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Contents

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.

II

(Acts whose publication is not obligatory)

COUNCIL

FIRST COUNCIL DIRECTIVE

of 21 December 1988

to approximate the laws of the Member States relating to trade marks

(89/104/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament (2),

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

Whereas the trade mark laws at present applicable in the Member States contain disparities which may impede the free movement of goods and freedom to provide services and may distort competition within the common market; whereas it is therefore necessary, in view of the establishment and functioning of the internal market, to approximate the laws of Member States;

Whereas it is important not to disregard the solutions and advantages which the Community trade mark system may afford to undertakings wishing to acquire trade marks;

Whereas it does not appear to be necessary at present to undertake full-scale approximation of the trade mark laws of the Member States and it will be sufficient if approximation is limited to those national provisions of law which most directly affect the functioning of the internal market;

Whereas the Directive does not deprive the Member States of the right to continue to protect trade marks acquired through use but takes them into account only in regard to the relationship between them and trade marks acquired by registration;

Whereas Member States also remain free to fix the provisions of procedure concerning the registration, the revocation and the invalidity of trade marks acquired by registration; whereas they can, for example, determine the form of trade mark registration and invalidity procedures, decide whether earlier rights should be invoked either in the registration procedure or in the invalidity procedure or in both and, if they allow earlier rights to be invoked in the registration procedure, have an opposition procedure or an *ex officio* examination procedure or both; whereas Member States remain free to determine the effects of revocation or invalidity of trade marks;

Whereas this Directive does not exclude the application to trade marks of provisions of law of the Member States other than trade mark law, such as the provisions relating to unfair competition, civil liability or consumer protection;

Whereas attainment of the objectives at which this approximation of laws is aiming requires that the conditions for obtaining and continuing to hold a registered trade mark are, in general, identical in all Member States; whereas, to this end, it is necessary to list examples of signs which may constitute a trade mark, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings; whereas the grounds for

(1) OJ No C 351, 31. 12. 1980, p. 1 and OJ No C 351, 31. 12. 1985, p. 4.
(2) OJ No C 307, 14. 11. 1983, p. 66 and OJ No C 309, 5. 12. 1988.
(3) OJ No C 310, 30. 11. 1981, p. 22.

refusal or invalidity concerning the trade mark itself, for example, the absence of any distinctive character, or concerning conflicts between the trade mark and earlier rights, are to be listed in an exhaustive manner, even if some of these grounds are listed as an option for the Member States which will therefore be able to maintain or introduce those grounds in their legislation; whereas Member States will be able to maintain or introduce into their legislation grounds of refusal or invalidity linked to conditions for obtaining and continuing to hold a trade mark for which there is no provision of approximation, concerning, for example, the eligibility for the grant of a trade mark, the renewal of the trade mark or rules on fees, or related to the non-compliance with procedural rules;

Whereas in order to reduce the total number of trade marks registered and protected in the Community and, consequently, the number of conflicts which arise between them, it is essential to require that registered trade marks must actually be used or, if not used, be subject to revocation; whereas it is necessary to provide that a trade mark cannot be invalidated on the basis of the existence of a non-used earlier trade mark, while the Member States remain free to apply the same principle in respect of the registration of a trade mark or to provide that a trade mark may not be successfully invoked in infringement proceedings if it is established as a result of a plea that the trade mark could be revoked; whereas in all these cases it is up to the Member States to establish the applicable rules of procedure;

Whereas it is fundamental, in order to facilitate the free circulation of goods and services, to ensure that henceforth registered trade marks enjoy the same protection under the legal systems of all the Member States; whereas this should however not prevent the Member States from granting at their option extensive protection to those trade marks which have a reputation;

Whereas the protection afforded by the registered trade mark, the function of which is in particular to guarantee the trade mark as an indication of origin, is absolute in the case of identity between the mark and the sign and goods or services; whereas the protection applies also in case of similarity between the mark and the sign and the goods or services; whereas it is indispensable to give an interpretation of the concept of similarity in relation to the likelihood of confusion; whereas the likelihood of confusion, the appreciation of which depends on numerous elements and, in particular, on the recognition of the trade mark on the market, of the association which can be made with the used or registered sign, of the degree of similarity between the trade mark and the sign and between the goods or services identified, constitutes the specific condition for such protection; whereas the ways in which likelihood of confusion may be established, and in particular the onus of proof, are a matter for national procedural rules which are not prejudiced by the Directive;

Whereas it is important, for reasons of legal certainty and without inequitably prejudicing the interests of a proprietor of an earlier trade mark, to provide that the latter may no longer request a declaration of invalidity nor may he oppose the use of a trade mark subsequent to his own of which he has knowingly tolerated the use for a substantial length of time, unless the application for the subsequent trade mark was made in bad faith;

Whereas all Member States of the Community are bound by the Paris Convention for the Protection of Industrial Property; whereas it is necessary that the provisions of this Directive are entirely consistent with those of the Paris Convention; whereas the obligations of the Member States resulting from this Convention are not affected by this Directive; whereas, where appropriate, the second subparagraph of Article 234 of the Treaty is applicable,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope

This Directive shall apply to every trade mark in respect of goods or services which is the subject of registration or of an application in a Member State for registration as an individual trade mark, a collective mark or a guarantee or certification mark, or which is the subject of a registration or an application for registration in the Benelux Trade Mark Office or of an international registration having effect in a Member State.

Article 2

Signs of which a trade mark may consist

A trade mark may consist of any sign capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings.

Article 3

Grounds for refusal or invalidity

1. The following shall not be registered or if registered shall be liable to be declared invalid:

(a) signs which cannot constitute a trade mark;

(b) trade marks which are devoid of any distinctive character;

(c) trade marks which consist exclusively of signs or indications which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin, or the time of production of the goods or of rendering of the service, or other characteristics of the goods or service;

(d) trade marks which consist exclusively of signs or indications which have become customary in the current language or in the *bona fide* and established practices of the trade;

(e) signs which consist exclusively of:

— the shape which results from the nature of the goods themselves, or

— the shape of goods which is necessary to obtain a technical result, or

— the shape which gives substantial value to the goods;

(f) trade marks which are contrary to public policy or to accepted principles of morality;

(g) trade marks which are of such a nature as to deceive the public, for instance as to the nature, quality or geographical origin of the goods or service;

(h) trade marks which have not been authorized by the competent authorities and are to be refused or invalidated pursuant to Article 6 *ter* of the Paris Convention for the Protection of Industrial Property, hereinafter referred to as the 'Paris Convention'.

2. Any Member State may provide that a trade mark shall not be registered or, if registered, shall be liable to be declared invalid where and to the extent that:

(a) the use of that trade mark may be prohibited pursuant to provisions of law other than trade mark law of the Member State concerned or of the Community;

(b) the trade mark covers a sign of high symbolic value, in particular a religious symbol;

(c) the trade mark includes badges, emblems and escutcheons other than those covered by Article 6 *ter* of the Paris Convention and which are of public interest, unless the consent of the appropriate authorities to its registration has been given in conformity with the legislation of the Member State;

(d) the application for registration of the trade mark was made in bad faith by the applicant.

3. A trade mark shall not be refused registration or be declared invalid in accordance with paragraph 1 (b), (c) or (d) if, before the date of application for registration and following the use which has been made of it, it has acquired a distinctive character. Any Member State may in addition provide that this provision shall also apply where the distinctive character was acquired after the date of application for registration or after the date of registration.

4. Any Member State may provide that, by derogation from the preceding paragraphs, the grounds of refusal of registration or invalidity in force in that State prior to the date on which the provisions necessary to comply with this Directive enter into force, shall apply to trade marks for which application has been made prior to that date.

Article 4

Further grounds for refusal or invalidity concerning conflicts with earlier rights

1. A trade mark shall not be registered or, if registered, shall be liable to be declared invalid:

(a) if it is identical with an earlier trade mark, and the goods or services for which the trade mark is applied for or is registered are identical with the goods or services for which the earlier trade mark is protected;

(b) if because of its identity with, or similarity to, the earlier trade mark and the identity or similarity of the goods or services covered by the trade marks, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association with the earlier trade mark.

2. 'Earlier trade marks' within the meaning of paragraph 1 means:

(a) trade marks of the following kinds with a date of application for registration which is earlier than the date of application for registration of the trade mark, taking account, where appropriate, of the priorities claimed in respect of those trade marks:

(i) Community trade marks;

(ii) trade marks registered in the Member State or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Trade Mark Office;

(iii) trade marks registered under international arrangements which have effect in the Member State;

(b) Community trade marks which validly claim seniority, in accordance with the Regulation on the Community trade mark, from a trade mark referred to in (a) (ii) and (iii), even when the latter trade mark has been surrendered or allowed to lapse;

(c) applications for the trade marks referred to in (a) and (b), subject to their registration;

(d) trade marks which, on the date of application for registration of the trade mark, or, where appropriate, of the priority claimed in respect of the application for registration of the trade mark, are well known in a Member State, in the sense in which the words 'well known' are used in Article 6 *bis* of the Paris Convention;

3. A trade mark shall furthermore not be registered or, if registered, shall be liable to be declared invalid if it is identical with, or similar to, an earlier Community trade mark within the meaning of paragraph 2 and is to be, or has been, registered for goods or services which are not similar to those for which the earlier Community trade mark is registered, where the earlier Community trade mark has a reputation in the Community and where the use of the later trade mark without due cause would take unfair advantage of, or be detrimental to, the distinctive character or the repute of the earlier Community trade mark.

4. Any Member State may furthermore provide that a trade mark shall not be registered or, if registered, shall be liable to be declared invalid where, and to the extent that:

(a) the trade mark is identical with, or similar to, an earlier national trade mark within the meaning of paragraph 2 and is to be, or has been, registered for goods or services which are not similar to those for which the earlier trade mark is registered, where the earlier trade mark has a reputation in the Member State concerned and where the use of the later trade mark without due cause would take unfair advantage of, or be detrimental to, the distinctive character or the repute of the earlier trade mark;

(b) rights to a non-registered trade mark or to another sign used in the course of trade were acquired prior to the date of application for registration of the subsequent trade mark, or the date of the priority claimed for the application for registration of the subsequent trade mark and that non-registered trade mark or other sign confers on its proprietor the right to prohibit the use of a subsequent trade mark;

(c) the use of the trade mark may be prohibited by virtue of an earlier right other than the rights referred to in paragraphs 2 and 4 (b) and in particular:

(i) a right to a name;

(ii) a right of personal portrayal;

(iii) a copyright;

(iv) an industrial property right;

(d) the trade mark is identical with, or similar to, an earlier collective trade mark conferring a right which expired within a period of a maximum of three years preceding application;

(e) the trade mark is identical with, or similar to, an earlier guarantee or certification mark conferring a right which expired within a period preceding application the length of which is fixed by the Member State;

(f) the trade mark is identical with, or similar to, an earlier trade mark which was registered for identical or similar goods or services and conferred on them a right which has expired for failure to renew within a period of a maximum of two years preceding application, unless the proprietor of the earlier trade mark gave his agreement for the registration of the later mark or did not use his trade mark;

(g) the trade mark is liable to be confused with a mark which was in use abroad on the filing date of the application and which is still in use there, provided that at the date of the application the applicant was acting in bad faith.

5. The Member States may permit that in appropriate circumstances registration need not be refused or the trade mark need not be declared invalid where the proprietor of the earlier trade mark or other earlier right consents to the registration of the later trade mark.

6. Any Member State may provide that, by derogation from paragraphs 1 to 5, the grounds for refusal of registration or invalidity in force in that State prior to the date on which the provisions necessary to comply with this Directive enter into force, shall apply to trade marks for which application has been made prior to that date.

Article 5

Rights conferred by a trade mark

1. The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade:

(a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered;

(b) any sign where, because of its identity with, or similarity to, the trade mark and the identity or similarity of the goods or services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association between the sign and the trade mark.

2. Any Member State may also provide that the proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade any sign which is identical with, or similar to, the trade mark in relation to goods or services which are not similar to those for which the trade mark is registered, where the latter has a reputation in the Member State and where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

3. The following, *inter alia*, may be prohibited under paragraphs 1 and 2:

(a) affixing the sign to the goods or to the packaging thereof;

(b) offering the goods, or putting them on the market or stocking them for these purposes under that sign, or offering or supplying services thereunder;

(c) importing or exporting the goods under the sign;

(d) using the sign on business papers and in advertising.

4. Where, under the law of the Member State, the use of a sign under the conditions referred to in 1 (b) or 2 could not be prohibited before the date on which the provisions necessary to comply with this Directive entered into force in the Member State concerned, the rights conferred by the trade mark may not be relied on to prevent the continued use of the sign.

5. Paragraphs 1 to 4 shall not affect provisions in any Member State relating to the protection against the use of a sign other than for the purposes of distinguishing goods or services, where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

Article 6

Limitation of the effects of a trade mark

1. The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade,

(a) his own name or address;

(b) indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, the time of production of goods or of rendering of the service, or other characteristics of goods or services;

(c) the trade mark where it is necessary to indicate the intended purpose of a product or service, in particular as accessories or spare parts;

provided he uses them in accordance with honest practices in industrial or commercial matters.

2. The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade, an earlier right which only applies in a particular locality if that right is recognized by the laws of the Member State in question and within the limits of the territory in which it is recognized.

Article 7

Exhaustion of the rights conferred by a trade mark

1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.

Article 8

Licensing

1. A trade mark may be licensed for some or all of the goods or services for which it is registered and for the whole or part of the Member State concerned. A license may be exclusive or non-exclusive.

2. The proprietor of a trade mark may invoke the rights conferred by that trade mark against a licensee who contravenes any provision in his licensing contract with regard to its duration, the form covered by the registration in which the trade mark may be used, the scope of the goods or services for which the licence is granted, the territory in which the trade mark may be affixed, or the quality of the goods manufactured or of the services provided by the licensee.

Article 9

Limitation in consequence of acquiescence

1. Where, in a Member State, the proprietor of an earlier trade mark as referred to in Article 4 (2) has acquiesced, for a period of five successive years, in the use of a later trade mark registered in that Member State while being aware of such use, he shall no longer be entitled on the basis of the earlier trade mark either to apply for a declaration that the later trade mark is invalid or to oppose the use of the later trade mark in respect of the goods or services for which the later trade mark has been used, unless registration of the later trade mark was applied for in bad faith.

2. Any Member State may provide that paragraph 1 shall apply *mutatis mutandis* to the proprietor of an earlier trade mark referred to in Article 4 (4) (a) or an other earlier right referred to in Article 4 (4) (b) or (c).

3. In the cases referred to in paragraphs 1 and 2, the proprietor of a later registered trade mark shall not be entitled to oppose the use of the earlier right, even though that right may no longer be invoked against the later trade mark.

Article 10

Use of trade marks

1. If, within a period of five years following the date of the completion of the registration procedure, the proprietor has not put the trade mark to genuine use in the Member State in connection with the goods or services in respect of which it is registered, or if such use has been suspended during an uninterrupted period of five years, the trade mark shall be subject to the sanctions provided for in this Directive, unless there are proper reasons for non-use.

2. The following shall also constitute use within the meaning of paragraph 1:

(a) use of the trade mark in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered;

(b) affixing of the trade mark to goods or to the packaging thereof in the Member State concerned solely for export purposes.

3. Use of the trade mark with the consent of the proprietor or by any person who has authority to use a collective mark or a guarantee or certification mark shall be deemed to constitute use by the proprietor.

4. In relation to trade marks registered before the date on which the provisions necessary to comply with this Directive enter into force in the Member State concerned:

(a) where a provision in force prior to that date attaches sanctions to non-use of a trade mark during an uninterrupted period, the relevant period of five years mentioned in paragraph 1 shall be deemed to have begun to run at the same time as any period of non-use which is already running at that date;

(b) where there is no use provision in force prior to that date, the periods of five years mentioned in paragraph 1 shall be deemed to run from that date at the earliest.

Article 11

Sanctions for non use of a trade mark in legal or administrative proceedings

1. A trade mark may not be declared invalid on the ground that there is an earlier conflicting trade mark if the latter does not fulfil the requirements of use set out in Article 10 (1), (2) and (3) or in Article 10 (4), as the case may be.

2. Any Member State may provide that registration of a trade mark may not be refused on the ground that there is an earlier conflicting trade mark if the latter does not fulfil the requirements of use set out in Article 10 (1), (2) and (3) or in Article 10 (4), as the case may be.

3. Without prejudice to the application of Article 12, where a counter-claim for revocation is made, any Member State may provide that a trade mark may not be successfully invoked in infringement proceedings if it is established as a result of a plea that the trade mark could be revoked pursuant to Article 12 (1).

4. If the earlier trade mark has been used in relation to part only of the goods or services for which it is registered, it shall, for purposes of applying paragraphs 1, 2 and 3, be deemed to be registered in respect only of that part of the goods or services.

Article 12

Grounds for revocation

1. A trade mark shall be liable to revocation if, within a continuous period of five years, it has not been put to genuine use in the Member State in connection with the goods or services in respect of which it is registered, and there are no proper reasons for non-use; however, no person may claim that the proprietor's rights in a trade mark should be revoked where, during the interval between expiry of the five-year period and filing of the application for revocation, genuine use of the trade mark has been started or resumed; the commencement or resumption of use within a period of three months preceding the filing of the application for revocation which began at the earliest on expiry of the continuous period of five years of non-use, shall, however, be disregarded where preparations for the commencement or resumption occur only after the proprietor becomes aware that the application for revocation may be filed.

2. A trade mark shall also be liable to revocation if, after the date on which it was registered,

(a) in consequence of acts or inactivity of the proprietor, it has become the common name in the trade for a product or service in respect of which it is registered;

(b) in consequence of the use made of it by the proprietor of the trade mark or with his consent in respect of the goods or services for which it is registered, it is liable to mislead the public, particularly as to the nature, quality or geographical origin of those goods or services.

Article 13

Grounds for refusal or revocation or invalidity relating to only some of the goods or services

Where grounds for refusal of registration or for revocation or invalidity of a trade mark exist in respect of only some of the goods or services for which that trade mark has been applied for or registered, refusal of registration or revocation or invalidity shall cover those goods or services only.

Article 14

Establishment *a posteriori* of invalidity or revocation of a trade mark

Where the seniority of an earlier trade mark which has been surrendered or allowed to lapse, is claimed for a Community trade mark, the invalidity or revocation of the earlier trade mark may be established *a posteriori*.

Article 15

Special provisions in respect of collective marks, guarantee marks and certification marks

1. Without prejudice to Article 4, Member States whose laws authorize the registration of collective marks or of

guarantee or certification marks may provide that such marks shall not be registered, or shall be revoked or declared invalid, on grounds additional to those specified in Articles 3 and 12 where the function of those marks so requires.

2. By way of derogation from Article 3 (1) (c), Member States may provide that signs or indications which may serve, in trade, to designate the geographical origin of the goods or services may constitute collective, guarantee or certification marks. Such a mark does not entitle the proprietor to prohibit a third party from using in the course of trade such signs or indications, provided he uses them in accordance with honest practices in industrial or commercial matters; in particular, such a mark may not be invoked against a third party who is entitled to use a geographical name.

Article 16

National provisions to be adopted pursuant to this Directive

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 28 December 1991. They shall immediately inform the Commission thereof.

2. Acting on a proposal from the Commission, the Council, acting by qualified majority, may defer the date referred to in paragraph 1 until 31 December 1992 at the latest.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field governed by this Directive.

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council

The President

V. PAPANDREOU

COUNCIL DIRECTIVE

of 21 December 1988

relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

(89/105/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament (2),

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

Whereas marketing authorizations for proprietary medicinal products issued pursuant to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4), as last amended by Directive 87/21/EEC (5), may be refused only for reasons relating to the quality, safety or efficacy of the proprietary medicinal products concerned;

Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products; whereas such measures include direct and indirect controls on the prices of medicinal products as a consequence of the inadequacy or absence of competition in the medicinal products market and limitations on the range of products covered by national health insurance systems;

Whereas the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; whereas, however, such measures should also be intended to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends;

Whereas disparities in such measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products;

Whereas the objective of this Directive is to obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States; whereas this information should be public;

Whereas, as a first step towards the removal of these disparites, it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto; whereas, however, these requirements do not effect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products; whereas these requirements also do not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive;

Whereas the further harmonization of such measures must take place progressively,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive.

2. The definition of 'medicinal products' laid down in Article 1 of Directive 65/65/EEC shall apply to this Directive.

3. Nothing in this Directive shall permit the marketing of a proprietary medicinal product in respect of which the authorization provided for in Article 3 of Directive 65/65/EEC has not been issued.

(1) OJ No C 17, 23. 1. 1987, p. 6 and OJ No C 129, 18. 5. 1988, p. 14.
(2) OJ No C 94, 11. 4. 1988, p. 62 and OJ No C 326, 19. 12. 1988.
(3) OJ No C 319, 30. 11. 1987, p. 47.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 15, 17. 1. 1987, p. 36.

Article 2

The following provisions shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product:

1. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed.

2. Should the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria. In addition, the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

3. At least once a year, the competent authorities shall publish in an appropriate publication, and communicate to the Commission, a list of the medicinal products the price of which has been fixed during the relevant period, together with the prices which may be charged for such products.

Article 3

Without prejudice to Article 4, the following provisions shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities:

1. Member States shall ensure that a decision is adopted on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization to increase the price of a medicinal product and communicated to the applicant within 90 days of its receipt. The applicant shall furnish the competent authorities with adequate information including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information.

   In case of an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the period.

   In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to apply in full the price increase requested.

2. Should the competent authorities decide not to permit the whole or part of the price increase requested, the decision shall contain a statement of reasons based on objective and verifiable criteria and the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

3. At least once a year, the competent authorities shall publish in an appropriate publication and communicate to the Commission, a list of the medicinal products for which price increases have been granted during the relevant period, together with the new price which may be charged for such products.

Article 4

1. In the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. Within 90 days of the start of this review, the competent authorities shall announce what increases or decreases in prices are being made, if any.

2. In exceptional cases, a person who is the holder of a marketing authorization for a medicinal product may apply for a derogation from a price freeze if this is justified by particular reasons. The application shall contain an adequate statement of these reasons. Member States shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. Should the derogation be granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Should there be an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the initial period.

Article 5

Where a Member State adopts a system of direct or indirect controls on the profitability of persons responsible for placing medicinal products on the market, the Member State concerned shall publish the following information in an appropriate publication and communicate it to the Commission:

(a) the method or methods used in the Member State concerned to define profitability: return on sales and/or return on capital;

(b) the range of target profit currently permitted to persons responsible for placing medicinal products on the market in the Member State concerned;

(c) the criteria according to which target rates of profit are accorded to an individual responsible for placing medicinal products on the market, together with the criteria according to which they will be allowed to retain profits above their given targets in the Member State concerned;

(d) the maximum percentage profit which any person responsible for placing medicinal products on the market is allowed to retain above his target in the Member State concerned.

This information shall be updated once a year or when significant changes are made.

Where, in addition to operating a system of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products which are excluded from the scope of the profit control scheme, Articles 2, 3 and 4 shall, where relevant, apply to such price controls. However, the said Articles shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.

Article 6

The following provisions shall apply if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list of medicinal products covered by the national health insurance system.

1. Member States shall ensure that a decision on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization to include a medicinal product in the list of medicinal products covered by the health insurance systems is adopted and communicated to the applicant within 90 days of its receipt. Where an application under this Article may be made before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, or where a decision on the price of a medicinal product and a decision on its inclusion within the list of products covered by the health insurance system are taken after a single administrative procedure, the time limit shall be extended for a further 90 days. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the time limit shall be suspended and the competent authorities shall forthwith notify the applicant of what detailed additional information is required.

   Where a Member State does not permit an application to be made under this Article before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, the Member State concerned shall ensure that the overall period of time taken by the two procedures does not exceed 180 days. This time limit may be extended in accordance with Article 2 or suspended in accordance with the provisions of the preceding subparagraph.

2. Any decision not to include a medicinal product in the list of products covered by the health insurance system shall contain a statement of reasons based upon objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of the remedies available to him under the laws in force and of the time limits allowed for applying for such remedies.

3. Before the date referred to in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists.

4. Within one year of the date referred to in in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission a complete list of the products covered by their health insurance system, together with their prices fixed by the national competent authorities. This information shall be updated at least once every year.

5. Any decision to exclude a product from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

6. Any decision to exclude a category of medicinal products from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication.

Article 7

The following provisions shall apply if the competent authorities of a Member State are empowered to adopt

decisions to exclude individual or categories of medicinal products from the coverage of its national health insurance system (negative lists).

1. Any decision to exclude a category of medicinal products from the coverage of the national health insurance system shall contain a statement of reasons based upon objective and verifiable criteria and be published in an appropriate publication.

2. Before the date referred to in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to exclude an individual medicinal product from the coverage of the national health insurance system.

3. Any decision to exclude an individual medicinal product from the coverage of the national health insurance system shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

4. Within one year of the date referred to in Article 11 (1), the competent authorities shall publish in an appropriate publication and communicate to the Commission a list of the individual medicinal products which have been excluded from the scope of its health insurance system. This information shall be updated at least every six months.

Article 8

1. Before the date referred to in Article 11 (1), Member States shall communicate to the Commission any criteria concerning the therapeutic classification of medicinal products which are used by the competent authorities for the purposes of the national social security system.

2. Before the date referred to in Article 11 (1), Member States shall communicate to the Commission any criteria which are used by the competent authorities in verifying the fairness and transparency of the prices charged for transfers within a group of companies of active principles or intermediate products used in the manufacture of medicinal products or finished medicinal products.

Article 9

1. In the light of experience, the Commission shall, not later than two years after the date referred to in Article 11 (1), submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to, or distortions of, the free movement of proprietary medicinal products, so as to bring this sector closer into line within the normal conditions of the internal market.

2. The Council shall decide on the Commission proposal not later than one year after its submission.

Article 10

1. A Committee called the 'Consultative Committee for the implementation of Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems' shall be set up and attached to the Commission.

2. The tasks of the committee shall be to examine any question relating to the application of this Directive which is brought up by the Commission or at the request of a Member State.

3. The committee shall consist of one representative from each Member State. There shall be one deputy for each representative. This deputy shall be entitled to participate in meetings of the committee.

4. A representative of the Commission shall chair the committee.

5. The committee shall adopt its rules of procedure.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1989 at the latest. They shall forthwith inform the Commission thereof.

2. Before the date referred to in paragraph 1, Member States shall communicate to the Commission the texts of any laws, regulations or administrative provisions relating to the pricing of medicinal products, the profitability of manufacturers of medicinal products and the coverage of medicinal products by the national health insurance system. Amendments and modifications to these laws, regulations or administrative provisions shall be communicated to the Commission forthwith.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products

(89/106/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

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

In cooperation with the European Parliament (2),

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

Whereas Member States are responsible for ensuring that building and civil engineering works on their territory are designed and executed in a way that does not endanger the safety of persons, domestic animals and property, while respecting other essential requirements in the interests of general well-being;

Whereas Member States have provisions, including requirements, relating not only to building safety but also to health, durability, energy economy, protection of the environment, aspects of economy, and other aspects important in the public interest;

Whereas these requirements, which are often the subject of national provisions laid down by law, regulation or administrative action, have a direct influence on the nature of construction products employed and are reflected in national product standards, technical approvals and other technical specifications and provisions which, by their disparity, hinder trade within the Community;

Whereas paragraph 71 of the White Paper on completing the internal market, approved by the European Council in June 1985, states that, within the general policy, particular emphasis will be placed on certain sectors, including construction; whereas the removal of technical barriers in the construction field, to the extent that they cannot be removed by mutual recognition of equivalence among all the Member States, should follow the new approach set out in the Council resolution of 7 May 1985 (4) which calls for the definition of essential requirements on safety and other aspects which are important for the general well-being, without reducing the existing and justified levels of protection in the Member States;

Whereas the essential requirements constitute both the general and specific criteria with which construction works must comply; whereas such requirements are to be understood as requiring that the said works conform with an appropriate degree of reliability with one, some or all of these requirements when and where this is laid down in regulations;

Whereas, as a basis for the harmonized standards or other technical specifications at European level and for the drawing up or granting of European technical approval, interpretative documents will be established in order to give concrete form to the essential requirements at a technical level;

Whereas these essential requirements provide the basis for the preparation of harmonized standards at European level for construction products; whereas, in order to achieve the greatest possible advantage for a single internal market, to afford access to that market for as many manufacturers as possible, to ensure the greatest possible degree of market transparency and to create the conditions for a harmonized system of general rules in the construction industry, harmonized standards should be established as far as, and as quickly as, possible; whereas these standards are drawn up by private bodies and must remain non-mandatory texts; whereas, for that purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonized document) adopted by one or both of those bodies upon a mandate given by the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (5);

Whereas the special nature of construction products requires the precise formulation of these harmonized standards; whereas it is therefore necessary to draw up interpretative documents in order to establish links between mandates for standards and the essential requirements; whereas harmonized standards, expressed as far as possible in terms

(1) OJ No C 93, 6. 4. 1987, p. 1.
(2) OJ No C 305, 16. 11. 1987, p. 74 and OJ No C 326, 19. 12. 1988.
(3) OJ No C 95, 11. 4. 1988, p. 29.
(4) OJ No C 136, 4. 6. 1985, p. 1.
(5) OJ No L 109, 26. 4. 1983, p. 8.

of product performance, take account of these interpretative documents, which shall be drawn up in cooperation with the Member States;

Whereas performance levels and requirements to be fulfilled by products in future in the Member States shall be laid down in classes in the interpretative documents and in the harmonized technical specifications in order to take account of different levels of essential requirements for certain works and of different conditions prevailing in the Member States;

Whereas harmonized standards should include classifications that allow construction products which meet the essential requirements and which are produced and used lawfully in accordance with technical traditions warranted by local climatological and other conditions to continue to be placed on the market;

Whereas a product is presumed fit for use if it conforms to a harmonized standard, a European technical approval or a non-harmonized technical specification recognized at Community level; whereas, in cases where products are of little importance with respect to the essential requirements and where they deviate from existing technical specifications, their fitness for use can be certified by recourse to an approved body;

Whereas products thus considered fit for use are easily recognizable by the EC mark; whereas they must be allowed free movement and free use for their intended purpose throughout the Community;

Whereas, in the case of products where European standards cannot be produced or foreseen within a reasonable period of time or of products which deviate substantially from a standard, the fitness for use of such products may be proved by recourse to European technical approvals on the basis of common guidelines; whereas the common guidelines for the granting of European technical approvals will be adopted on the basis of the interpretative documents;

Whereas, in the absence of harmonized standards and European technical approvals, national or other non-harmonized technical specifications may be recognized as providing a suitable basis for a presumption that the essential requirements are met;

Whereas it is necessary to ensure the conformity of products with harmonized standards and with non-harmonized technical specifications recognized at European level by means of procedures of production control by manufacturers and of supervision, testing assessment and certification by independent qualified third parties, or by the manufacturer himself;

Whereas a special procedure should be provided as an interim measure for products where standards or technical approvals recognized at European level do not yet exist; whereas this procedure should facilitate recognition of the results of tests performed in another Member State according to the technical requirements of the Member State of destination;

Whereas a Standing Committee on Construction should be set up comprising experts designated by Member States to assist the Commission on questions arising from the implementation and practical application of this Directive;

Whereas the responsibility of Member States for safety, health and other matters covered by the essential requirements on their territory should be recognized in a safeguard clause providing for appropriate protective measures,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Field of application — Definitions — Requirements — Technical specifications — Free movement of goods

Article 1

1. This Directive shall apply to construction products in so far as the essential requirements in respect of construction works under Article 3 (1) relate to them.

2. For the purposes of this Directive, 'construction product' means any product which is produced for incorporation in a permanent manner in construction works, including both buildings and civil engineering works.

'Construction products' are hereinafter referred to as 'products'; construction works including both buildings and civil engineering works are hereinafter referred to as 'works'.

Article 2

1. Member States shall take all necessary measures to ensure that the products referred to in Article 1, which are intended for use in works, may be placed on the market only if they are fit for this intended use, that is to say they have such characteristics that the works in which they are to be incorporated, assembled, applied or installed, can, if properly designed and built, satisfy the essential requirements referred to in Article 3 when and where such works are subject to regulations containing such requirements.

2. When products are subject to other Community directives with regard to other aspects, the EC conformity mark, hereinafter referred to as the 'EC mark', referred to in Article 4 (2) shall indicate in these cases that the requirements of those other directives have also been complied with.

3. When a future directive concerns mainly other aspects and only to a minor extent the essential requirements of this Directive, that subsequent directive shall contain provisions ensuring that it also covers the requirements of this Directive.

4. This Directive shall not affect the right of Member States to specify — with due observance of the provisions of the Treaty — the requirements they deem necessary to ensure that workers are protected when using products, provided it does not mean the products are modified in a way unspecified in this Directive.

Article 3

1. The essential requirements applicable to works which may influence the technical characteristics of a product are set out in terms of objectives in Annex I. One, some or all of these requirements may apply; they shall be satisfied during an economically reasonable working life.

2. In order to take account of possible differences in geographical or climatic conditions or in ways of life as well as different levels of protection that may prevail at national, regional or local level, each essential requirement may give rise to the establishment of classes in the documents referred to in paragraph 3 and the technical specifications referred to in Article 4 for the requirement to be respected.

3. The essential requirements shall be given concrete form in documents (interpretative documents) for the creation of the necessary links between the essential requirements laid down in paragraph 1 and the standardization mandates, mandates for guidelines for European technical approval or the recognition of other technical specifications within the meaning of Articles 4 and 5.

Article 4

1. Standards and technical approvals shall, for the purposes of this Directive, be referred to as 'technical specifications'.

For the purposes of this Directive, harmonized standards shall be the technical specifications adopted by CEN, Cenelec or both, on mandates given by the Commission in conformity with Directive 83/189/EEC on the basis of an opinion given by the Committee referred to in Article 19 and in accordance with the general provisions concerning cooperation between the Commission and these two bodies signed on 13 November 1984.

2. Member States shall presume that the products are fit for their intended use if they enable works in which they are employed, provided the latter are properly designed and built, to satisfy the essential requirements referred to in Article 3, and those products bear the EC mark. The EC mark shall indicate:

(a) that they comply with the relevant national standards transposing the harmonized standards, references to which have been published in the *Official Journal of the European Communities*. Member States shall publish the references of these national standards;

(b) that they comply with a European technical approval, delivered according to the procedure of Chapter III, or

(c) that they comply with the national technical specifications referred to in paragraph 3 in as much as harmonized specifications do not exist; a list of these national specifications shall be drawn up according to the procedure in Article 5 (2).

3. Member States may communicate to the Commission the texts of their national technical specifications which they regard as complying with the essential requirements referred to in Article 3. The Commission shall forward these national technical specifications forthwith to the other Member States. In accordance with the procedure provided for in Article 5 (2), it shall notify the Member States of those national technical specifications in respect of which there is presumption of conformity with the essential requirements referred to in Article 3.

This procedure will be initiated and managed by the Commission in consultation with the committee referred to in Article 19.

Member States shall publish the references to these technical specifications. The Commission shall also publish them in the *Official Journal of the European Communities*.

4. Where a manufacturer, or his agent, established in the Community, has not applied, or has applied only in part, the existing technical specifications referred to in paragraph 2, which require, according to the criteria set out in Article 13 (4), the product to be submitted for a declaration of conformity as defined in Annex III (2) (ii), second and third possibilities, the corresponding decisions under Article 13 (4) and Annex III shall apply and such a product's fitness for use within the meaning of Article 2 (1) shall be established in accordance with the procedure set out in Annex III (2) (ii), second possibility.

5. The Commission, in consultation with the committee referred to in Article 19, shall draw up, manage and revise periodically a list of products which play a minor part with respect to health and safety and in respect of which a declaration of compliance with the 'acknowledged rule of technology', issued by the manufacturer, will authorize such products to be placed on the market.

6. The EC mark signifies that products satisfy the requirements of paragraphs 2 and 4 of this Article. It is for the

manufacturer, or his agent established in the Community, to take responsibility for affixing the EC mark on the product itself, on a label attached to it, on its packaging, or on the accompanying commercial documents.

The model of the EC mark and conditions of its use are given in Annex III.

Products referred to in paragraph 5 shall not bear the EC mark.

Article 5

1. Where a Member State or the Commission is of the opinion that the harmonized standards or European technical approvals referred to in Article 4 (2), points (a) and (b), or the mandates referred to in Chapter II, do not satisfy the provisions of Articles 2 and 3, that Member State or the Commission shall notify the committee referred to in Article 19, setting out its reasons. The committee shall deliver an urgent opinion.

In the light of the opinion of the committee, and after consultation with the committee set up under Directive 83/189/EEC where it concerns harmonized standards, the Commission shall inform Member States if the standards or approvals concerned should be withdrawn in the publications referred to in Article 7 (3).

2. On reception of the communication referred to in Article 4 (3), the Commission shall consult the committee referred to in Article 19. In the light of the opinion of the committee, the Commission shall notify Member States whether the technical specification in question should benefit from the presumption of conformity and, if so, publish a reference to it in the *Official Journal of the European Communities*.

If the Commission or a Member State believes that a technical specification no longer fulfills the conditions necessary for presumption of conformity with the provisions of Articles 2 and 3, the Commission shall consult the committee referred to in Article 19. In the light of the opinion of the said committee, the Commission shall notify the Member States whether the national technical specification in question should continue to benefit from presumption of conformity, and, if not, whether the reference to it referred to in Article 4 (3) should be withdrawn.

Article 6

1. Member States shall not impede the free movement, placing on the market or use in their territory of products which satisfy the provisions of this Directive.

Member States shall ensure that the use of such products, for the purpose for which they were intended, shall not be impeded by rules or conditions imposed by public bodies or private bodies acting as a public undertaking or acting as a public body on the basis of a monopoly position.

2. Member States shall, however, allow products not covered by Article 4 (2) to be placed on the market in their territory if they satisfy national provisions consistent with the Treaty until the European technical specifications referred to in Chapters II and III provide otherwise. The Commission and the committee referred to in Article 19 will monitor and review the development of the European technical specifications on a regular basis.

3. If the relevant European technical specifications, either themselves or on the basis of the interpretative documents referred to in Article 3 (3), distinguish between different classes corresponding to different performance levels, Member States may determine the performance levels also to be observed in their territory only within the classifications adopted at Community level and only subject to the use of all or some classes or one class.

CHAPTER II

Harmonized standards

Article 7

1. In order to ensure the quality of harmonized standards for products, the standards shall be established by the European standards organizations on the basis of mandates given by the Commission in accordance with the procedure laid down in Directive 83/189/EEC and, after consulting the committee referred to in Article 19, in accordance with the general provisions concerning cooperation between the Commission and these bodies signed on 13 November 1984.

2. The resulting standards shall be expressed as far as practicable in product performance terms, having regard to the interpretative documents.

3. Once the standards have been established by the European standards organizations, the Commission shall publish the references of the standards in the 'C' series of the *Official Journal of the European Communities*.

CHAPTER III

European technical approval

Article 8

1. European technical approval is a favourable technical assessment of the fitness for use of a product for an intended use, based on fulfilment of the essential requirements for building works for which the product is used.

2. European technical approval may be granted to:

(a) products for which there is neither a harmonized standard, nor a recognized national standard, nor a mandate for a harmonized standard, and for which the Commission, after consulting the committee referred to in Article 19, considers that a standard could not, or not yet, be elaborated; and

(b) products which differ significantly from harmonized or recognized national standards.

Even in the case where a mandate for a harmonized standard has been issued, the provisions referred to in (a) do not exclude the granting of European technical approval for products for which guidelines for such approval exist. This shall apply until the entry into force of the harmonized standard in the Member States.

3. In special cases, the Commission may, as a derogation from paragraph 2 (a), authorize the issue of European technical approval, after consulting the committee referred to in Article 19, for products for which there is a mandate for a harmonized standard, or for which the Commission has established that a harmonized standard can be elaborated. The authorization shall be valid for a fixed period.

4. European technical approval shall in general be issued for a five-year period. This period may be extended.

Article 9

1. European technical approval for a product shall be based on examinations, tests and an assessment on the basis of the interpretative documents referred to in Article 3 (3) and of the guidelines referred to in Article 11 for this product or the corresponding family of products.

2. Where guidelines referred to in Article 11 do not or not yet exist, European technical approval may be issued by reference to the relevant essential requirements and the interpretative documents where the assessment of the product is adopted by the approval bodies acting jointly in the organization referred to in Annex II. If the approval bodies cannot agree, the matter shall be referred to the committee referred to in Article 19.

3. The European technical approval for a product shall be issued in a Member State in accordance with the procedure laid down in Annex II at the request of the manufacturer or his agent established in the Community.

Article 10

1. Each Member State shall notify the other Member States and the Commission of the names and addresses of the bodies which it has authorized to issue European technical approvals.

2. The approval bodies must satisfy the requirements of this Directive and in particular must be able:

— to assess the fitness for use of new products on the basis of scientific and practical knowledge,

— to take impartial decisions in relation to the interests of the manufacturers concerned or their agents, and

— to collate the contributions of all the interested parties in a balanced assessment.

3. The list of approval bodies which are competent to issue European technical approvals, as well as any amendments to that list, shall be published in the 'C' series of the *Official Journal of the European Communities*.

Article 11

1. The Commission shall, after consulting the committee referred to in Article 19, issue mandates for establishing guidelines for European technical approval for a product or family of products to the organization of approval bodies designated by the Member States.

2. The guidelines for European technical approval for a product or family of products should contain the following, in particular:

(a) a list of the relevant interpretative documents referred to in Article 3 (3);

(b) specific requirements for the products within the meaning of the essential requirements referred to in Article 3 (1);

(c) the test procedures;

(d) method of assessing and judging the results of the tests;

(e) the inspection and conformity procedures which must correspond to Articles 13, 14 and 15;

(f) the period of validity of the European technical approval.

3. The guidelines for European technical approval shall, after consultation with the committee referred to in Article 19, be published by the Member States in their official language or languages.

CHAPTER IV

Interpretative documents

Article 12

1. The Commission shall, after consulting the committee referred to in Article 19, instruct technical committees in

which the Member States participate to draw up the interpretative documents referred to in Article 3 (3).

2. The interpretative documents shall:

(a) give concrete form to the essential requirements laid down in Article 3 and in Annex I by harmonizing the terminology and the technical bases and indicating classes or levels for each requirement where necessary and where the state of scientific and technical knowledge so permits;

(b) indicate methods of correlating these classes or levels of requirement with the technical specifications referred to in Article 4, for example, methods of calculation and of proof, technical rules for project design, etc.;

(c) serve as a reference for the establishment of harmonized standards and guidelines for European technical approval and for recognition of national technical specifications in accordance with Article 4 (3).

3. The Commission shall publish the interpretative documents in the 'C' series of the *Official Journal of the European Communities* after soliciting the opinion of the committee referred to in Article 19.

CHAPTER V

Attestation of conformity

Article 13

1. The manufacturer, or his agent established in the Community, shall be responsible for the attestation that products are in conformity with the requirements of a technical specification within the meaning of Article 4.

2. Products that are the subject of an attestation of conformity shall benefit from the presumption of conformity with technical specifications within the meaning of Article 4. Conformity shall be established by means of testing or other evidence on the basis of the technical specifications in accordance with Annex III.

3. The attestation of conformity of a product is dependent on:

(a) the manufacturer having a factory production control system to ensure that production conforms with the relevant technical specifications; or

(b) for particular products indicated in the relevant technical specifications, in addition to a factory production control system, an approved certification body being involved in assessment and surveillance of the production control or of the product itself.

4. The choice of the procedure within the meaning of paragraph 3 for a given product or family of products shall be specified by the Commission, after consultation of the committee referred to in Article 19, according to:

(a) the importance of the part played by the product with respect to the essential requirements, in particular those relating to health and safety;

(b) the nature of the product;

(c) the effect of the variability of the product's characteristics on its serviceability;

(d) the susceptibility to defects in the product manufacture;

in accordance with the particulars set out in Annex III.

In each case, the least onerous possible procedure consistent with safety shall be chosen.

The procedure thus determined shall be indicated in the mandates and in the technical specifications or in the publication thereof.

5. In the case of individual (and non-series) production, a declaration of conformity in accordance with Annex III (2) (ii), third possibility, shall suffice, unless otherwise provided by the technical specifications for products which have particularly important implications for health and safety.

Article 14

1. In accordance with Annex III, the procedures described shall lead:

(a) in the case of Article 13 (3) (a), to the production of a declaration of conformity for a product by the manufacturer, or his agent established in the Community; or

(b) in the case of Article 13 (3) (b), to the issue by an approved certification body of a certificate of conformity for a system of production control and surveillance or for the product itself.

Detailed rules for the implementation of the procedures of attestation of conformity are given in Annex III.

2. The manufacturer's declaration of conformity or the certificate of conformity shall entitle the manufacturer, or his agent established in the Community, to affix the corresponding EC mark on the product itself, on a label attached to it, on its packaging or on the accompanying commercial documents. The model of the EC mark and the rules for its use in respect of each of the procedures of attestation of conformity are given in Annex III.

Article 15

1. Member States shall ensure that the EC mark is correctly used.

2. Where it is establishes that the EC mark has been affixed to a product which does not satisfy, or no longer satisfies, this Directive, the Member State in which conformity was attested shall ensure that, if necessary, the use of the EC mark is forbidden and unsold products are withdrawn, or marks obliterated, until such time as the product concerned is brought back to conformity.

The Member State concerned shall immediately inform the other Member States and the Commission, giving all the qualitative and quantitative details necessary to identify the product which does not conform.

3. Member States shall ensure that the affixing to products or their packing of marks which are likely to be confused with the EC mark shall be prohibited.

CHAPTER VI

Special procedures

Article 16

1. In the absence of technical specifications, as defined in Article 4, for any given product, the Member State of destination shall, on request in individual cases, consider the product to be in conformity with the national provisions in force if they have satisfied tests and inspections carried out by an approved body in the producing Member State according to the methods in force in the Member State of destination or recognized as equivalent by that Member State.

2. The producing Member State shall inform the Member State of destination, in accordance with whose provisions the tests and inspections are to be carried out, of the body it intends to approve for this purpose. The Member State of destination and the producing Member State shall provide each other with all necessary information. On conclusion of this exchange of information the producing Member State shall approve the body thus designated. If a Member State has misgivings, it shall substantiate its position and inform the Commission.

3. Member States shall ensure that the designated bodies afford one another all necessary assistance.

4. Where a Member State establishes that an approved body is not carrying out the tests and inspections properly in conformity with its national provisions, it shall notify the Member State in which the body is approved thereof. That Member State shall inform the notifying Member State within a reasonable time limit of what action has been taken. If the notifying Member State does not consider the action taken to be sufficient, it may prohibit the placing on the market and use of the product in question or make it subject to special conditions. It shall inform the other Member State and the Commission thereof.

Article 17

Member States of destination shall attach the same value to reports and attestations of conformity issued in the producing Member State in accordance with the procedure referred to in Article 16, as they do to their own corresponding national documents.

CHAPTER VII

Approved bodies

Article 18

1. Each Member State shall forward to the Commission a list of names and addresses of certification bodies, inspection bodies and testing laboratories which have been designated by that Member State for tasks to be carried out for the purposes of technical approvals, conformity certifications, inspections and tests according to this Directive.

2. Certification bodies, inspection bodies and testing laboratories shall comply with the criteria laid down in Annex IV.

3. Member States shall indicate the products which fall within the competence of the bodies and laboratories referred to in paragraph 1 and the nature of the tasks to be assigned to them.

CHAPTER VIII

Standing Committee on Construction

Article 19

1. A Standing Committee on Construction is hereby set up.

2. The committee shall be made up of representatives appointed by the Member States. It shall be chaired by a representative of the Commission. Each Member State shall appoint two representatives. The representatives may be accompanied by experts.

3. The committee shall draw up its own rules of procedure.

Article 20

1. The committee referred to in Article 19 may, at the request of its chairman or a Member State, examine any question posed by the implementation and the practical application of this Directive.

2. The provisions necessary for:

(a) the establishment of classes of requirements in so far as they are not included in the interpretative documents and the establishment of the procedure for attesting conformity in mandates for standards pursuant to Article 7 (1) and guidelines for approvals pursuant to Article 11 (1);

(b) the giving of instructions for the drawing-up of interpretative documents pursuant to Article 12 (1) and decisions on interpretative documents pursuant to Article 12 (3);

(c) the recognition of national technical specifications in accordance with Article 4 (3);

shall be adopted in accordance with the procedure laid down in paragraphs 3 and 4.

3. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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

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

If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

CHAPTER IX

Safeguard clause

Article 21

1. Where a Member State ascertains that a product declared to be in conformity with the terms of this Directive does not comply with Articles 2 and 3, it shall take all appropriate measures to withdraw those products from the market, prohibit the placing thereof on the market or restrict free movement thereof.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-conformity is due to:

(a) failure to comply with Articles 2 and 3, where the product does not meet the technical specifications referred to in Article 4;

(b) incorrect application of the technical specifications referred to in Article 4;

(c) shortcomings in the technical specifications referred to in Article 4 themselves.

2. The Commission shall carry out a consultation of the parties concerned as soon as possible. Where the Commission finds, after this consultation, that the action is justified, it shall immediately so inform the Member State that took the action as well as the other Member States.

3. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards or technical specifications, the Commission, after consulting the parties concerned, shall bring the matter before the committee referred to in Article 19, as well as the committee set up under Directive 83/189/EEC in the case of shortcomings in a harmonized standard, within two months if the Member State which has taken the measures intends to uphold them, and shall start the procedures referred to in Article 5 (2).

4. The Member State concerned shall take appropriate action against whomsoever made the declaration of conformity and shall inform the Commission and the other Member States thereof.

5. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

CHAPTER X

Final provisions

Article 22

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive within 30 months of its notification (1). They shall forthwith inform the Commission thereof.

(1) This Directive was notified to the Member States on 27 December 1988.

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.

Article 23

At the latest by 31 December 1993, the Commission, in consultation with the committee referred to in Article 19, shall re-examine the practicability of the procedures laid down by this Directive and, where necessary, submit proposals for appropriate amendments.

Article 24

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

ANNEX I

ESSENTIAL REQUIREMENTS

The products must be suitable for construction works which (as a whole and in their separate parts) are fit for their intended use, account being taken of economy, and in this connection satisfy the following essential requirements where the works are subject to regulations containing such requirements. Such requirements must, subject to normal maintenance, be satisfied for an economically reasonable working life. The requirements generally concern actions which are forseeable.

1. **Mechanical resistance and stability**

   The construction works must be designed and built in such a way that the loadings that are liable to act on it during its constructions and use will not lead to any of the following:

   (a) collapse of the whole or part of the work;

   (b) major deformations to an inadmissible degree;

   (c) damage to other parts of the works or to fittings or installed equipment as a result of major deformation of the load-bearing construction;

   (d) damage by an event to an extent disproportionate to the original cause.

2. **Safety in case of fire**

   The construction works must be designed and built in such a way that in the event of an outbreak of fire:

   — the load-bearing capacity of the construction can be assumed for a specific period of time,

   — the generation and spread of fire and smoke within the works are limited,

   — the spread of the fire to neighbouring construction works is limited,

   — occupants can leave the works or be rescued by other means,

   — the safety of rescue teams is taken into consideration.

3. **Hygiene, health and the environment**

   The construction work must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of any of the following:

   — the giving-off of toxic gas,

   — the presence of dangerous particles or gases in the air,

   — the emission of dangerous radiation,

   — pollution or poisoning of the water or soil,

   — faulty elimination of waste water, smoke, solid or liquid wastes,

   — the presence of damp in parts of the works or on surfaces within the works.

4. **Safety in use**

   The construction work must be designed and built in such a way that it does not present unacceptable risks of accidents in service or in operation such as slipping, falling, collision, burns, electrocution, injury from explosion.

5. **Protection against noise**

   The construction works must be designed and built in such a way that noise perceived by the occupants or people nearby is kept down to a level that will not threaten their health and will allow them to sleep, rest and work in satisfactory conditions.

6. **Energy economy and heat retention**

   The construction works and its heating, cooling and ventilation installations must be designed and built in such a way that the amount of energy required in use shall be low, having regard to the climatic conditions of the location and the occupants.

ANNEX II

EUROPEAN TECHNICAL APPROVAL

1. A request for approval may be made by a manufacturer, or his agent established in the Community, only to a single body authorized for this purpose.

2. The approval bodies designated by the Member States form an organization. In the performance of its duties, this organization is obliged to work in close coordination with the Commission, which shall consult the committee referred to in Article 19 of the Directive on important matters. Where a Member State has designated more than one approval body, the Member State shall be responsible for coordinating such bodies; it shall also designate the body which shall be spokesman in the organization.

3. The common procedural rules for making the request, the preparation and the granting of approvals are drawn up by the organization comprising the designated approval bodies. The common procedural rules are adopted by the Commission on the basis of the opinion of the committee in accordance with Article 20.

4. In the framework of the organization comprising them, the approval bodies shall afford each other all necessary support. This organization is also responsible for coordination on specific questions of technical approval. If necessary, the organization shall establish sub-groups for this purpose.

5. The European technical approvals are published by the approval bodies, which notify all other approved bodies. At the request of an authorized approval body, a complete set of supporting documents for an approval which has been granted is to be forwarded to the latter for information.

6. The costs arising from the European technical approval procedure shall be paid by the applicant in accordance with national rules.

ANNEX III

ATTESTATION OF CONFORMITY WITH TECHNICAL SPECIFICATIONS

1. METHODS OF CONTROL OF CONFORMITY

When the procedures for attestation of conformity of a product with technical specifications pursuant to Article 13 are being determined, the following methods of control of conformity shall be used; the choice and combination of methods for any given system shall depend on requirements for the particular product or group of products according to the criteria indicated in Article 13 (3) and (4):

(a) initial type-testing of the product by the manufacturer or an approved body;

(b) testing of samples taken at the factory in accordance with a prescribed test plan by the manufacturer or an approved body;

(c) audit-testing of samples taken at the factory, on the open market or on a construction site by the manufacturer or an approved body;

(d) testing of samples from a batch which is ready for delivery, or has been delivered, by the manufacturer or an approved body;

(e) factory production control;

(f) initial inspection of factory and of factory production control by an approved body;

(g) continuous surveillance, judgement and assessment of factory production control by an approved body.

In the Directive, factory production control means the permanent internal control of production exercised by the manufacturer. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures. This production control system documentation shall ensure a common understanding of quality assurance and enable the achievement of the required product characteristics and the effective operation of the production control system to be checked.

2. SYSTEMS OF CONFORMITY ATTESTATION

Preference is given to application of the following systems of conformity attestation.

(i) Certification of the conformity of the product by an approved certification body on the basis of:

(a) *(tasks for the manufacturer)*

(1) factory production control;

(2) further testing of samples taken at the factory by the manufacturer in accordance with a prescribed test plan;

(b) *(tasks for the approved body)*

(3) initial type-testing of the product;

(4) initial inspection of factory and of factory production control;

(5) continuous surveillance, assessment and approval of factory production control;

(6) possibly, audit-testing of samples taken at the factory, on the market or on the construction site.

(ii) Declaration of conformity of the product by the manufacturer on the basis of:

First possibility:

(a) *(tasks for the manufacturer)*

(1) initial type-testing of the product;

(2) factory production control;

(3) possibly, testing of samples taken at the factory in accordance with a prescribed test plan;

(b) *(tasks for the approved body)*

(4) certification of factory production control on the basis of:

— initial inspection of factory and of factory production control,

— possibly, continuous surveillance, assessment and approval of factory production control.

Second possibility:

(1) initial type-testing of the product by an approved laboratory;

(2) factory production control.

Third possibility:

(a) initial type-testing by the manufacturer;

(b) factory production control.

3. BODIES INVOLVED IN THE ATTESTATION OF CONFORMITY

With respect to the function of the bodies involved in the attestation of conformity, distinction shall be made between

(i) *certification body,* which means an impartial body, governmental or non-governmental, possessing the necessary competence and responsibility to carry out conformity certification according to given rules of procedure and management;

(ii) *inspection body,* which means an impartial body having the organization, staffing, competence and integrity to perform according to specified criteria functions such as assessing, recommending for acceptance and subsequent audit of manufacturers' quality control operations, and selection and evaluation of products on site or in factories or elsewhere, according to specific criteria;

(iii) *testing laboratory,* which means a laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products.

In case (i) and (ii) (first possibility) of paragraph 2, the three functions 3 (i) to (iii) may be performed by one and the same body or by different bodies, in which case the inspection body and/or the testing laboratory involved in the attestation of conformity carries out its function on behalf of the certification body.

For the criteria concerning the competence, impartiality and integrity of certification bodies, inspection bodies and testing laboratories, see Annex IV.

4. EC CONFORMITY MARK, EC CERTIFICATE OF CONFORMITY, EC DECLARATION OF CONFORMITY

4.1. **EC conformity mark**

The EC conformity mark shall consist of the symbol CE as given below.

It shall be accompanied by:

— the name or identifying mark of the producer,

and, where appropriate:

— indications to identify the characteristics of the product, where appropriate to technical specifications,

— the last two digits of the year of manufacture,

— the identification symbol of the inspection body involved,

— the number of the EC certificate of conformity.

4.2. **EC certificate of conformity**

The EC certificate of conformity shall contain in particular:

— name and address of the certification body,

— name and address of the manufacturer or his agent established in the Community,

— description of the product (type, identification, use . . .),

— provisions to which the product conforms,

— particular conditions applicable to the use of the product,

— the certificate's number,

— conditions and period of validity of the certificate, where applicable,

— name of, and position held by, the person empowered to sign the certificate.

4.3. **EC declaration of conformity**

The EC declaration of conformity shall contain in particular:

— name and address of the manufacturer or his agent established in the Community,

— description of the product (type, identification, use . . .),

— provision to which the product conforms,

— particular conditions applicable to the use of the product,

— name and address of the approved body, where applicable,

— name of, and position held by, the person empowered to sign the declaration on behalf of the manufacturer or of his authorized representative.

4.4. The certificate and declaration of conformity shall be presented in the official language or languages of the Member State in which the product is to be used.

ANNEX IV

APPROVAL OF TESTING LABORATORIES, INSPECTION BODIES AND CERTIFICATION BODIES

The testing laboratories, the inspection bodies and the certification bodies designated by the Member States must fulfil the following minimum conditions:

1. availability of personnel and of the necessary means and equipment;

2. technical competence and professional integrity of personnel;

3. impartiality, in carrying out the tests, preparing the reports, issuing the certificates and performing the surveillance provided for in the Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with construction products;

4. maintenance of professional secrecy by personnel;

5. subscription of a civil liability insurance unless that liability is covered by the State under national law.

Fulfilment of the conditions under 1 and 2 shall be verified at intervals by the competent authorities of Member States.

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption

(89/107/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas differences between national laws relating to food additives and the conditions for their use hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the common market;

Whereas the approximation of these laws is therefore necessary;

Whereas these requirements should be included in a comprehensive directive, where neccessary drawn up in stages;

Whereas the drawing-up of lists of categories of food additives to be covered by a directive is a matter to be decided by the Council acting under the procedure laid down in Article 100a of the Treaty;

Whereas the use of food additives belonging to such categories should be authorized only on the basis of agreed scientific and technological criteria laid down by the Council;

Whereas in drawing up lists of additives and the conditions for their use the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (3), should be consulted before the adoption of provisions likely to affect public health;

Whereas it must be possible to adopt the list of authorized additives to scientific and technical developments; whereas in that case, it may be appropriate also to have, in addition to the rules of procedure laid down by the Treaty, a system permitting the Member States to contribute, by the adoption of temporary national measures, to the search for a Community solution;

Whereas the determination of the criteria of purity for such food additives and the drawing-up of methods of analysis and sampling are technical matters to be entrusted to the Commission;

Whereas existing Community provisions on colouring matters, preservatives, anti-oxidants and emulsifiers, stabilizers, thickeners and gelling agents will require amendment on the basis of this Directive;

Whereas, in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure instituting close cooperation between Member States and the Commission within the Standing Committee on Foodstuffs set up by Commission Decision 69/414/EEC (4),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to food additives the various categories of which are given in Annex I and which are used or intended to be used as ingredients during the manufacture or preparation of a foodstuff and are still present in the final product, even if in altered form, hereinafter called 'food additives'.

2. For the purposes of this Directive 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

(1) OJ No C 99, 13. 4. 1987, p. 65 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 328, 22. 12. 1986, p. 5.
(3) OJ No L 136, 20. 5. 1974, p. 1.
(4) OJ No L 291, 19. 11. 1969, p. 9.

3. This Directive shall not apply to:

(a) processing aids (1);

(b) substances used in the protection of plants and plant products in conformity with Community rules relating to plant health;

(c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC (2);

(d) substances added to foodstuffs as nutrients (for example minerals, trace elements or vitamins).

Article 2

1. In respect of any category of food additive listed in Annex I for which lists have been drawn up pursuant to Article 3 (3), only those food additives included in such lists may be used in the manufacture or preparation of foodstuffs and only under the conditions of use specified therein.

2. The inclusion of food additives in one of the categories in Annex I shall be on the basis of the principal function normally associated with the food additive in question. However, the allocation of the additive to a particular category does not exclude the possibility of the additive being authorized for several functions.

3. Food additives shall be included in a list on the basis of the general criteria described in Annex II.

Article 3

1. Particular provisions in respect of the additives in the categories given in Annex I shall be laid down in a comprehensive directive, including existing specific directives on particular categories of additives. That directive may, however, be drawn up in stages.

2. The Council shall, acting on a proposal from the Commission under the procedure laid down in Article 100a of the Treaty, adopt:

(a) a list of additives the use of which is authorized to the exclusion of all others;

(b) the list of foodstuffs to which these additives may be added, the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use;

(c) the rules on additives used as carrier substances and solvents, including where necessary their purity criteria.

3. The following shall be adopted under the procedure laid down in Article 11:

(a) the criteria of purity for the additives in question;

(b) where necessary, the methods of analysis needed to verify that the criteria of purity referred to in (a) are satisfied;

(c) where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs;

(d) other rules necessary to ensure compliance with the provisions of Article 2.

Article 4

1. Where a Member State, as a result of new information or of a re-assessment of existing information made since this Directive, or the comprehensive directive referred to in Article 3, was adopted, has detailed grounds for considering that the use of additives in food, although it complies with this Directive or any list drawn up under Article 3, endangers human health, that Member State may temporarily suspend or restrict application of the provisions in question in its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine the grounds given by the Member State referred to in paragraph 1 as soon as possible within the Standing Committee on Foodstuffs, and shall then deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to this Directive or to the comprehensive directive referred to in Article 3 are necessary in order to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 11, with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 5

1. In order to take account of scientific or technical developments which have occurred since the adoption of a list in accordance with Article 3, a Member State may

(1) For the purpose of this Directive, 'processing aid' means any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

(2) OJ No L 184, 15. 7. 1988, p. 61.

provisionally authorize the marketing and use within its territory of an additive from one of the categories listed in Annex I and not included in the relevant list provided that the following conditions are satisfied:

(a) the authorization shall be limited to a maximum period of two years;

(b) the Member State shall ensure that foodstuffs containing an additive which it has authorized are officially monitored;

(c) in the authorization the Member State may require that foodstuffs manufacted with the additive in question shall bear a special indication.

2. The Member State shall communicate to the other Member States and to the Commission the text of any authorization decision adopted pursuant to paragraph 1, within two months of the date on which the decision takes effect.

3. Before the two-year period stipulated in paragraph 1 (a) has expired the Member State may request the Commission to include in the list adopted in accordance with Article 3 the additive which had been the subject of national authorization pursuant to paragraph 1 of this Article. At the same time, the Member State shall provide the evidence which, in its view, supports such inclusion and shall indicate how the additive is to be used. If the Commission considers this request to be justified, it shall operate the procedure laid down in Article 100a of the Treaty in order to amend the list adopted in accordance with Article 3. The Council shall act on a proposal from the Commission, within 18 months from the date on which the matter was referred to it.

4. If, within the two-year period stipulated in paragraph 1, the Commission does not submit a proposal in accordance with paragraph 3, or if the Council does not act within the 18-month period stipulated in paragraph 3, the national authorization must be cancelled. At the same time, any authorization granted by another Member State for the same additive must be cancelled.

5. No new authorization for the same additive may be granted unless the scientific or technical development made since the cancellation provided for in paragraph 4 so justifies.

Article 6

Provisions that may have effect upon public health shall be adopted after consultation with the Scientific Committee for Food.

Article 7

1. Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) — for food additives sold singly or mixed with each other, for each additive, the name laid down by any Community provisions applying and its EEC number or, in the absence of such provisions, a description of the additive that is sufficiently precise to enable it to be distinguished from additives with which it could be confused, in descending order of the proportion by weight in the total,

— when other substances or materials or food ingredients to facilitate storage, sale, standardization, dilution or dissolution of a food additive or food additives are incorporated in the additives, the name of the additive in accordance with the first indent and an indication of each component in descending order of the proportion by weight in the total;

(b) — either the statement 'for use in food',

— or the statement 'restricted use in food',

— or a more specific reference to its intended food use;

(c) if necessary, the special conditions of storage and use;

(d) directions for use, if the omission thereof would preclude appropriate use of the additive;

(e) a mark identifying the batch or lot;

(f) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;

(g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions, or in their absence national provisions, applying to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;

(h) the net quantity;

(i) any other information provided for in the comprehensive Directive referred to in Article 3.

2. By way of derogation from paragraph 1, the information required in point (a), second indent, and points (d) to (g), may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'intended for the manufacture of foodstuffs and not for retail sale' appears on a conspicuous part of the packaging or container of the product in question.

Article 8

Food additives intended for sale to the ultimate consumer may be marketed only if their packagings or containers bear the following information, which must be conspicuous, clearly legible and indelible:

(a) the name under which the product is sold. This name shall be constituted by the name laid down by any Community provisions applying to the product in question plus its EEC number or, in the absence of such provisions, by a description of the product that is sufficiently precise to enable it to be distinguished from products with which it could be confused;

(b) the information required by Article 7 (1) (a) to (f), and (h);

(c) the date of minimum durability within the meaning of Article 9 of Council Directive 79/112/EEC [1];

(d) any other information provided for in the comprehensive directive referred to in Article 3.

Article 9

Articles 7 and 8 shall not affect more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures, or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or the transport of such substances.

Article 10

Member States shall refrain from laying down requirements more detailed than those contained in Articles 7 and 8 concerning the manner in which the particulars provided for therein are to be shown.

The particulars provided for in Articles 7 and 8 shall appear in a language easily understandable to purchasers unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from being indicated in various languages.

Article 11

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the Committee's opinion;

(b) where the intended measures are not in accordance with the opinion of the committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures.

Article 12

1. Member States shall take all measures necessary to ensure that food additives belonging to the categories defined in Annex I may be marketed only if they conform to the definitions and rules laid down in this Directive and the Annexes thereto.

2. Member States may not prohibit, restrict or obstruct the marketing of food additives, food or food ingredients on grounds relating to food additives, if these comply with the provisions of this Directive, the existing specific directives and the comprehensive directive referred to in Article 3.

3. Paragraph 2 shall not affect national provisions applicable in the absence of corresponding provisions in the comprehensive directive referred to in Article 3.

Article 13

Measures to bring existing Community directives into line with this Directive shall be adopted according to the procedure laid down in Article 11.

Article 14

1. Member States shall take all measures necessary to comply with this Directive within 18 months of its notification. They shall forthwith inform the Commission thereof. The measures taken shall:

— authorize, two years after notification of this Directive, the marketing and use of food additives complying with this Directive;

[1] OJ No L 33, 8. 2. 1979, p. 1.

— prohibit, not later than three years after notification (1) of this Directive, the marketing and use of food additives which do not comply with this Directive.

2. Paragraph 1 shall not affect existing Community provisions or those national provisions which, in the absence of the comprehensive directives referred to in Article 3, apply to certain groups of food additives or specify the foodstuffs in or on which food additives complying with this Directive may be used.

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

(1) This Directive was notified to the Member States on 28 December 1988.

ANNEX I

Categories of food additives

Colour
Preservative
Anti-oxidant
Emulsifier
Emulsifying salt
Thickener
Gelling agent
Stabilizer (1)
Flavour enhancer
Acid
Acidity regulator (2)
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent (3)
Flour treatment agent
Firming agent
Humectant
Sequestrant (4)
Enzyme (4) (5)
Bulking agent
Propellent gas and packaging gas

(1) This category also comprises foam stabilizers.
(2) These can act as two-way acidity regulators.
(3) These substances include lubricants.
(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.
(5) Only those used as additives.

ANNEX II

General criteria for the use of food additives

1. Food additives can be approved only provided that:

— there can be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,

— they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,

— they do not mislead the consumer.

2. The use of food additives may be considered only where there is evidence that the proposed use of the additive would have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as 'need'. The use of food additives should serve one or more of the purposes set out from points (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

(a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;

(b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

(c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;

(d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3. To assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

4. All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

5. Food additives must at all times comply with the approved criteria of purity.

6. Approval for food additives must:

(a) specify the foodstuffs to which these additives may be added and the conditions under which they may be added;

(b) be limited to the lowest level of use necessary to achieve the desired effect;

(c) take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups.

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

(89/108/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas the manufacture of and trade in quick-frozen foodstuffs intended for human consumption (hereinafter referred to as 'quick-frozen foodstuffs') are assuming increasing importance in the Community;

Whereas the differences between national laws relating to quick-frozen foodstuffs hamper the free movement thereof; whereas they may create unequal conditions of competition and therefore have a direct effect on the establishment and functioning of the common market;

Whereas it is therefore necessary to approximate these laws;

Whereas to that end the Community rules must be given the widest possible scope, extending to all quick-frozen foodstuffs intended for human consumption and including not only products intended for supply without further processing to the ultimate consumer and to restaurants, hospitals, canteens and to other similar mass caterers, but also products having to be further processed or prepared;

Whereas, however, these rules need not apply to products not offered for sale as quick-frozen foodstuffs;

Whereas it is in any case appropriate to lay down the general principles which any quick-frozen foodstuffs must satisfy;

Whereas at a later stage special provisions over and above the general principles may, where necessary, be adopted for certain categories of quick-frozen foodstuffs, in accordance with the procedure applicable to each of these categories;

Whereas the purpose of quick-freezing is to preserve the intrinsic characteristics of foodstuffs by a process of rapid freezing; whereas it is necessary to attain a temperature of − 18 °C or lower at all points in the product;

Whereas at − 18 °C all microbiological activity likely to impair the quality of a foodstuff is suspended; whereas it is therefore necessary to maintain at least that temperature, subject to a certain technically inevitable tolerance, during the storage and distribution of quick-frozen foodstuffs before their sale to the ultimate consumer;

Whereas for technical reasons certain temperature increases are inevitable and may therefore be tolerated provided they do not harm the quality of the products, which may be ensured by complying with good storage and distribution practice, taking account in particular of the proper level of stock rotation;

Whereas the performance of certain technical equipment at present in use for the local distribution of quick-frozen foodstuffs is not capable of ensuring in every case full compliance with the temperature limits imposed in this Directive, and it is therefore necessary to provide for a transitional system allowing for existing material to be used for its normal lifetime;

Whereas this Directive need merely state the objectives to be attained as regards both the equipment used for the quick-freezing process and the temperatures to be observed in the storage, handling, transport and distribution installations and equipment;

Whereas it is incumbent upon Member States to ensure by means of official checks that the equipment used is capable of meeting these objectives;

Whereas such checks render superfluous any system of official certification for trade purposes;

Whereas it is desirable to provide for the possibility of using cryogenic fluids in direct contact with quick-frozen foodstuffs; whereas therefore these fluids must be sufficiently inert not to impart to the foodstuffs any constituents in quantities liable to constitute a hazard to human health, or to

(1) OJ No C 175, 15. 7. 1985, p. 296 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 104, 25. 4. 1985, p. 17.

give rise to an unacceptable change in the composition of foodstuffs, or to impair their organoleptic characteristics;

Whereas in order to attain this objective it is necessary to adopt a list of these substances and to lay down criteria for their purity and conditions for their use;

Whereas quick-frozen foodstuffs intended for the ultimate consumer and for restaurants, hospitals, canteens and other similar mass caterers are subject, as far as their labelling is concerned, to the rules laid down by 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), as last amended by Directive 86/197/EEC (2); whereas the present Directive need therefore merely lay down the particulars which are specific to quick-frozen foodstuffs;

Whereas, to facilitate trade, rules should also be adopted for the labelling of quick-frozen foodstuffs not intended for supply in the frozen state to the ultimate consumer or to restaurants, hospitals, canteens and other similar mass caterers;

Whereas, in order to simplify and speed up the procedure, the Commission should be assigned the task of adopting implementing measures of a technical nature;

Whereas, in all cases in which the Council empowers the Commission to implement the rules laid down for foodstuffs, a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (3) should be laid down,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to quick-frozen foods intended for human consumption, hereinafter referred to as 'quick-frozen foodstuffs'.

2. For the purposes of this Directive 'quick-frozen foodstuffs' means foodstuffs

— which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of − 18 °C or lower at all points, and

— which are marketed in such a way as to indicate that they possess this characteristic.

For the purposes of this Directive, ice-cream and other edible ices shall not be regarded as quick-frozen foodstuffs.

3. This Directive shall apply without prejudice to Community provisions relating to:

(a) the common organization of markets in the agricultural and fisheries sectors;

(b) veterinary hygiene.

Article 2

Only the products defined in Article 1 (2) may bear the names provided for in Articles 8 and 9.

Article 3

1. Raw materials used in the manufacture of quick-frozen foodstuffs must be of sound, genuine and merchantable quality and be of the required degree of freshness.

2. Preparation and quick-freezing of products must be carried out promptly, using appropriate technical equipment, in order to limit chemical, biochemical and microbiological changes to a minimum.

Article 4

The cryogenic media authorized, to the exclusion of all others, for use in direct contact with quick-frozen foodstuffs shall be the following:

— air,

— nitrogen,

— carbon dioxide.

By way of derogation from the first paragraph, Member States may retain until 31 December 1992 national laws authorizing the use of dichlorodifluoromethane (R 12) as a cryogenic medium.

The purity criteria to be satisfied by these cryogenic media shall be determined, as far as necessary, in accordance with the procedure laid down in Article 12.

Article 5

1. The temperature of quick-frozen foodstuffs must be stable and maintained, at all points in the product, at − 18 °C or lower, with possibly brief upward fluctuations of no more than 3 °C during transport.

(1) OJ No L 33, 8. 2. 1979, p. 1.
(2) OJ No L 144, 29. 5. 1986, p. 38.
(3) OJ No L 291, 19. 11. 1969, p. 9.

2. However, tolerances in the temperature of the product in accordance with good storage and distribution practice shall be permitted during local distribution and in retail display cabinets subject to the following conditions:

(a) these tolerances shall not exceed 3 °C;

(b) they may, however reach 6 °C in retail display cabinets, if and to the extent that the Member States so decide. In that case, the Member States shall select the temperature in the light of stock or product rotation in the retail trade. They shall inform the Commission of the measures taken and of the grounds for those measures.

The Commission shall review the tolerance provided for in the previous subparagraph in the light of technical developments and shall make proposals to the Council if appropriate before 1 January 1993.

3. For a period of eight years from the notification of this Directive, the Member States may, for local distribution, authorize tolerances of up to 6 °C.

Article 6

1. The Member States shall:

(a) ensure that the equipment used for quick-freezing, storage, transport, local distribution and retail display cabinets is such that compliance with the requirements of this Directive can be guaranteed;

(b) conduct random official checks on the temperature of quick-frozen foodstuffs.

2. Member States shall not require that, as a preliminary to or during the marketing of quick-frozen foodstuffs, compliance with the provisions of paragraph 1 be attested by means of an official certificate.

Article 7

Quick-frozen foodstuffs intended for supply to the ultimate consumer must be packed by the manufacturer or packer in suitable pre-packaging which protects them from microbial or other forms of external contamination and against drying.

Article 8

1. Directive 79/112/EEC shall apply to products covered by this Directive and intended for supply without further processing to the ultimate consumer and to restaurants, hospitals, canteens and other similar mass caterers on the following conditions:

(a) one or more of the following shall be added to the sales name:

in Danish: 'dybfrossen',

in German: 'tiefgefroren' or 'Tiefkühlkost' or 'tiefgekühlt' or 'gefrostet',

in Spanish: 'ultracongelado' or 'congelado rapidamente',

in Greek: 'βαθείας κατάψυξης' or 'ταχείας κατάψυξης' or 'υπερ-κατεψυγμένα',

in English: 'quick-frozen',

in French: 'surgelé',

in Italian: 'surgelato',

in Dutch: 'diepvries',

in Portuguese: 'ultracongelado';

(b) in addition to the date of minimum durability, the period during which quick-frozen products may be stored by the purchaser and the storage temperature and/or type of storage equipment required must be indicated;

(c) the labelling of any quick-frozen foodstuff must include a reference from which the batch may be identified;

(d) the label of any quick-frozen foodstuff must bear a clear message of the type 'do not refreeze after defrosting'.

Article 9

1. The labelling of the products defined in Article 1 (2) which are not intended for sale to the ultimate consumer or to restaurants, hospitals, canteens and other similar mass caterers shall contain only the following mandatory particulars:

(a) the sales name supplemented in accordance with Article 8 (1) (a) of this Directive;

(b) the net quantity expressed in units of mass;

(c) a reference enabling the batch to be identified;

(d) the name or business name and address of the manufacturer or packer, or of a seller established within the Community.

2. The particulars provided for in paragraph 1 shall appear on the packaging, container or wrapping, or on a label attached thereto.

3. This Article shall not affect any Community metrological provisions which are more detailed or more comprehensive.

Article 10

Member States may not, for reasons related to their manufacturing specifications, presentation or labelling,

prohibit or restrict the marketing of any of the products defined in Article 1 (2) which comply with this Directive and, with measures taken for its application.

Article 11

The sampling procedures for quick-frozen foodstuffs, the procedures for monitoring their temperature and for monitoring temperatures in the means of transport and warehousing and storage shall be determined in accordance with the procedure laid down in Article 12, before the end of a 24-month period following notification of this Directive.

Article 12

1. Where the procedure provided for in this Article is invoked, the matter shall be referred to the Standing Committee on Foodstuffs, hereinafter referred to as the 'committee', by its chairman, acting either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its opinion on the draft within a period to be determined by the chairman having regard to the urgency of the matter. It shall decide by a qualified majority, as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures proposed where these are in conformity with the opinion of the committee;

(b) where the measures proposed are not in conformity with the opinion of the committee or where no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall act by a qualified majority;

(c) if, upon the expiry of a period of three months from the date on which the matter is brought before the Council, the latter has failed to take any measures, the Commission shall adopt the proposed measures.

Article 13

1. The Member States shall take the measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

— permit no later than 18 months after notification [1] of the Directive trade in products which comply with this Directive,

— prohibit no later than 24 months after notification of the Directive trade in products which do not comply with this Directive.

2. As regards retail display cabinets, for a period of eight years following notification of this Directive, Member States may retain the laws applying on the date when this Directive enters into force.

In this case, the Member States shall inform the Commission, stating the reasons for their decision.

Article 14

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU

[1] This Directive was notified to the Member States on 10 January 1989.

COUNCIL DIRECTIVE

of 21 December 1988

on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

(89/109/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (3), as last amended by the act of Accession of Spain and Portugal (4), has been substantially amended on a number of occasions; whereas on making the new amendments to the said Directive, the opportunity should be taken to consolidate the provisions of the existing relevant texts with a view to ensuring legal clarity;

Whereas Directive 76/893/EEC was adopted on the grounds that the differences that existed at that time between the national laws relating to the aforesaid materials and articles impeded the free movement thereof, could create unequal conditions of competition and could thereby directly affect the establishment or functioning of the common market;

Whereas those laws had to be approximated if free movement was to be achieved for the aforesaid materials and articles, taking account primarily of human health requirements but also, within the limits required for the protection of health, of economic and technological needs;

Whereas the chosen method was to lay down, in the first place, in a framework directive, general principles on the basis of which legal differences between certain groups of materials and articles had been and could subsequently be eliminated by means of specific directives; whereas this method has proved itself and should therefore be retained;

Whereas covering or coating substances, all or part of which form part of foodstuffs, could not be considered to be simply in contact with these foodstuffs; whereas, in that case, account had to be taken of possible direct consumption by consumers; whereas the rules laid down in this Directive are therefore inappropriate in such circumstances;

Whereas the principle underlying this Directive should be that any material or article intended to come into contact or which is intentionally in contact either directly or indirectly with foodstuffs, must be sufficiently stable not to transfer substances to the foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic properties thereof;

Whereas, in order to achieve this objective, it may prove necessary to lay down various types of limitations, alone or in combination; whereas it is appropriate to retain in specific directives those limitations which are most appropriate to the desired objective, having regard to the technological characteristics peculiar to each group of materials and articles;

Whereas, in order to allow the informed use of the materials and articles, appropriate labelling should be provided for; whereas the methods used for such labelling may vary according to the user;

Whereas this Directive does not apply to the labelling of products which, by reason of their behaviour in the presence of foodstuffs, must not be designed to come into contact or be in contact with them;

Whereas the drafting of specific directives implementing the basic principles and of amendments thereto constitute technical implementing measures; whereas, in order to simplify and expedite the procedure, the adoption of these measures should be entrusted to the Commission;

Whereas the Scientific Committee for Food, set up by Commission Decision 74/234/EEC (5), should be asked for its opinion before provisions liable to affect public health are adopted under specific directives;

(1) OJ No C 99, 13. 4. 1987, p. 65 and OJ No C 12, 16. 1. 1989.
(2) OJ No C 328, 22. 12. 1986, p. 5.
(3) OJ No L 340, 9. 12. 1976, p. 19.
(4) OJ No L 302, 15. 11. 1985, p. 216.
(5) OJ No L 136, 20. 5. 1974, p. 1.

Whereas it is desirable that in all cases where the Council empowers the Commission to implement rules relating to foodstuffs, provision should be made for a procedure establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC (1),

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose, hereinafter referred to as 'materials and articles'.

Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to this Directive.

2. This Directive shall apply to materials and articles which are in contact with water which is intended for human consumption. It shall not, however, apply to fixed public or private water supply equipment.

3. This Directive shall not apply to antiques.

Article 2

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

— endanger human health,

— bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Article 3

1. The groups of materials and articles listed in Annex I and, where appropriate, combinations of these materials and articles shall be subject to specific directives.

2. The specific directives, including amendments to existing specific directives, shall be adopted in accordance with the procedure laid down in Article 8.

3. The specific directives may include:

(a) a list of the substances the use of which is authorized to the exclusion of all others (positive list);

(b) purity standards for such substances;

(c) special conditions of use for these substances and/or the materials and articles in which they are used;

(d) specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;

(e) an overall limit on the migration of constituents into or onto foodstuffs;

(f) if necessary, provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles;

(g) other rules to ensure compliance with Article 2;

(h) the basic rules necessary for checking compliance with the provisions of points (d), (e), (f) and (g);

(i) detailed rules concerning sample taking and the methods of analysis required to check compliance with the provisions of points (a) to (g).

Provisions liable to affect public health shall be adopted after consulting the Scientific Committee for Food. They must fulfill the criteria set out in Annex II.

Article 4

1. Notwithstanding Article 3, a Member State may, where a list of substances has been drawn up in accordance with paragraph 3 (a) of that Article, authorize the use within its territory of a substance not included in the list, subject to compliance with the following conditions:

(a) the authorization must be limited to a maximum period of two years;

(b) the Member State must carry out an official check on materials and articles manufactured from a substance of which it has authorized the use;

(c) materials and articles thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the other Member States and to the Commission the text of any authorization drawn up pursuant to paragraph 1 within two months of the date of its taking effect.

3. Before the expiry of the two-year period provided for in paragraph 1 (a), the Member State may submit to the Commission a request for the inclusion in the list referred to

(1) OJ No L 291, 19. 11. 1969, p. 9.

in Article 3 (3) (a) of the substance given national authorization in accordance with paragraph 1 of this Article. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which this substance is intended.

Within 18 months of the submission of the request, a decision shall be taken on the basis of information relating to public health, after consulting the Scientific Committee for Food and in accordance with the procedure laid down in Article 9 as to whether the substance in question may be included in the list referred to in Article 3 (a) or whether the national authorization should be revoked. If provisions prove necessary pursuant to Article 3 (3) (b), (c) and (d), these shall be adopted in accordance with the same procedure. Notwithstanding paragraph 1 (a) of this Article, the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Should it be decided pursuant to the preceding subparagraph that the national authorization should be revoked, this decision shall apply to any other national authorization in respect of the substance in question. The decision may stipulate that the ban on the use of this substance shall extend to uses other than those referred to in the request for inclusion in the list.

Article 5

1. Where a Member State, as a result of new information or of a reassessment of existing information made since one of the specific directives was adopted, has detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible within the Standing Committee on Foodstuffs the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take the appropriate measures.

3. If the Commission considers that amendments to the specific directives in question are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 9 with a view to adopting those amendments; the Member State which has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 6

1. Without prejudice to any exceptions provided for in the specific directives, materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by:

(a) — the words 'for food use',

— or a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon,

— or a symbol determined in accordance with the procedure laid down in Article 9;

(b) where appropriate, any special conditions to be observed when they are being used;

(c) — either the name or trade name and the address or registered office,

— or the registered trade mark,

of the manufacturer or processor, or of a seller established within the Community.

2. The particulars listed in paragraph 1 must be conspicuous, clearly legible and indelible:

(a) at the retail stage:

— on the materials and articles or on the packaging,

— or on labels affixed to the materials and articles or to their packaging,

— or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; in the case mentioned in paragraph 1 (c), however, the latter option shall only be open if these particulars or a label bearing them cannot, for technical reasons, be affixed to the said materials and articles at either the manufacturing or the marketing stage;

(b) at the marketing stages other than the retail stage:

— on the accompanying documents,

— on the labels or packaging,

— or on the materials and articles themselves.

3. However, the particulars provided for in paragraph 1 shall not be compulsory for materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

4. The particulars provided for in paragraph 1 (a) and (b) shall be confined to materials and articles which comply:

(a) with the criteria laid down in Article 2;

(b) with the specific directives, in the absence of such directives, with any national provisions.

5. The specific directives shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.

In the absence of specific directives, Member States may retain existing provisions or adopt provisions to this effect.

6. Member States shall ensure that retail trade in materials and articles is prohibited if the particulars required under paragraph 1 (a) and (b) are not given in a language easily understood by purchasers, unless the purchaser is informed by other means. This provision shall not preclude such particulars appearing in several languages.

Article 7

1. Member States shall not, for reasons relating to composition, behaviour in the presence of foodstuffs or labelling, prohibit or restrict either trade in or the use of materials and articles complying with this Directive or with the specific directives.

2. Paragraph 1 shall not affect national provisions which are applicable in the absence of the specific directives.

Article 8

Amendments made to existing specific directives in order to bring them into line with this Directive shall be adopted in accordance with the procedure laid down in Article 9.

Article 9

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter to the Standing Committee on Foodstuffs either on his own initiative or at the request of the representative of a Member State.

2. The Commission representative shall submit to the committee a draft of measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the qualified majority laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the intended measures when they are in accordance with the committee's opinion;

(b) where the intended measures are not in accordance with the opinion of the committee, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act on a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

Article 10

1. Directive 76/893/EEC is hereby repealed.

2. References to the Directive repealed under paragraph 1 shall be construed as references to this Directive.

References to the Articles of the repealed Directive should be read in accordance with the correlation table appearing in Annex III.

Article 11

1. Member States shall take all measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures taken shall:

— permit, not later than 18 months after notification (1), trade in and use of materials and articles complying with this Directive, without prejudice to the application of national provisions which, in the absence of specific directives, apply to certain groups of materials and articles;

— prohibit not later than 36 months after notification trade in and use of materials and articles which do not comply with this Directive.

2. Paragraph 1 shall not affect those national provisions which, in the absence of the specific directives, apply to certain groups of materials and articles intended to come into contact with foodstuffs.

Article 12

This Directive shall not apply to materials and articles intended for export outside the Community.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council

The President

V. PAPANDREOU

(1) This Directive was notified to the Member States on 10 January 1989.

ANNEX I

List of groups of materials and articles covered by specific directives

Plastics, including varnish and coatings
Regenerated cellulose
Elastomers and rubber
Paper and board
Ceramics
Glass
Metals and alloys
Wood, including cork
Textile products
Paraffin waxes and micro-crystalline waxes

ANNEX II

Health criteria to be applied in the drafting of specific directives

1. Where appropriate, positive lists of substances shall be established for materials and articles intended to come into contact with foodstuffs. The acceptability of a substance for inclusion in a positive list shall be determined by considering both the quantity of the substance which is liable to migrate into foodstuffs and the toxicity of the substance.

2. A substance shall only be included in a positive list where, under normal or foreseeable conditions of use of any material or article of which it forms a part, the substance is not liable to migrate into foodstuffs in a quantity likely to constitute a danger to human health.

3. For certain materials it may be inappropriate to establish a positive list because such a list would offer no tangible benefit in terms of safeguarding human health. In such circumstances, any substances for which specific migration limits need to be established in order to prevent their being transferred to foodstuffs in quantities likely to constitute a danger to health shall be identified. The criteria set out in paragraphs 1 and 2 shall also apply to these substances.

4. All substances shall be kept under review and reassessed whenever this is justified by fresh scientific data or a re-evaluation of existing scientific data.

5. Where an acceptable daily intake or a tolerable daily intake is established for a particular substance, the need to establish a specific migration limit in order that this intake is not exceeded shall be considered. Where such a specific migration limit is established for a substance, due regard shall be paid to other possible sources of exposure to the substance.

6. In certain circumstances, a specific migration limit on a substance may not be the most valid means of safeguarding human health. In such circumstances, the need to protect human health shall be the primary consideration in determining what action might be appropriate.

ANNEX III

CORRELATION TABLE

Directive 76/893/EEC	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article —
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article —	Article 8
Article 9	Article —
Article 10	Article 9
Article —	Article 10
Article 11	Article —
Article 12	Article 12
Article 13	Article 11
Article 14	Article —
Article 15	Article 13