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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 3636/93

of 16 December 1993

opening and providing for the administration of Community tariff quotas for certain fruits and fruit juices

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission,

Whereas pursuant to the Agreement with the United States of America on the Mediterranean preferences, citrus and pasta, the Community has undertaken to suspend provisionally and in part the customs duties applicable to certain fruits and fruit juices within the limits of Community tariff quotas of appropriate volumes and of varying duration; whereas in order to ensure the balance of reciprocal concessions provided for in the Agreement, the Commission may, by means of a Regulation, suspend the application of the tariff measures in question;

Whereas the use of these tariff quotas is, however, conditional on presentation to the Community customs authorities of a certificate of authenticity issued by the competent authorities of the country of origin certifying that the products comply with the specific characteristics laid down;

Whereas Community tariff quotas for sweet oranges of high quality, citrus hybrids known as 'Minneolas' and certain types of frozen concentrated orange juice should therefore be opened for all or part of 1994;

Whereas all Community importers should be ensured equal and continuous access to the said quotas and the duty rates laid down for the quotas should be applied consistently to all imports of the products in question into all Member States until the quotas are exhausted;

Whereas the decision for the opening, in the execution of its international obligations, of tariff quotas should be taken by the Community; whereas, to ensure the efficiency of a common administration of these quotas, there is no reasonable obstacle to authorizing the Member States to draw from the quota-volumes the necessary quantities corresponding to actual imports; whereas this method of administration requires close cooperation between the Member States and the Commission and the latter must in particular be able to monitor the rate at which the quotas are used up and inform the Member States accordingly;

Whereas since the Kingdom of Belgium, the Kingdom of the Netherlands and the Grand Duchy of Luxembourg are united within, and jointly represented by, the Benelux Economic Union, any operation concerning the administration of quantities drawn by that economic union may be carried out by any one of its members,

HAS ADOPTED THIS REGULATION:

Article 1

The customs duties applicable to imports of the following products shall be suspended during the periods, at the levels and within the limits of the Community tariff quotas shown below:

Series No	CN code (*)	Description	Quota period	Quota volume (tonnes)	Rate of duty (%)
09.0025	ex 0805 10 11, 15, 19, 41, 45, 49	Sweet oranges of high quality	From 1 February to 30 April 1994	20 000	10
09.0027	ex 0805 20 90	Citrus hybrids known as 'Minneolas'	From 1 February to 30 April 1994	15 000	2
09.0033	ex 2009 11 99	Frozen concentrated orange juice having a degree of concentration of up to 50 degrees Brix, in containers of two litres or less, not containing blood orange concentrate	From 1 January to 31 December 1994	1 500	13

(*) See Taric codes in Annex III.

Article 2

1. For the purposes of this Regulation:

- (a) sweet oranges of high quality means oranges of similar varietal characteristics which are mature, firm, well-formed, at least fairly well coloured, of fairly smooth texture and are free from decay, broken skins which are not healed, hard or dry skins, exanthema, growth cracks, bruises (except those incident to normal handling and packing), and are free from damage caused by dryness or mushy condition, split, rough, wide or protruding navels, creasing, scars, oil spots, scale, sunburn, dirt or other foreign material, disease, insects or damage caused by mechanical or other means, provided that not more than 15 % of the fruit in any lot fails to meet these specifications and, included in this amount, not more than 5 % shall be allowed for defects causing serious damage and, included in this latter amount, not more than 0,5 % may be affected by decay;
- (b) citrus fruit hybrids known as 'Minneolas' means hybrids of the citrus fruit variety 'Minneola' (*Citrus paradisi Macf. cv. Duncan* and *Citrus reticulata blanca cv. Dancy*);
- (c) frozen concentrated orange juice having a degree of concentration of up to 50 degrees Brix means orange juice that has a density of 1,229 g/cm³ or less at 20 °C.

2. Use of the tariff quotas referred to in paragraph 1 shall be subject to:

- presentation, in support of the entry for release for free circulation, of a certificate of authenticity conforming to one of the models in Annex I, issued by the competent authorities of the country of origin — listed in Annex II — certifying that the products

shown on it possess the specific characteristics referred to in paragraph 1, or

- in the case of concentrated orange juice, presentation to the Commission before importation of a general attestation in which the competent authority of the country of origin certifies that concentrated orange juice produced in that country does not contain the juice of blood oranges. The Commission shall inform the Member States to enable them to notify the customs departments concerned.

Article 3

The tariff quotas referred to in Article 1 shall be managed by the Commission, which may take any appropriate administrative measures to ensure that they are managed efficiently.

Article 4

Where an importer presents a product covered by this Regulation for release for free circulation in a Member State, applying to take advantage of the preferential arrangements, and the entry is accepted by the customs authorities, the Member State concerned shall, by notifying the Commission, draw an amount corresponding to its requirements from the quota volume.

Requests for drawings, indicating the date on which the entries were accepted, must be sent to the Commission without delay.

Drawings shall be granted by the Commission in chronological order of the dates on which the customs authorities of the Member States concerned accepted the entries for release for free circulation, to the extent that the available balance so permits.

If a Member State does not use a drawing in full it shall return any unused portion to the corresponding quota volume as soon as possible.

If the quantities requested are greater than the available balance of the quota volume, the balance shall be allocated among applicants pro rata. The Commission shall inform the Member States accordingly.

Article 5

Each Member State shall ensure that importers of the products in question have equal and continuous access to the quotas for as long as the balance of the relevant quota volume so permits.

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

Done at Brussels, 16 December 1993.

Article 6

Member States and the Commission shall cooperate closely to ensure that this Regulation is complied with.

Article 7

The Commission may, by means of a Regulation, suspend the application of the tariff quotas opened for by this Regulation if the reciprocity provided for in the Agreement is no longer ensured.

Article 8

This Regulation shall enter into force on 1 January 1994.

For the Council

The President

R. URBAIN

ANEXO I — BILAG I — ANHANG I — ΠΑΡΑΡΤΗΜΑ I — ANNEX I — ANNEXE I — ALLEGATO I — BIJLAGE I — ANEXO I

MODELOS DE CERTIFICADO
MODELLER TIL CERTIFIKAT
MUSTER DER BESCHEINIGUNGEN
ΥΠΟΔΕΙΓΜΑ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ
MODEL CERTIFICATES
MODÈLES DE CERTIFICAT
MODELLI DI CERTIFICATO
MODELLEN VAN CERTIFICAAT
MODELOS DE CERTIFICADO

1 Exporter (Name, full address, country)	2 Number	00000	
3 Consignee (Name, full address, country)	CERTIFICATE OF AUTHENTICITY FRESH SWEET ORANGES 'HIGH QUALITY'		
	4 Country of origin	5 Country of destination	
6 Place and date of shipment — Means of transport	7 Supplementary details		
8 Marks and numbers — Number and kind of packages — DETAILED DESCRIPTION OF GOODS	9 Gross weight (kg)	10 Net weight (kg)	
	11 CERTIFICATION BY THE COMPETENT AUTHORITY I hereby certify that the above sweet oranges consist of oranges of similar varietal characteristics which are mature, firm, well-formed, fairly well-coloured, of fairly smooth texture and are free from decay, broken skins which are not healed, hard or dry skins, exanthema, growth cracks, bruises (except those incident to proper handling and packing), and are free from damage caused by dryness or mushy condition, split, rough, wide or protruding navels, creasing, scars, oil spots, scale, sunburn, dirt or other foreign material, disease, insects or damage caused by mechanical or other means, provided that not more than 15 % of the fruit in any lot fails to meet these specifications and, included in this amount, not more than 5 % shall be allowed for defects causing serious damage, and, included in this latter amount, not more than 0,5 % may be affected by decay.		
12 Competent authority (Name, full address, country)	At, on <div style="display: flex; justify-content: space-around;"> (Signature) (Seal) </div>		

1 Exporter (Name, full address, country)	2 Number	00000	
3 Consignee (Name, full address, country)	CERTIFICATE OF AUTHENTICITY FRESH MINNEOLA		
	4 Country of origin	5 Country of destination	
6 Place and date of shipment — Means of transport	7 Supplementary details		
8 Marks and numbers — Number and kind of packages — DETAILED DESCRIPTION OF GOODS	9 Gross weight (kg)	10 Net weight (kg)	
11 CERTIFICATION BY THE COMPETENT AUTHORITY I hereby certify that the citrus described in this certificate are fresh citrus hybrid of the variety Minneola (<i>Citrus paradisi</i> Macf. C.V. Duncan and <i>Citrus reticulata</i> blanco C.V. Dancy).			
12 Competent authority (Name, full address, country)	At, on (Signature) (Seal)		

1 Exporter (Name, full address, country)	2 Number	00000	
3 Consignee (Name, full address, country)	CERTIFICATE OF AUTHENTICITY CONCENTRATED ORANGE JUICE		
	4 Country of origin	5 Country of destination	
6 Place and date of shipment — Means of transport	7 Supplementary details		
8 Marks and numbers — Number and kind of packages — DETAILED DESCRIPTION OF GOODS	9 Gross weight (kg)	10 Net weight (kg)	
	11 CERTIFICATION BY THE COMPETENT AUTHORITY I hereby certify that the above frozen concentrated orange juice has a density of 1,229 g/cm ³ or less and does not contain blood orange juice.		
12 Competent authority (Name, full address, country)	At, on <div style="display: flex; justify-content: space-around;"> (Signature) (Seal) </div>		

ANEXO II — BILAG II — ANHANG II — ΠΑΡΑΡΤΗΜΑ II — ANNEX II — ANNEXE II — ALLEGATO II — BIJLAGE II — ANEXO II

País de origen Oprindelsesland Ursprungsland Χώρα καταγωγής Country of origin Pays d'origine Paesi di origine Land van oorsprong País de origem	Autoridad competente Kompetent myndighed Zuständige Behörde Αρχόδια υπηρεσία Competent authority Autorité compétente Autorità competente Bevoegde autoriteit Autoridade competente
1. <i>Para los 3 contingentes — For de 3 kontingenter — Für die 3 Kontingente — Για τις 3 ποσοστώσεις — For the 3 quotas — Pour les 3 contingents — Per i 3 contingentii — Voor de 3 contingenten — Para os 3 contingentes</i>	
Estados Unidos De Forenede Stater USA ΗΠΑ USA États-Unis d'Amérique Stati Uniti Verenigde Staten Estados Unidos da América	United States Department of Agriculture
Cuba Cuba Kuba Κούβα Cuba Cuba Cuba Cuba Cuba	Ministère de l'Agriculture
Argentina Argentina Argentinien Αργεντινή Argentina Argentine Argentina Argentinii Argentina	Dirección Nacional de Producción y Comercialización de la Secretaría de Agricultura, Ganadería y Pesca
2. <i>Únicamente para los híbridos de agrios conocidos por el nombre de «Minneolas» — udelukkende til krydsninger af citrusfrugter, benævnt »Minneolas« — Nur für Kreuzungen von Zitrusfrüchten, bekannt unter dem Namen „Minneolas“ — μόνα για τα υβρίδια εσπεριδοειδών γνωστά με την ονομασία «Minneolas» — Only for citrus fruit known as 'Minneolas' — Uniquement pour les hybrides d'agrumes connus sous le nom de «Minneolas» — Solo per ibridi d'agrume conosciuti sotto il nome di «Minneolas» — Uitsluitend voor kruisingen van citrusvruchten die bekend staan als „minneola's” — Somente para os citrinos híbridos conhecidos pelo nome de «Minneolas»</i>	
Israel Israel Israel Ισραήλ Israel Israël Israele Israël Israel	Ministry of Agriculture, Department of Plant Protection and Inspection
Chypre Cypren Zypern Κύπρος Cyprus Chypre Cipro Cyprus Chipre	Ministry of Commerce and Industry Produce Inspection Service

ANEXO III — BILAG III — ANHANG III — ΠΑΡΑΡΤΗΜΑ ΙΙΙ — ANNEX III — ANNEXE III — ALLEGATO III —
BIJLAGE III — ANEXO III

Número de orden Løbenummer Laufende Nummer Αύξων αριθμός Order No Numéro d'ordre Numero d'ordine Volgnummer Número de ordem	Código NC KN-kode KN-Code Κωδικός ΣΟ CN code Code NC Codice NC GN-code Código NC	Código Taric Taric-kode Taric-Code Κωδικός Taric Taric code Code Taric Codice Taric Taric-code Código Taric
09.0025	ex 0805 10 11 ex 0805 10 15 ex 0805 10 19 ex 0805 10 41 ex 0805 10 45 ex 0805 10 49	* 10 * 10 * 10 * 18 * 18 * 18
09.0027	ex 0805 20 90	* 17 * 27
09.0033	ex 2009 11 99	* 10

COUNCIL REGULATION (EC) No 3637/93

of 16 December 1993

opening and providing for the administration of Community tariff quotas bound in GATT for certain agricultural and industrial products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 113 thereof,

Having regard to the proposal from the Commission,

Whereas the Community has undertaken, within the framework of the General Agreement on Tariffs and Trade (GATT), to open yearly reduced or zero-duty Community tariff quotas on certain conditions for certain agricultural and industrial products; whereas the tariff quotas in question should accordingly be opened for 1994, specifying, where appropriate, the agreed entry conditions;

Whereas all Community importers should be ensured equal and continuous access to the said quotas and the duty rates laid down for the quotas should be applied consistently to all imports of the products in question into all Member States until the quotas are exhausted;

Whereas the decision for the opening, in the execution of its international obligations, of tariff quotas should be

taken by the Community; whereas, to ensure the efficiency of a common administration of these quotas, there is no reasonable obstacle to authorizing the Member States to draw from the quota-volumes the necessary quantities corresponding to actual imports; whereas this method of administration requires close cooperation between the Member States and the Commission and the latter must in particular be able to monitor the rate at which the quotas are used up and inform the Member States accordingly;

Whereas, since the Kingdom of Belgium, the Kingdom of the Netherlands and the Grand Duchy of Luxembourg are united within and jointly represented by the Benelux Economic Union, any operation concerning the administration of quantities drawn by that economic union may be carried out by any one of its members,

HAS ADOPTED THIS REGULATION:

Article 1

1. The customs duties applicable to imports of the following products shall be suspended during the periods, at the levels and within the limits of the Community tariff quotas shown below:

Order No	CN code (a)	Description	Quota period	Quota volume	Rate of duty (%)
09.0006	0302 40 90 0303 50 90 0304 10 93 ex 0304 10 98 0304 90 25	Herring, subject to compliance with the reference prices	From 16 June 1994 to 14 February 1995	34 000 tonnes	0
09.0007	ex 0305 51 10 ex 0305 51 90 0305 59 11 0305 59 19 ex 0305 62 00 0305 69 10	Cod of the species <i>Gadus morhua</i> or <i>Gadus ogac</i> and fish of the species <i>Boreogadus saida</i> , dried, salted or in brine, whole, headless or in pieces	From 1 January to 31 December 1994	25 000 tonnes	0
09.0009	ex 0302 69 65 ex 0303 78 10 ex 0304 90 47	Silver hake (<i>Merluccius bilinearis</i>), fresh, chilled or frozen	From 1 January to 31 December 1994	2 000 tonnes	8

(a) See Taric codes annexed.

Order No	CN code (a)	Description	Quota period	Quota volume	Rate of duty (%)
09.0011	ex 0304 20 29	Frozen cod fillets (<i>Gadus morhua</i>)	From 1 January to 31 December 1994	10 000 tonnes	8
09.0013	ex 4412 19 00 ex 4412 99 90	Plywood of coniferous species, without the addition of other substances: — of a thickness greater than 8,5 mm, the faces of which are not further prepared than the peeling process — sanded, and of a thickness greater than 18,5 mm	From 1 January to 31 December 1994	600 000 m ³	0
09.0015 09.0017	4801 00 01	Newsprint ⁽¹⁾ : — from Canada — from other third countries	From 1 January to 31 December 1994	600 000 tonnes 50 000 tonnes	0 0
09.0019	7202 21 10 7202 21 90 7202 29 00	Ferro-silicon	From 1 January to 31 December 1994	12 600 tonnes	0
09.0021	7202 30 00	Ferro-silicon-manganese	From 1 January to 31 December 1994	18 550 tonnes	0
09.0023	ex 7202 49 10 ex 7202 49 50	Ferro-chromium containing not more than 0,10% by weight of carbon and more than 30% but not more than 90% of chromium (super-refined ferrochromium)	From 1 January to 31 December 1994	2 950 tonnes	0
09.0039	0805 30 10	Lemons (<i>Citrus limon</i> , <i>Citrus limonum</i>)	From 15 January to 14 June 1994	10 000 tonnes	6
09.0041	0802 11 90 0802 12 90	Almonds, whether or not shelled, other than bitter almonds	From 1 January to 31 December 1994	45 000 tonnes	2

(a) See Taric codes annexed.

⁽¹⁾ Entry under this subheading is subject to conditions determined by the relevant Community provisions.

2. Imports of products listed in paragraph 1 which are subject to a lower or equal customs duty under other preferential tariff arrangements shall not be charged against the corresponding tariff quota.

Article 2

1. Without prejudice to the Community's international obligations, Member States may charge against the tariff quotas referred to in Article 1 (1) under order Nos 09.0015 and 09.0017 other types of paper

corresponding, except as regards the criterion relating to watermarks, to the definition of newsprint contained in additional note 1 of Chapter 48 of Part Two of the combined nomenclature and falling within CN code 4801 00 90.

2. From 30 November 1994 imports of newsprint from Canada or from other third countries may be charged against the remainder of either of the quota volumes for newsprint referred to in Article 1 (1) not used by 29 November 1994 and not expected to be used by 31 December 1994.

Article 3

The tariff quotas referred to in Article 1 shall be managed by the Commission, which may take any appropriate administrative measures to ensure that they are managed efficiently.

Article 4

Where an importer presents a product covered by this Regulation for release for free circulation in a Member State, applying to take advantage of the preferential arrangements, and the entry is accepted by the customs authorities, the Member State concerned shall, by notifying the Commission, draw an amount corresponding to its requirements from the quota volume.

Requests for drawings, indicating the date on which the entries were accepted, must be sent to the Commission without delay.

Drawings shall be granted by the Commission in chronological order of the dates on which the customs authorities of the Member States concerned accepted the entries for release for free circulation, to the extent that the available balance so permits.

If a Member State does not use a drawing in full, it shall return any unused portion to the corresponding quota volume as soon as possible.

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

Done at Brussels, 16 December 1993.

If the quantities requested are greater than the available balance of the quota volume, the balance shall be allocated among applicants pro rata. The Commission shall inform the Member States accordingly.

Article 5

Each Member State shall ensure that importers of the products in question have equal and continuous access to the quotas for as long as the balance of the relevant quota volume so permits.

Article 6

Member States and the Commission shall cooperate closely to ensure that this Regulation is complied with.

Article 7

The Commission may, by means of a Regulation, suspend the application of the tariff quotas opened for lemons and almonds under order Nos 09.0039 and 09.0041 if the reciprocity provided for is no longer ensured.

Article 8

This Regulation shall enter into force on 1 January 1994.

For the Council

The President

R. URBAIN

ANNEX

Taric codes

Order No	CN code	Taric code
09.0006	ex 0304 10 98	* 14 * 16
09.0007	ex 0305 51 10	* 10 * 20
	ex 0305 51 90	* 10 * 20
	ex 0305 62 00	* 10 * 30
09.0009	ex 0302 69 65	* 10
	ex 0303 78 10	* 10
	ex 0304 90 47	* 20
09.0011	ex 0304 20 29	* 12 * 18
09.0013	ex 4412 19 00	* 10
	ex 4412 99 90	* 10
09.0023	ex 7202 49 10	* 10
	ex 7202 49 50	* 10

COUNCIL DIRECTIVE 93/113/EC

of 14 December 1993

concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition

THE COUNCIL OF THE EUROPEAN UNION,

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 of the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽⁴⁾, lays down the principles relating to the admission and the use of additives;

Whereas Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in feedingstuffs ⁽⁵⁾ constitutes a guide for defining the scientific information necessary to identify and characterize these products as well as the studies necessary to evaluate, in particular, their efficacy and innocuousness for humans, animals and the environment;

Whereas advances in scientific and technological knowledge permit the use of certain enzymes, micro-organisms and their preparations in animal nutrition in order in particular to improve the digestibility of such nutrients, or to stabilize the flora of the digestive system of animals and to reduce the ejection of certain undesirable substances into the environment; whereas at the moment no criteria exist for the examination of requests for authorization for use as additives of this new generation of products;

Whereas it is essential, pending amendment of the guidelines and in order to allow the preparation of dossiers for these products, to allow provisionally the use and marketing of enzymes, micro-organisms and their preparations at national level, provided they do not present any danger to human or animal health;

Whereas allowing these products necessitates an inventory of them in each Member State, and the transmission to the Commission of certain information justifying their inclusion in national lists;

Whereas Member States may not restrict the marketing of livestock products obtained from feeds containing enzymes, micro-organisms or their preparations when these are included on a national list established according to this Decision;

Whereas this Directive does not apply to enzymes, micro-organisms, or to their preparations when used as silage agents;

Whereas this Directive applies without prejudice to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ⁽⁶⁾;

Whereas this Directive is to apply without prejudice to Directive 70/524/EEC;

Whereas Directive 87/153/EEC should quickly be amended accordingly, with a view to making available the necessary rules for the specific examination of additives belonging to the new group of enzymes and micro-organisms; whereas, in the meantime, the dossiers to be submitted with a view to assessing products included in the national lists must be prepared according to the guidelines established for additives in general;

Whereas it is advisable that industry be given sufficient time to apply the new labelling provisions laid down for enzymes, micro-organisms and their preparations as well as premixtures and feedingstuffs containing them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition.

⁽¹⁾ OJ No C 116, 27. 4. 1993, p. 6.

⁽²⁾ OJ No C 329, 6. 12. 1993.

⁽³⁾ OJ No C 201, 26. 7. 1993, p. 34.

⁽⁴⁾ OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Directive 93/114/EC (see page 24 of this Official Journal).

⁽⁵⁾ OJ No L 64, 7. 3. 1987, p. 19.

⁽⁶⁾ OJ No L 117, 8. 5. 1990, p. 15.

2. This Directive shall apply without prejudice to Directive 70/524/EEC and particularly to the provisions concerning the authorization of enzymes, micro-organisms and their preparations for use as additives.

Article 2

1. By way of derogation from Article 3 of Directive 70/524/EEC, Member States shall temporarily allow the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition within their territory, provided that, on the basis of the information available, the products do not present a danger to human or animal health, and that they are included in the list established by virtue of Article 3.

2. All forms of use for animal nutrition other than the incorporation of such products into feedingsuffs shall be prohibited.

Article 3

On the basis of the information provided by the persons responsible for putting the products into circulation Member States shall forward:

(a) to the Commission before 1 November 1994:

- a list of enzymes and micro-organisms and their preparations according to the model given in Annex I,
- an identification note drawn up for each product according to the model given in Annex II by the person responsible for putting the product into circulation;

(b) to the Commission and to the other Member States before 1 January 1996, the dossiers to justify these authorizations by the person(s) responsible requesting the inclusion of their product(s) in the list referred to in the first indent of point (a).

Article 4

1. As and when the requested information reaches it, the Commission shall communicate to Member States the lists of enzymes, micro-organisms or their preparations sent to it in accordance with Article 3.

2. Where enzymes, micro-organisms or preparations manufactured from them are included in several national lists, it may be agreed between the Member States concerned that a single dossier should be submitted by one of them. In this case the Member State appointed to submit the dossier shall inform the Commission accordingly.

3. Before 31 March 1996 and on the basis of the dossiers which have been forwarded to it in accordance with Article 3, the Commission shall publish in the 'C' series of the *Official Journal of the European Communities* a list of enzymes, micro-organisms and

their preparations permitted in the various Member States.

Article 5

Before 1 January 1997, a ruling will be given in accordance with the procedure laid down in Article 24 of Directive 70/524/EEC on the dossiers referred to in Article 3 (b) concerning the authorization of additives in animal nutrition.

Article 6

Where Member States find it impossible to satisfy one of the conditions referred to in Article 3, for an enzyme, micro-organisms or preparation used in their territory, they shall take all the necessary measures to ensure that the enzyme, micro-organism or preparation obtained from them is no longer used or marketed in their territories.

Article 7

1. Enzymes, micro-organisms and their preparations, as well as premixtures and compound feedingsuffs in which they have been incorporated, may be marketed only if the particulars listed below, which must be clearly visible, legible and indelible and for which the producer, packer, importer, vendor or distributor established within the Community shall be held responsible, are shown on the packaging, the container or on a label attached thereto:

A. for enzymes and their preparations:

- (a) the specific name of the active constituent(s) according to their enzymatic activity(ies) and the identification number(s) according to the International Union of Biochemistry;
- (b) the activity units (activity units ⁽¹⁾ per g or activity units per ml);
- (c) the name or business name and the address or registered place of business of the person responsible for the particulars in this paragraph;
- (d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;
- (e) the expiry date of the guarantee or the storage life from the date of manufacture;
- (f) the batch reference number and the date of manufacture;
- (g) directions for use and where appropriate, a safety recommendation;
- (h) the net weight and for liquid additives either the net volume or the net weight;
- (i) the indication 'to be used exclusively for the manufacture of feedingsuffs';

(1) Units of activity expressed as μmole of product released per minute per gram of enzymatic preparation.

B. for micro-organisms and their preparations:

- (a) the identifications of the strain(s) according to a recognized international code of nomenclature and the deposit number of the strain(s);
- (b) the number of colony-forming units (CFU/g);
- (c) the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;
- (e) the expiry date of the guarantee or the storage life from the date of manufacture;
- (f) the batch reference number and the date of manufacture;
- (g) the directions for use and, where appropriate, a safety recommendation;
- (h) the net weight and for liquid additives either the net volume or the net weight;
- (i) the indication 'to be used exclusively in the manufacture of feedingstuffs';
- (j) where appropriate, indication of any particular significant characteristics due to the manufacturing process;

C. for premixtures containing enzymes:

- (a) the description 'premixture';
- (b) the indication 'to be used exclusively in the manufacture of feedingstuffs';
- (c) the directions for use and any safety recommendations regarding the use of premixtures;
- (d) the animal species or category of animals for which the premixture is intended;
- (e) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (f) the net weight and for liquids either the net volume or the net weight;
- (g) the specific name of the active constituent(s) according to their enzymatic activity(ies) and the identification number(s) according to the International Union of Biochemistry;
- (h) the activity units (activity units per g or activity units per ml);
- (i) the expiry date of the guarantee or the storage life from the date of manufacture;
- (j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

D. for premixtures containing micro-organisms:

- (a) the description 'premixture';
- (b) the indication 'to be used exclusively in the manufacture of feedingstuffs';

- (c) the directions for use and any safety recommendations regarding the use of premixtures;
- (d) the animal species or category of animals for which the premixture is intended;
- (e) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;
- (f) the net weight and for liquids either the volume or net weight;
- (g) the identification of the strain(s) according to a recognized international code of nomenclature and the deposit number(s) of the strain(s);
- (h) the number of colony-forming units (CFU/g);
- (i) the expiry date of the guarantee or the storage life from the date of manufacture;
- (j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;
- (k) where appropriate, indication of any particular significant characteristics due to the manufacturing process;

E. for compound feeds into which enzymes have been incorporated:

- (a) the specific name of the active constituent(s) according to their enzymatic activity(ies) and the identification number according to the International Union of Biochemistry;
- (b) the activity units (activity units per kg or activity units per l) provided that such units are measurable by an official or scientifically valid method);
- (c) the expiry date of the guarantee or the storage life from the date of manufacture.

F. For compound feeds into which micro-organisms have been incorporated:

- (a) the identification of the strain(s) according to a recognized international code of nomenclature and the deposit number(s) of the strain(s);
- (b) the number of colony-forming units (CFU/kg) provided that the number is measurable by an official or scientifically valid method;
- (c) the expiry date of the guarantee or the storage life from the date of manufacture;
- (d) where appropriate, indication of any particular significant characteristics due to the manufacturing process.

2. Particulars other than those prescribed in paragraph 1, under A, B, C and D such as the trade name, may be included on the packaging, containers or on a label attached thereto, provided that they are clearly separated from the said particulars.

Article 8

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than:

- 1 January 1995 as regards Article 7, and
- 1 October 1994 as regards the other provisions.

They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they

adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 9

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 14 December 1993.

For the Council

The President

A. BOURGEOIS

ANNEX I

Model layout for the list mentioned in Article 3 (a) first indent

Trade name	Active constituent(s) ⁽¹⁾	Activity unit(s) per g or number of colony-forming units per g	Person responsible for putting into circulation (name and address)

⁽¹⁾ For micro-organisms: the identification of the strain according to a recognized international code of nomenclature and the deposit number of the strain.

For enzymes: the specific name according to their enzymatic activity, the identification number according to the International Union of Biochemistry and, where they are of microbial origin, the identification of the strain according to a recognized international code of nomenclature and the deposit number of the strain.

ANNEX II

MODEL OF IDENTIFICATION NOTE REFERRED TO ARTICLE 3 (a) SECOND INDENT

(to be filled in by the person responsible for putting the product into circulation)

1. Identity of the product

Trade name.

Qualitative and quantitative composition:

- active substance ⁽¹⁾,
- other components,
- impurities,
- undesirable substances.

Name or business name and address or registered place of business of the manufacturer.

Place of manufacture

Name or business name and address or registered place of business of the person responsible for placing the product on the market, if he is not the manufacturer.

2. Specifications concerning the active substance

2.1. For micro-organisms:

- name and taxonomic description according to an international code of nomenclature ⁽²⁾,
- name and place of culture collection where the strain is registered and deposited and the number of registration and deposit,
- state whether genetic manipulation has taken place,
- the number of colony-forming units (CFU/g).

2.2. For enzymes:

- name according to main enzymatic activities and Community number ⁽³⁾,
- state the biological origin. In the case of microbial origin, the information required in the first two indents of point 2.1, must be given,
- state whether the organism of origin has been genetically manipulated,
- relevant activities with regard to appropriate types of chemically pure substrates (expressed in activity units ⁽⁴⁾ per g).

NB: If the active substance is a mixture of active components, all the components must be described separately with an indication of their proportion in the mixture.

3. Properties of the product

Main effect:

- information concerning effectiveness,
- justification for the presence of each component if the substance is a mixture of active components.

Other effects.

⁽¹⁾ If the active substance is a mixture of clearly definable active components, indicate the main components.

⁽²⁾ Such as 'Bergey's Manual of Systematic Bacteriology', 'The Yeasts, a taxonomic study' by Lodder and Kreger van Rij, 'Ainsworth and Bisby's Dictionary of the Fungi' by Hawksworth, Sutton and Ainsworth or 'The Genus *Asperigillus*' by Raper and Fennel.

⁽³⁾ Enzyme Nomenclature Recommendations (1984) of the Nomenclature Committee of the International Union of Biochemistry, Academic Press 1984.

⁽⁴⁾ Activity units expressed as μ mole of product released per minute per gram of enzymatic preparation.

4. Product safety

Available information on safety.

5. Conditions for the use of product

Uses provided for in animal nutrition (species or categories of animal, type of feedingstuffs, period of use, etc).

Proposed dosage in premixes and feedingstuffs (appropriate units of biological activity such as CFU per gram of product for micro-organisms or activity units per gram for enzyme preparations).

Other known uses of the active substance or the preparation (in foodstuffs, human or veterinary medicine, industry etc).

Recommendations concerning product safety in relation to targeted species, the consumer and the environment.

If necessary, measures for the prevention of risks and means of protection during manufacture and use.

6. Technological information

Stability of the product:

- with regard to atmospheric agents,
- during the preparation of premixes and feedingstuffs,
- during the storage of premixes and feedingstuffs,
- description of the process of manufacture and methods used concerning the control of the quality of the product during its manufacture.

7. Control

Method(s) of analysis for determining the active component(s) in:

- the product itself,
- premixes,
- feedingstuffs.

8. Attestation of the person responsible certifying the accuracy of the information given.

COUNCIL DIRECTIVE 93/114/EC

of 14 December 1993

amending Directive 70/524/EEC concerning additives in feedingstuffs

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European 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 Council Directive 70/524/EEC concerning additives in feedingstuffs ⁽⁴⁾ lays down the principles relating to the authorization and the use of additives;

Whereas the inclusion of enzyme and micro-organisms in Directive 70/524/EEC means that products belonging to both of these new categories and their manufacturers are subject to the same requirements which apply to the authorization of additives and to manufacturers in general; whereas it is particularly necessary to ensure that the products marketed are innocuous to the environment, workers, animal owners and consumers of animal products and furthermore that they satisfy the requirements set as regards effectiveness, quality and ability to be checked;

Whereas in order to make possible the evaluation and authorization of enzymes produced by or derived from genetically modified organisms, the Commission must provide an assessment of such products with the aim of preventing damage to human or animal health or the environment;

Whereas it appears necessary for the Scientific Committee for Feedingstuffs to be assisted by experts in the field of genetic engineering and in assessing risks linked to the use of genetically modified organisms, so as to ensure that the testing procedure is such as to rule out any damaging effects on human or animal health or the environment caused by the products concerned;

Whereas in the Community authorization procedure for additives the requirements of Directive 90/220/EEC ⁽⁵⁾ concerning a specific environmental risk evaluation must be applied in respect of all additives containing or consisting of genetically modified organisms; whereas these requirements should therefore be inserted in Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition ⁽⁶⁾, and that they apply concomitantly with this Directive;

Whereas advances in scientific and technological knowledge permit the use of certain enzymes, micro-organisms and their preparations in animal nutrition in order to improve the digestibility of nutrients or to stabilize the flora of the digestive system of animals and to reduce the quantity of certain environmentally undesirable substances;

Whereas Directive 93/113/EEC ⁽⁷⁾ permits the Member States to allow temporarily and subject to certain conditions the use and marketing of enzymes, micro-organisms and their preparations at national level until those products receive Community authorization pursuant to Directive 70/524/EEC;

Whereas the granting of such authorization implies that special labelling provisions be inserted in the abovementioned Directive for this new generation of additives and for the premixtures and feedingstuffs into which they are incorporated,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 70/524/EEC is hereby amended as follows:

1. the following Article shall be inserted after Article 7:

'Article 7a

If an additive contains or consists of genetically modified organisms within the meaning of Article 2

⁽¹⁾ OJ No C 117, 17. 4. 1993, p. 11

⁽²⁾ OJ No C 329, 6. 12. 1993.

⁽³⁾ OJ No C 201, 26. 7. 1993, p. 33.

⁽⁴⁾ OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 93/55/EEC (OJ No L 206, 18. 8. 1993, p. 11).

⁽⁵⁾ OJ No L 117, 8. 5. 1990, p. 15.

⁽⁶⁾ OJ No L 64, 7. 3. 1987, p. 19.

⁽⁷⁾ See page 17 of this Official Journal.

(1) and (2) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (*), a specific environmental risk assessment similar to that laid down in the abovementioned Directive shall be carried out; for this purpose, the following documents to be included in the dossier submitted pursuant to Article 9 of this Directive in order to ensure compliance with the principles set out in Article 7 (2) of this Directive:

- a copy of any written consent or consents of the competent authorities to the deliberate release of genetically modified organisms for research and development purposes pursuant to Article 6 (4) of Directive 90/220/EEC and the result of the release(s) with respect to the risk in each case to human health and the environment;
- the complete technical dossier supplying the information requested in Annexes I and II to Directive 90/220/EEC and the environmental risk assessment resulting from this information; the results of any investigations performed for the purposes of research or development.

(*) OJ No L 117, 8. 5. 1990, p. 15'

2. Article 14 (1) is amended as follows:

(a) the title of point A shall be replaced by the following:

'A. for all additives with the exception of enzymes and micro-organisms:'

(b) in point B, subparagraph (d) shall read as follows:

'(d) trace elements, colorants including pigments, preservatives and other additives with the exception of those belonging to the groups of enzymes and micro-organisms: active substance level.;

(c) the following point shall be added:

'C. for additives belonging to the groups:

- (a) of enzymes: the specific name of the active components(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the identification number according to the International Union of Biochemistry, the activity units ⁽¹⁾ (activity units per g or activity units per ml), the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph, and the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the words 'to be used exclusively in the manufacture of

feedingstuffs', the directions for use and, where appropriate, the safety recommendation where the column entitled 'Other provisions', in Annex I or II contains special provisions concerning the additives, the net weight and for liquid additives either the net volume or the net weight and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

- (b) of micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/g), the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph, the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the words 'to be used exclusively in the manufacture of feedingstuffs', the directions for use and, where appropriate, a safety recommendation where the column entitled 'Other provisions' in Annex I or II contains special provisions concerning the additives, the net weight and for liquid additives either the net volume or the net weight and where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(1) Activity units expressed as μmole of product released per minute per gram of enzymatic preparation.

3. in Article 15 (1) B

(a) subparagraph (h) shall become subparagraph (j) and shall be replaced by the following:

'(j) other additives belonging to the groups referred to in (b) to (i) for which no maximum level is laid down and additives belonging to other groups provided for in Annex I or II: specific name of the additive in accordance with Annex I or II and active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods';

(b) the following subparagraphs shall be added:

'(h) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the expiry date of the guarantee or the storage life from the date of manufacture, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(i) micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/g), the expiry date of the guarantee of the storage life from the date of manufacture, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

4. the following subparagraphs shall be added to Article 16 (1):

'(h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with Annex I or II, the identification number according to the International Union of Biochemistry, the activity units (activity units per kg or activity unit per l), the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

(i) for micro-organisms: the identification of the strain(s) in accordance with Annex I or II, the file number of the strain(s), the number of colony-forming units (CFU/kg), the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in Annex I or II;

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 October 1994. They shall forthwith notify the Commission thereof.

When Member States adopt these provisions they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 December 1993.

for the Council
The President
A. BOURGEOIS