COMMISSION OF THE EUROPEAN COMMUNITIES

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Report from the Commission
to
the Council and to the European Parliament

Implementation of Article 9 of
Council Directive 89/398/EEC
on the approximation of the laws of the Member States
relating to foodstuffs intended for particular nutritional uses

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1. Council Directive 89/398/EEC was adopted on 3 May 1989 and notified to Member States on 16 May 1989.

2. The directive sets out the definition for these products as well as provisions concerning their labelling, presentation and advertising. It further provides for the adoption of specific provisions for a number of groups of such products as listed in its Annex I, by means of specific Commission Directives.

3. Foods for particular nutritional uses (dietetic foods) not belonging to the groups listed in Annex I can be marketed in the Community provided they fulfill the requirements set out in the directive. Given however the nature of the products, it was important to provide a mechanism which would permit their efficient official monitoring.

4. This mechanism is set out in Article 9 of the directive. For reasons of clarity the relevant text is reproduced below:

"1. When a product as reffered to above (i.e. non-Annex I) is placed on the market for the first time the manufacturere or, where a product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.

2. Where the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer, shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification.

3. Where necessary, the competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product's compliance with Article 1 (2) together with the information provided for in Article 7 (3) (a). If such work is contained in a readily available publication, a mere reference to this publication shall suffice."

Article 9 also provided that Member States communicate to the Commission the identity of the competent authorities where the notifications were to be sent.

The Commission in accordance with the requirements of the directive published the list of the competent authorities in the Official Journal of the European Communities[1].

The Commission has gathered information on the implementation of this article. This information was provided by Member States and other interested parties. The information received was dated during a period ranging from June 1993 to January 1994 (with clarifications received up to April 1994).

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[1]OJ C 168 of 19.06.1993, p. 6

and OJ C 273 of 09.10.1993, p. 10

The following table summarizes the situation:

Member State	**B**	**DK**	**GR**	**DE**	**ES**	**F**	**IRL**	**IT**	**L**	**N**	**P**	**UK**
Notifications (Total)	0	0	0	0	1006	34	0	680	0	4	11	-

Some comments are necessary to clarify the above figures. It was felt best to provide more information where available per Member State.

Spain

333 products have been classified by the authorities as products complying with directive 89/398/EEC but not included in the products listed in its Annex I. These products are not further characterised. 673 of the products are classified as not being in conformity with directive 89/398/EEC. In their vast majority they comprise products containing mainly vitamins, minerals, trace elements, amino-acids and extracts of medicinal plants alone or in combination which in Spain are considered as pharmaceutical specialities and have to appear on a special register.

Italy

253 products of those notified are table-top sweeteners or products containing artificial sweeteners. The vast majority of the remainder are diet integrators containing vitamins, minerals, amino-acids, essential fatty acids, proteins and dietary fibre, alone or in combination.

Portugal

Products notified included non-alcoholic drinks, chewing gum and foofstuffs without addition of sugars and a table-top sweetener.

France

Notifications concerned products intended for low birthweight infants, pregnant and breastfeeding women, growing children, milk based products for young children, specialized fibre products and product containing medium chain triglycerides.

The Netherlands

All products notified were low lactose products.

United Kingdom

Due to a decentralised system of notification figures for this Member State were not available.

From the above it is obvious that the majority of the products notified were either products containing artificial sweeteners or diet integrators/food supplements containing vitamins, minerals, trace elements, amino-acids, etc. Forthcoming Community legislation on sweeteners will take care of the former products while the vast majority of the latter are not usually intended for the particular nutritional needs of specific categories of persons and therefore should not be considered as being included in the field of application of Directive 89/398/EEC.

The remaining products which were notified were few in number and indeed in many Member States no products were notified at all. This is mainly attributed to the fact that nearly all dietetic products on the market belong to one of the groups of products listed in Annex I of directive 89/398/EEC and as such are not subject to the notification procedure prescribed by Article 9 of the directive.

The Commission is to this date not aware of any problems with the notification procedures itself. Indeed the comments received by Industry are positive. Therefore the Commission has no reason whatsoever to propose any changes to it.

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