COMMISSION OF THE EUROPEAN COMMUNITIES

COM(94) 600 final

Brussels, 16.12.1994

94/0327 (COD)

Proposal for a
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE
amending Directive 89/398/EEC
on the approximation of the laws of the Member States relating to
foodstuffs intended for particular nutritional uses

(presented by the Commission)

EXPLANATORY MEMORANDUM

Justification of the proposal in terms of subsidiarity

1. **What are the objectives of the proposed measure with regard to the Community's obligations?**

   The specific directives which follow on from the framework Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses contain provisions on the composition of the dietary products in question. Amendments to these directives, including updates allowing for technological innovation, have to be approved in accordance with the procedure of the Standing Committee for Foodstuffs (regulatory committee IIIa) and require consultation of the Scientific Committee for Food. This procedure takes so long that the industries which have produced innovations are unlikely to benefit fully from their research, since their competitors have plenty of time to adapt their products to the new composition rules before the law can be amended to enable the products to be marketed. This proposal introduces a procedure by which temporary marketing authorizations can be granted for products resulting from such research. This should enable industries to enjoy a return on their efforts to develop improved products, of which consumers are the main beneficiaries. The procedure should also ensure that European industry is competitive at world level.

2. **Does competence for the proposed measure lie solely with the Community or is it shared with the Member States?**

   This sector is being harmonized at Community level, so the proposed measure falls within the exclusive competence of the Community.

3. **To what extent is this a problem on a Community scale?**

   Given that the proposal is designed to ensure that Community rules do not hamper innovation in the products sector of European industry, this is a problem on a Community scale.

4. **What is the most effective solution taking into account the means available to the Community and the Member States?**

   Since it is impossible to guarantee shorter deadlines for the directive adaptation procedure, the most effective solution is temporary authorization to market new products resulting from innovation pending the adaptation of Community law and its transposition into national law.

However, such marketing authorization could be granted only after consultation of the Scientific Committee for Food to check that the proposed technological innovation does not pose a risk to consumer health. In addition, Member States would be consulted through the Standing Committee for Foodstuffs to determine the sort of reception which would be given to the draft modification of the Directive concerned. This would have to be submitted to the Committee as soon as possible following the temporary authorization decision.

An alternative solution would have been to allow Member States to grant temporary marketing authorizations. However, such authorization could be granted only in respect of the national territory of the Member State concerned, and this would have created new barriers to the free movement of foodstuffs.

5. **What practical additional benefit will the proposed measure provide and what would be the cost of failure to take action?**

The proposed measure will enable firms which manufacture dietary products to derive proper benefit from their research by allowing them sufficient time to put their new products on the market without being faced immediately by their competitors, who currently exploit the lengthiness and transparency of the procedure to adapt their product range and incorporate other people's innovations into it. Lack of action would discourage these firms from carrying out research in the sector, given the cost of such research and the lack of any potential benefit. This situation would be prejudicial to the consumer, who is the main beneficiary of technological innovations.

6. **What forms of action are open to the Commission?**

Framework Directive 89/398/EEC will have to be amended to enable the Commission to grant temporary marketing authorizations.

7. **Is it absolutely necessary to adopt uniform rules or would a directive establishing general principles and leaving implementation to the Member States be sufficient?**

Since the idea is to introduce a Community procedure for temporary marketing authorization, the only solution is to amend Directive 89/398/EEC, adding a provision which lays down the precise conditions for granting authorization.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure referred to in Article 189b of the Treaty,

Whereas Article 4 of Council Directive 89/398/EEC[3] provides that specific provisions applicable to the groups of foodstuffs appearing in Annex I thereto must be laid down by means of specific Commission directives;

Whereas those specific directives reflect the state of knowledge at the time of their adoption; whereas, therefore, any amendment to include innovations based on scientific and technical progress must be approved in accordance with the procedure laid down in Article 13 of Directive 89/398/EEC;

Whereas this procedure, which includes consultation of the Scientific Committee for Food and requires a favourable opinion from the Standing Committee for Foodstuffs, means that the period after which a specific directive can be amended is relatively long;

Whereas the length of the procedure reduces the opportunity available to the industry which has produced the technological innovation to benefit from the fruits of its research;

Whereas a procedure must be laid down which allows the foods resulting from these innovations to be marketed on a temporary basis pending the amendment of the specific directive concerned;

Whereas, however, on the grounds of consumer health protection, marketing authorization can be granted only after consultation of the Scientific Committee for Food;

Whereas authorization can be granted only if the product poses no danger to human health,

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(1) OJ No

(2) OJ No

(3) OJ No L 186, 30.6.1989, p. 27.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Article 4 of Directive 89/398/EEC, the following paragraph 1A is added:

"1A To enable foodstuffs intended for particular nutritional uses and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting the Scientific Committee for Food and the Member States represented within the Standing Committee for Foodstuffs, authorize for a two-year period the marketing of food which does not comply with the rules as to composition laid down by the specific directives referred to in Annex I. Where necessary, the Commission may include in the authorization decision labelling rules relating to the change in composition."

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 September 1997. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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DOCUMENTS

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