Potassium permanganate	Fungicide, bactericide; only in fruit trees, olive trees and vines.
(*) Quartz sand	Repellent

▼ **M12**

Name	Description; compositional requirements; conditions for use
Sulphur	Fungicide, acaricide, repellent

(*) In certain Member States the products market with (*) are not considered as plant protection products and are not subject to the provisions of the plant protection products legislation.

▼ **M15**

2. Products for pest and disease control in livestock buildings and installations:

Products listed in Section 1

Rodenticides

C. FEED MATERIALS

▼ **M26**1. **Feed materials from plant origin**

- 1.1. Cereals, grains, their products and by-products. Only the following substances are included in this category:

oats as grains, flakes, middlings, hulls and bran; barley as grains, protein and middlings; rice germ expeller; millet as grains; rye as grains and middlings; sorghum as grains; wheat as grains, middlings, bran, gluten feed, gluten and germ; spelt as grains; triticale as grains; maize as grains, bran, middlings, germ expeller and gluten; malt culms; brewers' grains.

- 1.2. Oil seeds, oil fruits, their products and by-products. Only the following substances are included in this category:

rape seed, expeller and hulls; soya bean as bean, toasted, expeller and hulls; sunflower seed as seed and expeller; cotton as seed and seed expeller; linseed as seed and expeller; sesame seed as expeller; palm kernels as expeller; pumpkin seed as expeller; olives, olive pulp; vegetable oils (from physical extraction).

- 1.3. Legume seeds, their product and by-products. Only the following substances are included in this category:

chickpeas as seeds, middlings and bran; ervil as seeds, middlings and bran; chickling vetch as seeds submitted to heat treatment, middlings and bran; peas as seeds, middlings, and bran; broad beans as seeds, middlings and bran; horse beans as seeds middlings and bran, vetches as seeds, middlings and bran and lupin as seeds, middlings and bran.

- 1.4. Tuber, roots, their products and by-products. Only the following substances are included in this category:

sugar beet pulp, potato, sweet potato as tuber, potato pulp (by-product of the extraction of potato starch), potato starch, potato protein and manioc.

- 1.5. Other seeds and fruits, their products and by-products. Only the following substances are included in this category:

carob, carob pods and meals thereof, pumpkins, citrus pulp; apples, quinces, pears, peaches, figs, grapes and pulps thereof; chestnuts, walnut expeller, hazelnut expeller; cocoa husks and expeller; acorns.

- 1.6. Forages and roughages. Only the following substances are included in this category:

lucerne, lucerne meal, clover, clover meal, grass (obtained from forage plants), grass meal, hay, silage, straw of cereals and root vegetables for foraging.

- 1.7. Other plants, their products and by-products. Only the following substances are included in this category:

molasses, seaweed meal (obtained by drying and crushing seaweed and washed to reduce iodine content), powders and extracts of plants, plant protein extracts (solely provided to young animals), spices and herbs.

- 1.8. The following feed materials may be used until 30 June 2004: rice as grain, rice broken, rice bran, rye feed, rye bran, turnip rape seed expeller, turnip rape seed hulls and tapioca.

▼ **M26****2. Feed materials from animal origin**

- 2.1. Milk and milk products. Only the following substances are included in the category:

raw milk as defined in Article 2 of Directive 92/46/EEC⁽¹⁾, milk powder, skimmed milk, skimmed-milk powder, buttermilk, buttermilk powder, whey, whey powder, whey powder low in sugar, whey protein powder (extracted by physical treatment), casein powder, lactose powder, curd and sour milk.

- 2.2. Fish, other marine animals, their products and by-products. Only the following substances are included in the category:

fish, fish oil and cod-liver oil not refined; fish molluscan or crustacean autolysates, hydrolysate and proteolysates obtained by an enzyme action, whether or not in soluble form, solely provided to young animals. Fish meal.

- 2.3. Eggs and egg products for use as poultry feed, preferably from the same holding.

3. Feed materials from mineral origin

Only the following substances are included in this category:

Sodium:

unrefined sea salt

coarse rock salt

sodium sulphate

sodium carbonate

sodium bicarbonate

sodium chloride;

Potassium:

potassium chloride;

Calcium:

lithotamnion and maerl

shells of aquatic animals (including cuttlefish bones)

calcium carbonate

calcium lactate

calcium gluconate;

Phosphorus:

defluorinated dicalcium phosphate

defluorinated monocalcium phosphate

monosodium phosphate

calcium-magnesium phosphate

calcium-sodium phosphate;

Magnesium:

magnesium oxide (anhydrous magnesia)

magnesium sulphate

magnesium chloride

magnesium carbonate

magnesium phosphate;

Sulphur:

sodium sulphate.

Bone dicalcium phosphate precipitate may be used until 30 June 2004.

⁽¹⁾ OJ L 268, 14.9.1992, p. 1.

▼ **M15**

D. FEED ADDITIVES, CERTAIN SUBSTANCES USED IN ANIMAL NUTRITION (DIRECTIVE 82/471/EEC) AND PROCESSING AIDS USED IN FEEDINGSTUFFS

▼ **M26**1. **Feed additives**

1.1. Trace elements. Only the following substances are included in this category:

E1 Iron:

ferrous (II) carbonate
ferrous (II) sulphate monohydrate and/or heptahydrate
ferric (III) oxide;

E2 Iodine:

calcium iodate, anhydrous
calcium iodate, hexahydrate
sodium iodide;

E3 Cobalt:

cobaltous (II) sulphate monohydrate and/or heptahydrate
basic cobaltous (II) carbonate, monohydrate;

E4 Copper:

copper (II) oxide
basic copper (II) carbonate, monohydrate
copper (II) sulphate, pentahydrate;

E5 Manganese:

manganous (II) carbonate
manganous oxide and manganic oxide
manganous (II) sulfate, mono- and/or tetrahydrate;

E6 Zinc:

zinc carbonate
zinc oxide
zinc sulphate mono- and/or heptahydrate;

E7 Molybdenum:

ammonium molybdate, sodium molybdate;

E8 Selenium:

sodium selenate
sodium selenite.

1.2. Vitamins, provitamins and chemically well defined substances having a similar effect. Only the following substances are included in this category:

Vitamins authorised under Directive 70/524/EEC ⁽¹⁾:

- preferably derived from raw materials occurring naturally in feedingstuffs, or
- synthetic vitamins identical to natural vitamins only for monogastric animals.

By derogation from the first subparagraph, and during a transitional period ending on 31 December 2005, the competent authority of each Member State may authorise the use of synthetic vitamins of types A, D and E for ruminants in so far as the following conditions are met:

- the synthetic vitamins are identical to the natural vitamins, and
- the authorisation issued by the Member States is founded on precise criteria and notified to the Commission.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1. Directive 70/524/EEC will be repealed with effect from 19.10.2004. From that date, Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29) shall apply.

▼ **M26**

Producers may benefit from this authorisation only if they have demonstrated to the satisfaction of the inspection body or authority of the Member State that the health and welfare of their animals cannot be guaranteed without the use of these synthetic vitamins.

1.3. Enzymes. Only the following substances are included in this category:

Enzymes authorised under Directive 70/524/EEC.

1.4. Microorganisms. Only the following microorganisms are included in this category:

microorganisms authorised under Directive 70/524/EEC.

1.5. Preservatives. Only the following substances are included in this category:

E 200 Sorbic acid

E 236 Formic acid

E 260 Acetic acid

E 270 Lactic acid

E 280 Propionic acid

E 330 Citric acid.

The use of lactic, formic, propionic and acetic acid in the production of silage shall be only permitted when weather conditions do not allow for adequate fermentation.

1.6. Binders, anti-caking agents and coagulants. Only the following substances are included in this category:

E 470 Calcium stearate of natural origin

E 551b Colloidal silica

E 551c Kieselgur

E 558 Bentonite

E 559 Kaolinitic clays

E 560 Natural mixtures of stearites and chlorite

E 561 Vermiculite

E 562 Sepiolite

E 599 Perlite.

1.7. Antioxidant substances. Only the following substances are included in this category:

E 306 Tocopherol-rich extracts of natural origin

1.8. Silage additives. Only the following substances are included in this category:

as from 19 October 2004, enzymes, yeasts and bacteria authorised by Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

2. **Certain products used in animal nutrition**

Only the following products are included in this category:

brewer's yeasts.

3. **Processing aids used in feedingstuffs**

3.1. Processing aids for silage. Only the following substances are included in this category:

— sea salt, coarse rock salt, whey, sugar, sugar beet pulp, cereal flour and molasses,

— up to 18 October 2004, enzymes, yeasts, and lactic, acetic, formic, and propionic bacteria.

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E. PRODUCTS AUTHORISED FOR CLEANING AND DISINFECTION OF LIVESTOCK BUILDINGS AND INSTALLATIONS (E.G. EQUIPMENT AND UTENSILS)

Potassium and sodium soap

Water and steam

Milk of lime

Lime

Quicklime

Sodium hypochlorite (e.g. as liquid bleach)

Caustic soda

Caustic potash

Hydrogen peroxide

Natural essences of plants

Citric, peracetic acid, formic, lactic, oxalic and acetic acid

Alcohol

Nitric acid (dairy equipment)

Phosphoric acid (dairy equipment)

Formaldehyde

Cleaning and disinfection products for teats and milking facilities

Sodium carbonate

F. OTHER PRODUCTS

▼ **M21***ANNEX III***MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SCHEME REFERRED TO IN ARTICLES 8 AND 9**

GENERAL PROVISIONS

1. Minimum inspection requirements

The inspection requirements of this Annex shall apply without prejudice of the measures adopted by the Member States necessary to ensure traceability of the products, as referred to in Article 9(12)(a) and (c), during the entire production chain, and to ensure that the provisions of this Regulation are satisfied.

2. Implementation▼ **M23**

The operators already in activity at the date mentioned in Article 2 of Regulation (EC) No 2491/2001 shall also be subject to the provisions referred to in point 3 and to the initial inspection provisions foreseen in sections A, B, C, D and E of the specific provisions of this Annex.

▼ **M21****3. Initial inspection**

When the inspection arrangements are first implemented, the operator responsible must draw up:

- a full description of the unit and/or premises and/or activity,
- all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with this Regulation, and in particular with the requirements in this Annex.

The description and practical measures concerned must be contained in a declaration, signed by the responsible operator.

In addition, this declaration must include an undertaking by the operator:

- to perform the operations in accordance with Articles 5, 6, 6a and, where relevant, Article 11 ► **M23** and/or Regulation (EC) No 223/2003 ◀,
- to accept, in the event of infringement or irregularities, the enforcement of the measures referred to in Article 9(9) and, where relevant, in Article 10(3), and
- to accept to inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production.

This declaration must be verified by the inspection body or authority that issues a report identifying the possible deficiencies and non-compliances with the provisions of this Regulation. The operator must countersign this report and take the necessary corrective measures.

4. Communications▼ **M23**

The operator responsible must notify any change in the description or of the practical measures referred to in point 3 and in the initial inspection provisions foreseen in sections A, B, C, D and E of the specific provisions of this Annex to the inspection body or authority in due time.

▼ **M21****5. Inspection visits**

The inspection body or authority must make a full physical inspection, at least once a year, of the production/preparation units or other premises. The inspection body or authority may take samples for testing of products not authorised under this Regulation or for checking production techniques not in conformity with this Regulation. Samples may also be taken and analysed for detecting possible contamination by unauthorised products. However, such analysis must be carried out where the use of unauthorised products is suspected. An inspection report must be drawn up after each visit, countersigned by the responsible person of the unit or his representative.

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Moreover, the inspection body or authority shall carry out random inspection visits, announced or not. The visits shall cover in particular those holdings or situations where specific risk or exchange of products from organic production with other products may exist.

6. Documentary accounts

Stock and financial records must be kept in the unit or premises, to enable the operator and the inspection body or authority to trace:

- the supplier and, where different, the seller, or the exporter of the products,
- the nature and the quantities of agricultural products as referred to in Article 1 delivered to the unit and, where relevant, of all materials bought and the use of such materials ► **M23** and, where relevant, the composition of the compound feedingstuffs ◀,
- the nature, the quantities and the consignees and, where different, the buyers of any products as referred to in Article 1, which have left the unit or the first consignee's premises or storage facilities,
- any other information required by the inspection body or authority for the purpose of proper inspection.

The data in the accounts must be documented with appropriate justification documents.

The accounts must demonstrate the balance between the input and the output.

7. Packaging and transport of products to other production/preparation units or premises

The operators shall ensure that products as referred to in Article 1 may be transported to other units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) ► **M23** the name of the product or a description of the compound feedingstuff accompanied by a reference to the organic production method in accordance with, as applicable, Article 5 of this Regulation or Article 3 of Regulation (EC) No 223/2003. ◀
- (c) the name and/or the code number of the inspection body or authority to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the inspection body or authority and which permits to link the lot with the accounts referred to in point 6.

The information under (a), (b), (c) and (d) can also be presented on an accompanying document, if such document can be undeniably linked with the packaging, container or vehicle of the product. This accompanying document shall include information on the supplier and/or the transporter.

However, the closing of packaging, containers or vehicles is not required where:

- transportation is direct between a producer and another operator who are both subject to the inspection system referred to in Article 9, and
- the products are accompanied by a document giving the information required under the previous subparagraph, and
- the inspection body or authority of both the expediting and the receiving operators have been informed of such transport operations and have agreed thereto. Such agreement might be provided for one or more transport operation(s).

8. Storage of products

For the storage of products, areas must be managed in order to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with this Regulation.

9. Products suspected not to satisfy the requirements of the Regulation

Where an operator considers or suspects that a product which he has produced, prepared, imported or been delivered from another operator, is

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not in compliance with this Regulation, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He only may put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the inspection body or authority. The inspection body or authority may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

Where an inspection body or authority has a substantiated suspicion that an operator intends to place on the market a product not in compliance with this Regulation but bearing a reference to the organic production method, this inspection body or authority can require that the operator may provisionally not market the product with this reference. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the inspection body or authority is sure that the product does not fulfil the requirements of this Regulation. However if the suspicion is not confirmed, the above decision shall be cancelled not later than a time period after having been taken. The inspection body or authority shall define this time period. The operator shall cooperate fully with the inspection body or authority in resolving the suspicion.

10. Access to facilities

The operator must give the inspection body or authority, for inspection purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents. He must provide the inspection body or authority with any information deemed necessary for the purposes of the inspection.

When requested by the inspection body or authority, the operator shall submit the results of its own voluntary inspection and sampling programmes.

In addition, importers and first consignees must submit any import authorisations under Article 11(6) and certificates of inspection for import from third countries.

11. Exchange of information

Where the operator and his subcontractors are inspected by different inspection bodies or authorities, the declaration referred to in point 3 must include an agreement by the operator on his behalf and that of his subcontractors, that the different inspection bodies or authorities can exchange information on the operations under their inspection and on the way this exchange of information can be implemented.

SPECIFIC PROVISIONS

A. *Production of plants, plant products, livestock and/or livestock products*

This section applies to any unit involved in production as defined in Article 4(2) of products referred to in Article 1(1)(a) for its own account or for account of a third party.

Production must take place in a unit of which the production premises, land parcels, pasturage, open-air exercise areas, open air runs, livestock buildings, and, where applicable, the premises for the storage of crops, crop products, livestock products, raw materials and inputs, are clearly separate from those of any other unit not producing in accordance with the rules laid down in this Regulation.

Processing, packaging and/or marketing may take place at the production unit, where these activities are limited to its own agricultural produce.

Quantities sold directly to the final consumer shall be accounted on a daily basis.

Storage, in the unit, of input products other than those permitted by Article 6(1)(b) and (c) and Article 6(3)(a), is prohibited.

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 point 7 of the general provisions of this Annex. The result of this verification shall be explicitly mentioned

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in the documentary accounts referred to in point 6 of the general provisions.

A.1. Plants and plant products from farm production or collection**1. Initial inspection**

The full description of the unit referred to under point 3 of the general provisions of this Annex must:

- be drawn up even where the producer limits his activity to the collection of wild plants,
- show 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, and
- 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).

In case of collection of wild plants, the practical measures referred to under point 3 of the general provisions of this Annex must include the guarantees given by third parties which the producer can provide to ensure that the provisions of Annex I, section A, point 4, are complied with.

2. Communications

Each year, before the date indicated by the inspection body or authority, the producer must notify the body or authority of its schedule of production of crop products, giving a breakdown by parcel.

3. Several production units run by the same operator

Where an operator runs several production units in the same area, the units producing crops or crop products not covered by Article 1, together with storage premises for input products (such as fertilisers, plant protection products, seed) must also be subject to the general inspection arrangements laid down in the general provisions of this Annex as well as to the specific inspections provisions as regards points 1, 2, 3, 4 and 6 of the general provisions.

The same variety as, or a variety that cannot be easily differentiated from those produced at the unit referred to in the second paragraph of section A, 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 (edible fruit bearing trees, 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 point 1 and in point 3 of the general provisions 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;

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- (d) in the case of grassland exclusively used for grazing.

A.2. Livestock and livestock products produced by animal husbandry**1. Initial inspection**

When the inspection system applying specifically to livestock production is first implemented, the full description of the unit referred to under point 3 of the general provisions of this Annex must include:

- a full description of the livestock buildings, pasturage, open-air exercise areas, open-air runs, etc., and, where applicable, the premises for the storage, packaging and processing of livestock, livestock products, raw materials and inputs,
- a full description of the installations for the storage of livestock manure.

The practical measures referred to under point 3 of the general provisions of this Annex must include:

- plan for spreading manure agreed with the inspection body or authority, together with a full description of the areas given over to crop production,
- where appropriate, as regards the spreading of manure, the written arrangements with other holdings complying with the provisions of this Regulation,
- management plan for the organic-production livestock unit (e.g. management for feeding, reproduction, health, etc.).

2. Identification of livestock

The livestock must be identified permanently using techniques adapted to each species, individually in the case of large mammals and individually or by batch in the case of poultry and small mammals.

3. Livestock records

Livestock records must be compiled in the form of a register and kept available to the inspection authorities or bodies at all times at the address of the holding.

Such records, which are to provide a full description of the herd or flock management system, must contain the following information:

- by species, as regards livestock arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record,
- as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination,
- details of any animals lost and reasons,
- as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply,
- as regards disease prevention and treatment and veterinary care: date of treatment, diagnosis, type of treatment product, method of treatment and practitioner's prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed.

4. Several production units run by the same operator

Where a producer, in accordance with points 1.6 of section B and 1.3 of section C of Annex I manages several production units, the units which produce livestock or livestock products not covered by Article 1 must also be subject to the inspection system as regards point 1 of this subsection on livestock and livestock products and as regards the provisions on livestock management, livestock records and the principles governing storage of animal husbandry products used.

A derogation with regard to the requirement of different involved species in point 1.6 of Annex I, part B, may be granted to holdings carrying out agricultural research by the inspection body or authority in agreement with the competent authority of the Member State, where the following conditions are met:

- appropriate measures, agreed with the inspection body or authority have been taken in order to guarantee the permanent separation between livestock, livestock products, manure and feedingstuffs of each of the units,
- the producer informs the inspection body or authority in advance of any delivery or selling of the livestock or livestock products,

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- the operator informs the inspection body or authority of the exact quantities produced in the units together with all characteristics permitting the identification of the products and confirms that the measures taken to separate the products have been applied.

5. Other requirements

By way of a derogation from those rules, the storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in Annex I, that they are stored in a supervised location and that they are entered in the farm register.

B. *Units for preparation of plant and livestock products and foodstuffs composed of plant and livestock products*

This section applies to any unit involved in the preparation, as defined in Article 4(3), of products referred to in Article 1(1), for its own account or for account of a third party, and including in particular also:

- units involved in packaging and/or re-packaging of such products,
- units involved in labelling and/or re-labelling of such products.

1. Initial inspection

The full description of the unit referred to under point 3 of the general provisions of this Annex must show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.

2. Documentary accounts

The documentary accounts referred to in point 6 of the general provisions shall include the verification referred to in point 5 of this subsection.

3. Preparation units handling also products not from organic production

Where products not referred to in Article 1 are also prepared, packaged or stored in the preparation unit concerned:

- the unit must have areas separated by place or time 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 at regular times or on a fixed day, they must be announced in advance, with a deadline agreed on with the inspection body or authority,
- every measure must be taken to ensure identification of lots and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Regulation,
- operations on products in accordance with the rules laid down in this Regulation must be carried out only after cleaning of the production equipment. The effectiveness of the cleaning measures must be checked and recorded.

4. Packaging and transport of products to preparation units

Milk, eggs and egg-products from organic farming shall be collected independently from products not produced in accordance with this Regulation. By derogation, and subject to the prior approval by the inspection body or authority, simultaneous collection may occur, where appropriate measures are taken to prevent any possible mixture or exchange with products not produced in accordance with this Regulation and to ensure the identification of the products produced in accordance with the provisions of this Regulation. The operator keeps the information relating to collection days, hours, circuit and date and time of reception of the products available to the inspection body or authority.

5. Reception of products from other units

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 point 7 of the general provisions of this Annex. The operator shall crosscheck the information on the label referred to in point 7 of the general provisions with the

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information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in point 6 of the general provisions.

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- C. *Imports of plants, plant products, livestock, livestock products and foodstuffs comprising plant and/or livestock products, animal feedingstuffs, compound feedingstuffs and feed materials from third countries*

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This section applies to any operator involved, as importer and/or as first consignee, in the import and/or reception, for its own account or for account of another operator, of products referred to in Article 1(1). For the purpose of this section:

- the importer shall mean the natural or legal person within the European Community who presents a consignment for release for free circulation into the European Community, either on its own, or through a representative,
- the first consignee shall mean the natural or legal person referred to in Article 11(3)(a) to whom the consignment is delivered and who will receive it for further preparation and/or marketing.

1. Initial inspection*Importers*

- The full description of the unit referred to under point 3 of the general provisions of this Annex must include the importer's premises and of his import activities, indicating 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 pending their delivery to the first consignee,
- In addition, the declaration referred to under point 3 of the general provisions must include an undertaking by the importer to ensure that any facilities that the importer will use for storage of products are submitted to inspection, to be carried out either by the inspection body or authority or, when these storage facilities are situated in another Member State or region, by an inspection body or authority approved for inspection in that Member State or region.

First consignee

- The full description of the unit referred to under point 3 of the general provisions must show the facilities used for the reception and storage. Where other activities, like processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well the transport of the products, take place, the relevant provisions under section B shall apply.

When the importer and the first consignee are the same legal person and operating in one single unit, the reports referred to in point 3 of the general provisions can be formalised within one single report.

2. Documentary accounts

When the importer and the first consignee are not operating in one single unit, both of them must keep stock and financial records.

On request of the inspection body or authority, any details on the transport arrangements from the exporter in the third country to the first consignee and, from the first consignee's premises or storage facilities to the consignees within the Community must be provided.

3. Information on imported consignments

The importer shall, at the latest by the time that the certificate is submitted to the relevant Member State's authority in accordance with Article 4 point 1 of Commission Regulation (EC) No 1788/2001 of 7 September 2001 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs⁽¹⁾, inform the inspection body or authority of each consignment to be imported into the Community, giving:

- the name and address of the first consignee,

⁽¹⁾ OJ L 243, 13.9.2001, p. 3.

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- any details this body or authority may require, such as a copy of the inspection certificate for the importation of products from organic farming. On the request of the inspection body or authority of the importer, the latter must pass the information to the inspection body or authority of the first consignee.

4. Importers and first consignees handling also products not from organic production

When imported products referred to in Article 1 are stored in storage facilities where also other agricultural products or foodstuffs are 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 consignments and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Regulation.

5. Inspection visits

The inspection body or authority shall inspect the stock and financial records mentioned in section C, point 2 and the certificates referred to in Article 11(1)(b) and Article 11(3) and established by Regulation (EC) No 1788/2001.

Where the importer performs the import operations by different units or premises, he must make available on request, the reports foreseen under point 3 and 5 of the general provisions of this Annex for each of these facilities.

6. Reception of products from a third country

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 certificate of inspection for import from third countries.

On receipt of a product as referred to in Article 1, imported from a third country, the first consignee shall check the closing of the packaging or container and the correspondence of the identification of the consignment with the certificate referred to in Regulation (EC) No 1788/2001. The result of this verification shall be explicitly mentioned in the accounts referred to in section C, point 2.

D. Units involved in the production, preparation or import of products referred to in Article 1(1) and which have contracted out to third parties in part or in total the actual operations concerned**Initial inspection**

With regard to the operations, which are contracted out to third parties, the full description referred to in point 3 of the general provisions shall include:

- a list of the subcontractors with a description of their activities and the inspection bodies or authorities to which they are subject; these subcontractors must have agreed to have their holding being subject to the inspection regime of Article 9, in accordance with the relevant sections of Annex III,
- all the practical measures, including *inter alia* an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to their suppliers, and, where different, their sellers, as well as to their consignees and, where different, their buyers.

▼ **M23****E. Units preparing animal feedingstuffs, compound feedingstuffs and feed materials**

This section applies to any unit involved in the preparation, as defined in Article 4 point 3 of products referred to in Article 1(1)(c) on its own account or on behalf of a third party.

▼ **M23****1. Initial inspection**

The full description of the unit referred to under point 3 of the General Provisions of this Annex must:

- indicate the facilities used for the reception, preparation and storage of the products intended for animal feed before and after the operations concerning them,
- indicate the facilities used for the storage of other products used to prepare feedingstuffs,
- indicate the facilities used to store products for cleaning and disinfection,
- indicate, where necessary, the description of the compound feedingstuff that the operator intends to produce, in accordance with Article 5(1)(a) of Directive 79/373/EEC, and the livestock species or class for which the compound feedingstuff is intended,
- indicate, where necessary, the name of the feed materials that the operator intends to prepare.

The measures to be taken by operators, referred to in point 3 of the General Provisions of this Annex, to guarantee compliance with this Regulation must include:

- in particular an indication of the precautionary measures to be taken in order to reduce the risk of contamination by unauthorised substances or products, the cleaning measures implemented and the monitoring of their effectiveness,
- identification of all elements of their activities crucial for guaranteeing at all times that the products referred to in Article 1(1)(c) prepared in such units comply with this Regulation and with Regulation (EC) No 223/2003,
- the establishment and implementation of, compliance with and updating of appropriate procedures, based on the principles of the HACCP (Hazard Analysis and Critical Control Points) system.

The inspection body or authority shall use these procedures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up an inspection plan. This inspection plan must provide for a minimum number of random samples depending on the potential risks.

2. Documentary accounts

For the purposes of proper inspection of the operations, the documentary accounts referred to in point 6 of the General Provisions of this Annex shall include information on the origin, nature and quantities of feed materials, additives, sales and finished products.

3. Preparation units

When preparing products, operators must ensure that:

- (a) organically-produced feedingstuffs or feedingstuffs derived therefrom, in-conversion feedingstuffs or feedingstuffs derived therefrom, and conventional feedingstuffs are effectively physically separated;
- (b) all equipment used in units preparing compound feedingstuffs covered by this Regulation is completely separated from equipment used for compound feedingstuffs not covered by this Regulation.

Notwithstanding the provisions of point (b) of the first subparagraph, until 31 December 2007, operations may take place using the same equipment provided that:

- separation in terms of time is guaranteed and suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing preparation of the products covered by this Regulation; operators must record these operations,
- operators must ensure that all appropriate measures are implemented, depending on the risks evaluated in accordance with point 1, and, where necessary, guarantee that products which do not conform to this Regulation cannot be placed on the market with an indication referring to organic farming.

The derogation provided for in the second subparagraph is subject to prior authorisation by the inspection body or authority. Such authorisation might be provided for one or more preparation operation(s).

The Commission will start to examine the provisions of point (b) of the first subparagraph before 31 December 2003. Account being taken from that examination, the date of 31 December 2007 may be revised if necessary.

▼ **M23****4. Inspection visits**

In addition to the complete annual visit, the inspection body or authority must make targeted visits based on a general evaluation of the potential risks of non-compliance with this Regulation; the inspection body or authority shall pay particular attention to the critical control points pointed out for the operator, with a view to establishing whether the surveillance and checking operations are carried out as they should be. All the premises used by the operator for the conduct of his activities may be inspected as frequently as the attendant risks warrant.

5. Transporting products to other production/preparation units or storage premises

Operators must ensure that the following conditions are met:

- (a) during transport, organically-produced feedingstuffs or feedingstuffs derived therefrom, in-conversion feedingstuffs or feedingstuffs derived therefrom, and conventional feedingstuffs must be effectively physically separated;
- (b) the vehicles and/or containers which have transported products that are not covered by this Regulation may be used to transport products covered by this Regulation if:
 - suitable cleaning measures, the effectiveness of which has been checked, have been carried out before commencing the transport of products covered by this Regulation; operators must record these operations,
 - operators must ensure that all appropriate measures are implemented, depending on the risks evaluated in accordance with point 1, and, where necessary, guarantee that products which do not conform to this Regulation cannot be placed on the market with an indication referring to organic farming,
 - the inspection body or authority of the operator has been informed of such transport operations and has agreed thereto. Such agreement might be provided for one or more transport operation(s);
- (c) the finished products referred to in this Regulation are transported separately from other finished products physically or in time;
- (d) during transport, the quantity of products at the start and each individual quantity delivered in the course of a delivery round must be recorded.

6. Receipt of products

On receipt of a product referred to in Article 1, operators must check the closure of the packaging or container where it is required and the presence of the indications referred to in point 7 of the General Provisions of this Annex. Operators must carry out a cross-check of the information on the label referred to in point 7 of the General Provisions against the information on the accompanying documents. The results of this verification must be explicitly mentioned in the accounts referred to in point 6 of the General Provisions.

*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.

▼ **M16***ANNEX V***PART A: 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 Ecológica — Sistema de control CE
DA: Økologisk Jordbrug — EF-kontrolordning
DE: Ökologischer Landbau — EG-Kontrollsystem or Biologische Landwirtschaft — EG-Kontrollsystem
EL: Βιολογική γεωργία — Σύστημα ελέγχου ΕΚ
EN: Organic Farming — EC Control System
FR: Agriculture biologique — Système de contrôle CE
IT: Agricoltura Biologica — Regime di controllo CE
NL: Biologische landbouw — EG-controlesysteem
PT: Agricultura Biológica — Sistema de Controlo CE
FI: Luonnonmukainen maataloustuotanto — EY:n valvontajärjestelmä
SV: Ekologiskt jordbruk — EG-kontrollsystem

PART B: COMMUNITY LOGO

- B.1. Conditions with regard to the presentation and use of the Community logo**
- B.1.1. The Community logo referred to above shall comprise of the models in part B.2 of this Annex.
- B.1.2. The indications that must be included in the logo are listed in part B.3 of this Annex. It is possible to combine the logo with the indication mentioned in part A to this Annex.
- B.1.3. To use the Community logo and the indications referred to in part B.3 of this Annex, the technical reproduction rules laid down in the graphic manual in part B.4 of this Annex must be complied with.

▼ M16

B.2. Models

Español



Dansk



Deutsch



Deutsch



Ελληνικά



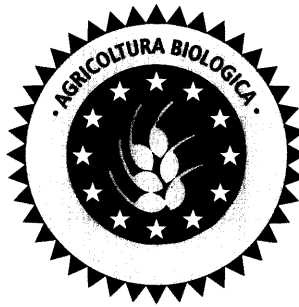
English



Français



Italiano



Nederlands



Português



Suomi



Svenska



▼ M16

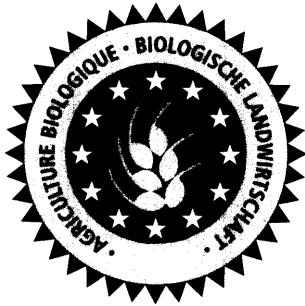
Nederlands/Français



Suomi/Svenska



Français/Deutsch



▼M16**B.3. Indications to be inserted in the Community logo****B.3.1. Single indications:**

ES:	AGRICULTURA ECOLÓGICA
DA:	ØKOLOGISK JORDBRUG
DE:	BIOLOGISCHE LANDWIRTSCHAFT or ÖKOLOGISCHER LANDBAU
EL:	ΒΙΟΛΟΓΙΚΗ ΓΕΩΡΓΙΑ
EN:	ORGANIC FARMING
FR:	AGRICULTURE BIOLOGIQUE
IT:	AGRICOLTURA BIOLOGICA
NL:	BIOLOGISCHE LANDBOUW
PT:	AGRICULTURA BIOLÓGICA
FI:	LUONNONMUKAINEN MAATALOUSTUOTANTO
SV:	EKOLOGISKT JORDBRUK

B.3.2. Combination of two indications:

Combinations of two indications referring to the languages mentioned under B.3.1. are authorised, subject of being developed in accordance with the following examples:

NL/FR:	BIOLOGISCHE LANDBOUW — AGRICULTURE BIOLOGIQUE
FI/SV:	LUONNONMUKAINEN MAATALOUSTUOTANTO — EKOLOGISKT JORDBRUK
FR/DE:	AGRICULTURE BIOLOGIQUE — BIOLOGISCHE LAND- WIRTSCHAFT

▼M16**B.4. Graphic manual****CONTENTS**

1. Introduction	
2. General use of the logo	
2.1. Coloured logo (reference colours)	
2.2. Single-colour logo: logo in black and white	
2.3. Contrast with background colours	
2.4. Typography	
2.5. Language	
2.6. Reduction sizes	
2.7. Particular conditions to use the logo	
3. Original Bromides	
3.1. Two-colour selection	
3.2. Outlines	
3.3. Single-colour: logo in black and white	
3.4. Colour samples sheets	

▼M16

1. INTRODUCTION

The graphic manual is an instrument for the operators to reproduce the logo.

2. GENERAL USE OF THE LOGO

2.1. COLOURED LOGO (reference colours)

When the coloured logo is used, this logo must appear in colour by using direct colours (Pantone) or a four-colour process. The reference colours are indicated hereunder.

LOGO IN PANTONE



GREEN: Pantone 367
 BLUE: Pantone Reflex Blue
 Text in blue

LOGO IN FOUR-COLOUR PROCESS



BLUE: 100 % cyan + 80 % magenta
 GREEN: 30,5 % cyan + 60 % yellow
 Text in blue

▼ **M16**

2.2. SINGLE-COLOUR LOGO: LOGO IN BLACK AND WHITE

The logo in black and white can be used as shown:



▼ M16**2.3. CONTRAST WITH BACKGROUND COLOURS**

If the logo is used in colour on coloured backgrounds which makes it difficult to read, use a delimiting outer circle around the logo to improve its contrast with the background colours as shown:

LOGO IN COLOURED BACKGROUND**2.4. TYPOGRAPHY**

Use Frutiger bold condensed in capitals for the wording. The letter size of the wording shall be reduced according to the norms set down in Section 2.6.

2.5. LANGUAGE

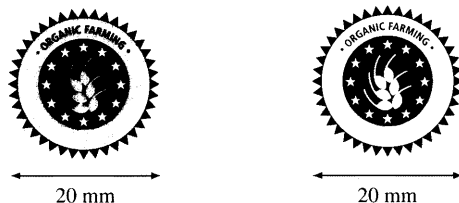
You are free to use the language version or versions of your choice according to the specifications indicated in B.3.

▼ **M16**

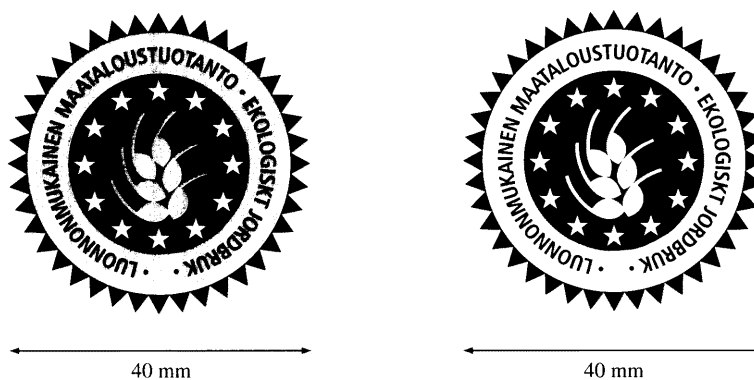
2.6. REDUCTION SIZES

If the application of the logo on different types of labelling makes reduction necessary, the minimum size shall be:

- (a) For a logo with a single indication: minimum size 20 mm diameter.



- (b) For a logo with a combination of two indications: minimum size 40 mm diameter.



2.7. PARTICULAR CONDITIONS TO USE THE LOGO

The use of the logo serves to confer specific value to the products. The most effective application of the logo is therefore in colour, since it will thus have a greater presence and be recognised more easily and quickly by the consumer.

The use of the logo using a single colour (black and white) as established in Section 2.2 is only recommended in cases where its application in colour is not practical.

▼ **M16**

3. ORIGINAL BROMIDES

3.1. TWO-COLOUR SELECTION

— Single indication in all the languages

ESPAÑOL

PANTONE 367

PANTONE REFLEX BLUE



▼M16

DANSK

PANTONE 367

PANTONE REFLEX BLUE



▼M16

DEUTSCH

PANTONE 367

PANTONE REFLEX BLUE



▼M16

DEUTSCH

PANTONE 367

PANTONE REFLEX BLUE



▼M16

ΕΛΛΗΝΙΚΑ

PANTONE 367

PANTONE REFLEX BLUE



▼M16

ENGLISH

PANTONE 367

PANTONE REFLEX BLUE

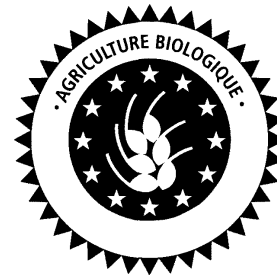
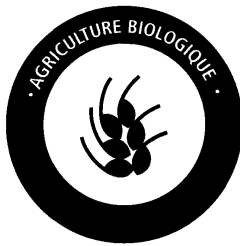
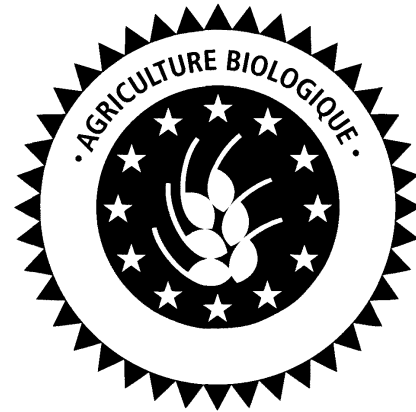


▼M16

FRANÇAIS

PANTONE 367

PANTONE REFLEX BLUE



▼M16

ITALIANO

PANTONE 367

PANTONE REFLEX BLUE

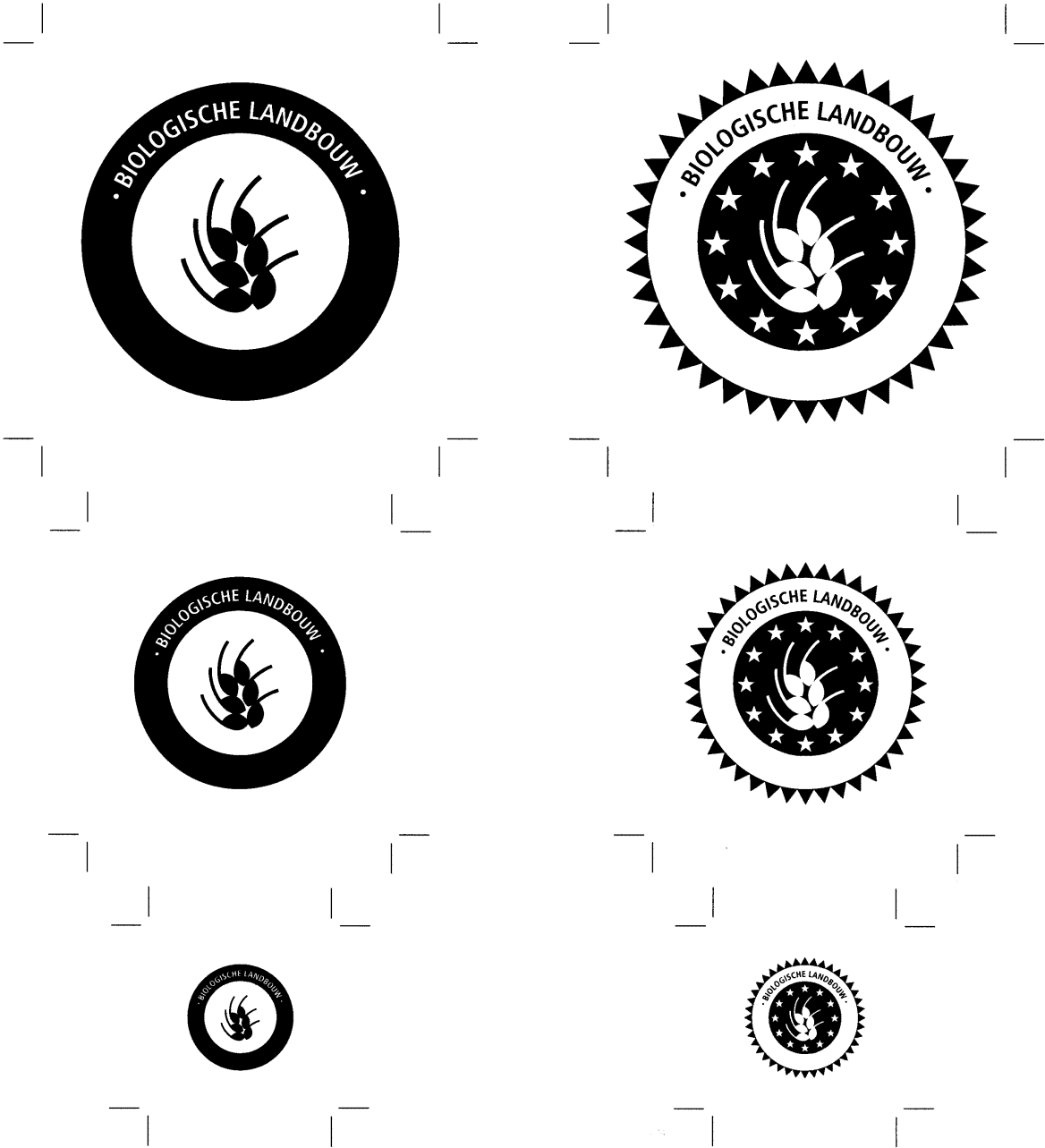


▼M16

NEDERLANDS

PANTONE 367

PANTONE REFLEX BLUE



▼M16

PORTUGUÊS

PANTONE 367

PANTONE REFLEX BLUE



▼M16

SUOMI

PANTONE 367

PANTONE REFLEX BLUE



▼M16

SVENSKA

PANTONE 367

PANTONE REFLEX BLUE



▼ **M16**

— The examples of the language combinations referred to in B.3.2

NEDERLANDS/FRANÇAIS

PANTONE 367

PANTONE REFLEX BLUE



▼M16

SUOMI/SVENSKA

PANTONE 367

PANTONE REFLEX BLUE

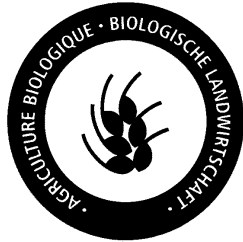
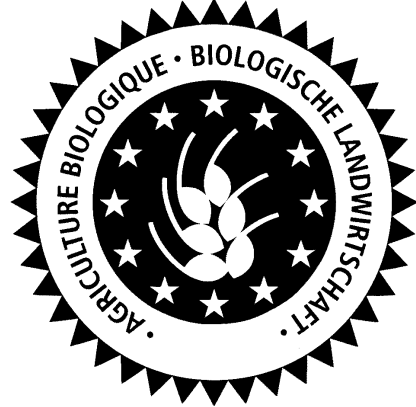
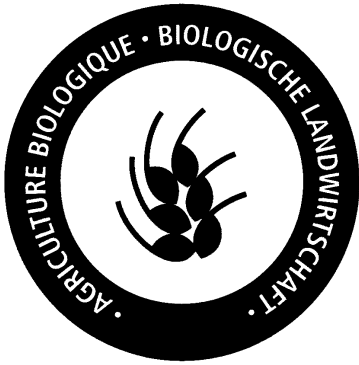


▼ M16

FRANÇAIS/DEUTSCH

PANTONE 367

PANTONE REFLEX BLUE



▼ **M16**

3.2. OUTLINES



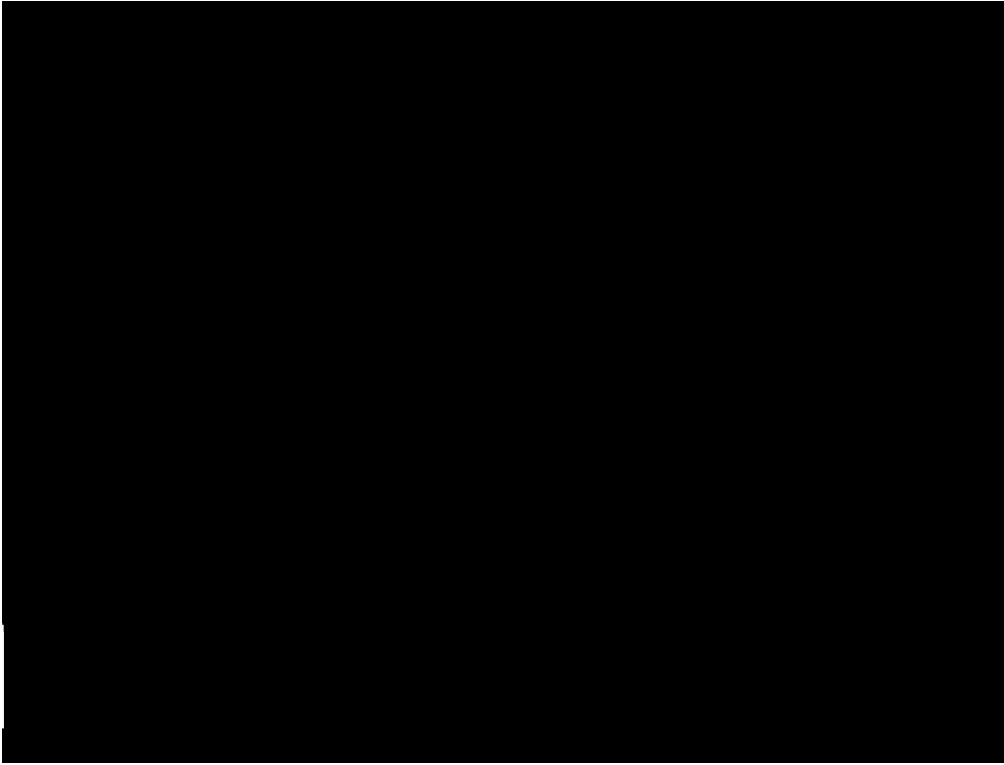
3.3. SINGLE-COLOUR: LOGO IN BLACK AND WHITE



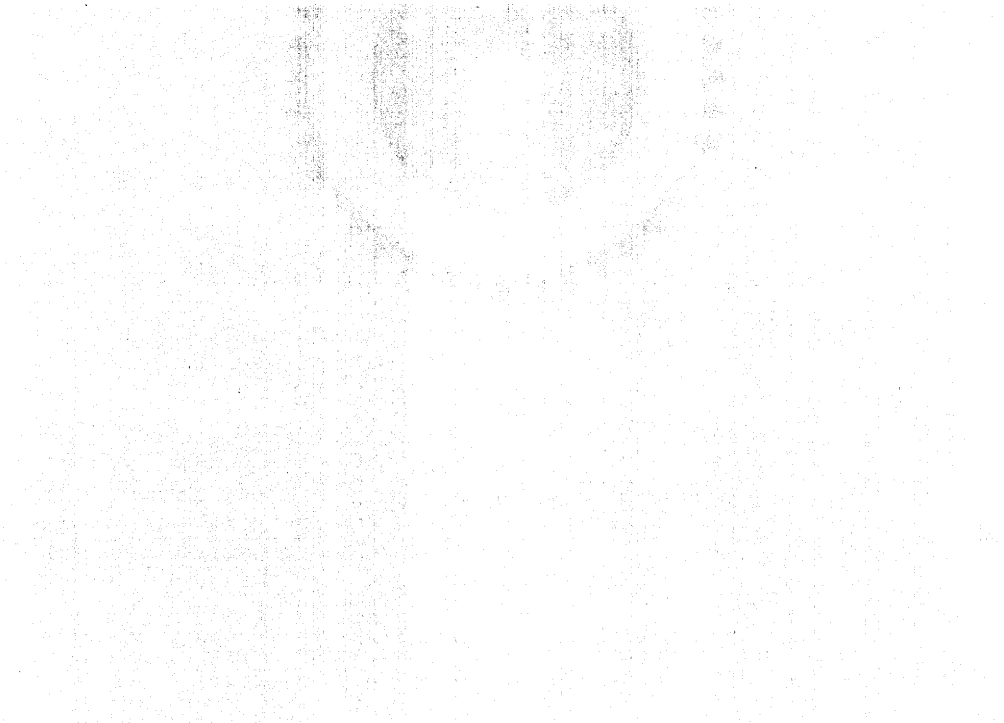
▼ **M16**

3.4. COLOUR SAMPLE SHEETS

PANTONE REFLEX BLUE



PANTONE 367



▼ **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.

▼ **M15**

Pending the adoption of rules in Sections A and B of this Annex, and in order to cover specifically the preparation of foodstuffs composed of one or more live-stock products, national rules shall apply.

▼ **M3**

► **M17** Notwithstanding reference to any ingredient in Sections A and C or any processing aid in Section B, any processing practice, such as smoking, shall be carried out and 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, additives 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

⁽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

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⁾.

▼ M17

**SECTION A — INGREDIENTS OF NON-AGRICULTURAL ORIGIN
(REFERRED TO IN ARTICLE 5(3)(c) AND ARTICLE
5(5a)(d) OF REGULATION (EEC) No 2092/91)**

▼ M3

A.1. Food additives, including carriers

	Name	Specific conditions (*)
▼ <u>M17</u>	E 170 Calcium carbonates	all authorised functions except colouring
▼ <u>M3</u>	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	—
▼ <u>M17</u>	E 422 Glycerol	plant extracts
▼ <u>M3</u>	E 440 (i) Pectin	—
	E 500 Sodiumcarbonates	—
	E 501 Potassiumcarbonates	—

⁽¹⁾ OJ No L 157, 24. 6. 1988, p 28.

▼ M3

	Name	Specific conditions (*)
E 503	Ammoniumcarbonates	—
E 504	Magnesiumcarbonates	—

▼ M17

E 516	Calcium sulphate	carrier
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▼ M5

E 524	Sodiumhydroxyde	surface treatment of Laugengebäck
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▼ M17

E 551	Silicon dioxide	anti-caking agent for herbs and spices
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▼ M3

E 938	Argon	—
E 941	Nitrogen	—
E 948	Oxygen	—

(*) 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.

▼ M17

▼ M12

A.5. Minerals (trace elements included), vitamins, aminoacids and other nitrogen compounds

Minerals (trace elements included), vitamins, aminoacids and other nitrogen compounds, only authorized as far their use is legally required in the foodstuffs in which they are incorporated.

▼ M17

SECTION B — PROCESSING AIDS AND OTHER PRODUCTS WHICH MAY BE USED FOR PROCESSING OF INGREDIENTS OF AGRICULTURAL ORIGIN FROM ORGANIC PRODUCTION, REFERRED TO IN ARTICLE 5(3)(d) AND ARTICLE 5(5a)(e) OF REGULATION (EEC) No 2092/91

▼ M3

	Name	Specific conditions
	Water	
	Calcium chloride	coagulation agent
	Calcium carbonate	
	Calcium hydroxide	
	Calcium sulphate	coagulation agent
	Magnesium chloride (or nigari)	coagulation agent

▼ M3

Name	Specific conditions
Potassium carbonate	drying of grapes

▼ M5

Sodium carbonate	sugar production
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▼ M12

Citric acid	oil production and hydrolysis of starch
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▼ M5

Sodium hydroxyde	► <u>M12</u> — sugar production — oil production from rape seed (<i>Brassica spp</i>) ► <u>M22</u> — ◀ ◀
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Sulphuric acid	sugar production
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▼ M17

Isopropanol (propan-2-ol)	in the crystallisation process in sugar preparation in due respect of the provisions of Directive 88/344/EEC, as last amended by Directive 97/60/EEC for a [...] period expiring on 31.12.2006
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▼ M3

Carbon dioxide	
----------------	--

Nitrogen	
----------	--

Ethanol	solvent
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Tannic acid	filtration aid
-------------	----------------

Egg white albumen	
-------------------	--

Casein	
--------	--

Gelatin	
---------	--

Isinglass	
-----------	--

Vegetable oils	► <u>M5</u> greasing, releasing or antifoaming agent ◀
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Silicon dioxide gel or colloidal solution	
---	--

Activated carbon	
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Talc	
------	--

Bentonite	
-----------	--

Kaolin	
--------	--

Diatomaceous earth	
--------------------	--

Perlite	
---------	--

Hazelnut shells	
-----------------	--

▼ M5

Rice meal	—
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▼ M3

Beeswax	releasing agent
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Carnauba wax	releasing agent
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▼ M17

Preparations of micro-organisms and enzymes:

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, and with the exception of enzymes derived from genetically modified organisms within the meaning of Article 2(2) of Directive 90/220/EEC.

▼ **M19****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) of the introduction of this Annex:

C.1.1. Edible fruits, nuts and seeds:

acorns	<i>Quercus</i> spp.
cola nuts	<i>Cola acuminata</i>
gooseberries	<i>Ribes uva-crispa</i>
maracujas (passion fruit)	<i>Passiflora edulis</i>
raspberries (dried)	<i>Rubus idaeus</i>
red currants (dried)	<i>Ribes rubrum</i>

C.1.2. Edible spices and herbs:

nutmeg	<i>Myristica fragrans</i> , until 31.12.2000 only
pepper green	<i>Piper nigrum</i> , until 30.4.2001 only
pepper (Peruvian)	<i>Schinus molle</i> L.
horseradish seeds	<i>Armoracia rusticana</i>
lesser galanga	<i>Alpinia officinarum</i>
safflower flowers	<i>Carthamus tinctorius</i>
watercress herb	<i>Nasturtium officinale</i>

C.1.3. Miscellaneous:

algae, including seaweed, permitted in conventional foodstuffs preparation

C.2. Vegetable products, processed by processes as referred to under definition 2(b) of the introduction of this Annex

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

cocoa	<i>Theobroma cacao</i>
coconut	<i>Cocos nucifera</i>
olive	<i>Olea europaea</i>
sunflower	<i>Helianthus annuus</i>
palm	<i>Elaeis guineensis</i>
rape	<i>Brassica napus, rapa</i>
safflower	<i>Carthamus tinctorius</i>
sesame	<i>Sesamum indicum</i>
soya	<i>Glycine max</i>

C.2.2. The following sugars, starches and other products from cereals and tubers:

beet sugar, until 1.4.2003 only
fructose
rice paper
unleavened bread paper
starch from rice and waxy maize, not chemically modified

▼ M19

C.2.3. Miscellaneous:

coriander, smoked	<i>Coriandrum sativum</i>	until 31.12.2000 only
pea protein	<i>Pisum</i> spp.	
rum, only obtained from cane sugar juice		
kirsch prepared on the basis of fruits and flavourings as referred to in section A.2 of this Annex		
mixtures of crops permitted in conventional foodstuffs preparation, and giving colouring and tasting qualities to confectionary, only for preparation of 'Gummi Bärchen', until 30.9.2000 only		
mixtures of the following peppers: <i>Piper nigrum</i> , <i>Schinus molle</i> and <i>Schinus terebinthifolium</i> , until 31.12.2000 only		

C.3. Animal products:

aquatic organisms, not originating from aquaculture, and permitted in conventional foodstuffs preparation		
buttermilk powder		until 31.8.2001 only
gelatin		
honey		until 28.2.2001 only
lactose		until 31.8.2001 only
whey powder 'herasuola'		

▼ M22

casings		until 1 April 2004 only
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▼ **M15***ANNEX VII*

Maximum number of animals per ha Class or species	Maximum number of animals per ha equivalent to 170 kg N/ha/year
Equines over six months old	2
Calves for fattening	5
Other bovine animals less than one year old	5
Male bovine animals from one to less than two years old	3,3
Female bovine animals from one to less than two years old	3,3
Male bovine animals two years old or over	2
Breeding heifers	2,5
Heifers for fattening	2,5
Dairy cows	2
Cull dairy cows	2
Other cows	2,5
Female breeding rabbits	100
Ewes	13,3
Goats	13,3
Piglets	74
Breeding sows	6,5
Pigs for fattening	14
Other pigs	14
Table chickens	580
Laying hens	230

▼ **M15***ANNEX VIII***Minimum surface areas indoors and outdoors and other characteristics of housing in the different species and types of production**

1. BOVINES, OVINE AND PIGS

	Indoors area (net area available to animals)		Outdoors area (exercise area, excluding pasturage)
	Live weight minimum (kg)	M ² /head	M ² /head
Breeding and fattening bovine and equidae	up to 100	1,5	1,1
	up to 200	2,5	1,9
	up to 350	4,0	3
	over 350	5 with a minimum of 1 m ² /100 kg	3,7 with a minimum of 0,75 m ² /100 kg
Dairy cows		6	4,5
Bulls for breeding		10	30
Sheep and goats		1,5 sheep/goat	2,5
		0,35 lamb/kid	2,5 with 0,5 per lamb/kid
Farrowing sows with piglets up to 40 days		7,5 sow	2,5
Fattening pigs	up to 50	0,8	0,6
	up to 85	1,1	0,8
	up to 110	1,3	1
Piglets	over 40 days and up to 30 kg	0,6	0,4
Brood pigs		2,5 female	1,9
		6,0 male	8,0

▼ **M15**

2. POULTRY

	Indoors area (net area available to animals)			Outdoors area (m ² of area available in rotation/ head)
	No animals/m ²	cm perch/animal	nest	
Laying hens	6	18	8 laying hens per nest or in case of common nest 120 cm ² /bird	4, provided that the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry (in fixed housing)	10 with a maximum of 21 kg live-weight/m ²	20 (for guinea fowl only)		4 broilers and guinea fowl 4,5 ducks 10 turkey 15 geese In all the species mentioned above the limit of 170 kg of N/ha/year is not exceeded
Fattening poultry in mobile housing	16 (*) in mobile poultry houses with a maximum of 30 kg live-weight/m ²			2,5, provided that the limit of 170 kg of N/ha/year is not exceeded

(*) Only in the case of mobile houses not exceeding 150 m² floor space which remain open at night.