

Dietetic foods: approximation of the laws of the Member States (amend. Directive 89/398/EEC)

1994/0076(COD) - 27/06/2008 - Follow-up document

In accordance with Article 9(5) of Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (dietetic foods), the European Commission is required to send a report to the European Parliament and the Council on the implementation of Article 9 of the Directive.

In 1994, the Commission sent to the Council a report on this issue under the original provisions of Article 9(5) of the Directive. The report covered the notifications received from the entry into force of the Directive in 1989 up to 1994. In 1999, Directive 1999/41/EC amended the provisions of Article 9(5), requiring regular reports on the implementation of the Article to be sent to the European Parliament and the Council.

To enable the Commission to report on the implementation of this Article, the Member States were asked in 2002 and 2006 by the Commission services to provide information on: i) the number of food products that have been notified under Article 9 to their competent authority; ii) details of the particular nutritional uses of the notified products. The Member States were asked to indicate, when possible, if the notifications were related to the first time of placing a product on the market or if the products had been previously notified in another Member State.

This report integrates the information provided by Member States in 2002 and 2006 and covers reported notifications received by Member States up to the end of 2005. This time limit was requested by the Commission services. However, subsequently the preparation of the report was coupled with the preparation of the report on foods for people with carbohydrate-metabolism disorders (diabetes) and the reflection on the need for a global revision of Directive 89/398/EEC (including the implementation of Article 9). Such overall consideration of the issues took more time than expected but allowed for a more complete overview of the relevant sector.

The report recalls that the provisions of Article 9 aim at facilitating the official monitoring of the products placed on the market. But, as a general comment, the majority of the Member States consider that the notification system should be rationalised to ensure more harmonised implementation of the provisions of this article across the EU. Categories of products such as "gluten-free" and "lactose-free", which represent a substantial proportion of the notifications, will be regulated through specific rules for the use of such terms as provided for in Directive 89/398/EEC on dietetic foods (Article 4a) and Regulation 1924/2006 on nutrition and health claims made on foods (recital 22). Consequently, only the remaining products for which specific rules cannot be laid down because they are innovative products or because they are not part of a generally recognised category of food will be covered by the provisions of Article 9.

Inconsistencies may arise from different interpretations of the definition of "foodstuffs for particular nutritional uses" in Article 1 of Directive 89/398/EEC on dietetic foods, which has different elements and appears to be open to different interpretations by the authorities.

The provisions in Article 1 of Directive 89/398/EEC on dietetic foods indicate that, in addition to being aimed at certain categories of persons, dietetic foods have to be, owing to their special composition or manufacturing process, clearly distinguishable from foodstuffs for normal consumption. This report shows that this definition is not uniformly interpreted among the Member States and therefore agreement on the scope of application needs to be sought. This would also help to clarify the differences in the scope of

application between different pieces of legislation such as Directive 2002/46/EC on food supplements and Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (fortified foods).

In the light of these considerations it becomes clear that revision of Article 9, together with revision of other relevant articles, as appropriate, would be required for more effective and harmonised implementation of the dietetic food legislation.