

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.6.2008
COM(2008) 393 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**ON THE 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**

TABLE OF CONTENTS

| | | |
|---------|--|----|
| 1. | Introduction | 4 |
| 1.1. | Purpose and scope of Directive 89/398/EEC and of Article 9 | 5 |
| 1.2. | Evolution of the legal framework | 6 |
| 2. | Notifications reported by the Member States | 7 |
| 2.1. | Details by individual Member State | 8 |
| 2.1.1. | Austria | 8 |
| 2.1.2. | Belgium | 8 |
| 2.1.3. | Cyprus | 8 |
| 2.1.4. | Czech Republic | 8 |
| 2.1.5. | Denmark | 8 |
| 2.1.6. | Estonia | 9 |
| 2.1.7. | Finland | 9 |
| 2.1.8. | France | 9 |
| 2.1.9. | Germany | 10 |
| 2.1.10. | Greece | 11 |
| 2.1.11. | Hungary | 12 |
| 2.1.12. | Ireland | 12 |
| 2.1.13. | Italy | 12 |
| 2.1.14. | Latvia | 12 |
| 2.1.15. | Lithuania | 13 |
| 2.1.16. | Luxembourg | 13 |
| 2.1.17. | Malta | 13 |
| 2.1.18. | The Netherlands | 13 |
| 2.1.19. | Poland | 13 |
| 2.1.20. | Portugal | 13 |
| 2.1.21. | Slovak Republic | 14 |
| 2.1.22. | Slovenia | 14 |
| 2.1.23. | Spain | 14 |

| | | |
|---------|---------------------|----|
| 2.1.24. | Sweden | 14 |
| 2.1.25. | United Kingdom..... | 15 |
| 3. | Discussion | 15 |
| 4. | Conclusion..... | 18 |

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

ON THE 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

1. INTRODUCTION

In accordance with Article 9, paragraph 5 of 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 uses¹ (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 (COM (94)475) 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/EC² 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:

1. The number of food products that have been notified under Article 9 to their competent authority.
2. 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.

¹ OJ L 186, 30.6.1989, p. 27–32.

² Directive 1999/41/EC of the European Parliament and of the Council of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. OJ L 172, 8.7.1999, p. 38–39.

Additionally, comments on the experience of implementing the provisions of Article 9 within the country and the functioning of these provisions of the Directive were welcomed.

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.

1.1. Purpose and scope of Directive 89/398/EEC and of Article 9

Directive 89/398/EEC concerns foodstuffs for particular nutritional uses, also called dietetic foods. Article 1 of the Directive states that these are "foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability."

The Article states also that a particular nutritional use must fulfil the particular nutritional requirements:

- (1) of certain categories of persons whose digestive processes or metabolism are disturbed; or
- (2) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or
- (3) of infants or young children in good health.

Annex I of the Directive contains a list of groups of foods for particular nutritional uses for which specific provisions will be laid down by specific Directives. The foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in Annex I are covered by the provisions of Article 9.

Article 9 specifies that:

"To permit efficient official monitoring of foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in Annex I, the following specific provisions shall apply:

1. When a product as referred to above is placed on the market for the first time the manufacturer 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."

The purpose of Article 9 of Directive 89/398/EEC is to permit the official monitoring of foodstuffs intended for particular nutritional uses that do not belong to the groups of foodstuffs listed in Annex I of the Directive, for which specific Directives have been or will be developed.

1.2. Evolution of the legal framework

Initially, in 1989, Annex I listed nine groups of foodstuffs:

1. Infant formulae
2. Follow-up milk and other follow-up foods
3. Baby foods
4. Low-energy and energy-reduced foods intended for weight control
5. Dietary foods for special medical purposes
6. Low-sodium foods, including low-sodium or sodium-free dietary salts
7. Gluten-free foods
8. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen
9. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

That Annex was amended by Directive 1999/41/EC and two groups of foodstuffs were deleted: low-sodium foods, including low-sodium or sodium-free dietary salts, and gluten-free foods.

Articles 4a and 4b were added to Directive 89/398/EEC. Article 4a states that rules for the use of terms concerning the reduction or absence of sodium or salt (sodium chloride, table salt) content, and the absence of gluten, shall be adopted through a comitology procedure.

Article 4b states that, regarding foods for persons suffering from carbohydrate-metabolism disorders (diabetes), the Commission shall, in accordance with the comitology procedure, either proceed with the preparation of special provisions or present any appropriate proposals for amending the Directive.

The current version of the Annex reads:

- "Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives:
 1. Infant formulae and follow-on formulae³
 2. Processed cereal-based foods and baby foods for infants and young children⁴
 3. Food intended for use in energy-restricted diets for weight reduction⁵
 4. Dietary foods for special medical purposes⁶
 5. Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen⁷;
- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by a specific Directive, dependent on the outcome of the procedure described in Article 4b:
 6. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes).^{7"}

2. NOTIFICATIONS REPORTED BY THE MEMBER STATES

This section summarises the information on notifications of dietetic foods that are not listed in Annex I of Directive 89/398/EEC. Therefore, categories of foods listed in Annex I are in principle not taken into account. However, due to different ways of reporting and transposing the legislation, it has not always been possible to make this distinction and to extract the exact number of notifications of dietetic foods falling within the scope of Article 9 from the total communicated.

The starting date for reception of the notifications varies from country to country, due to differences in the time taken to apply the necessary procedures through national legislation.

³ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. *OJ L 401*, 30.12.2006, p. 1–33.

⁴ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version). *OJ L 339*, 6.12.2006, p. 16–35.

⁵ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction. *OJ L 55*, 6.3.1996, p. 22–26.

⁶ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes. *OJ L 91*, 7.4.1999, p. 29–36.

⁷ No specific directives have been adopted yet.

For countries that joined the European Union on 1 May 2004, the period taken into consideration starts from 1 May 2004, the date of accession.

Data from Bulgaria and Romania are not included in the report as it covers notifications received until the end of 2005.

2.1. Details by individual Member State

2.1.1. *Austria*

A total of 128 notifications have been received by the Austrian competent authority. The notified foods are described as:

- foods for persons suffering from celiac disease - gluten-free foods (92),
- foods for persons suffering from phenylketonuria (12),
- foods for pregnant or breast-feeding (lactating) women (10),
- foods for premature infants and carbohydrate-substitution after birth; enriched mother milk for pre-term infants (10),
- foods for persons suffering from hypercholesterolemia (6).

2.1.2. *Belgium*

One product has been notified to the Belgian competent authority. The request was for a “diet honey”, a product containing 60% sweeteners, for the replacement of honey for people who suffer from diabetes. It was not accepted, because it was considered not to be in line with Council Directive 2001/110/EC relating to honey. However, it has to be noted that, as mentioned above, foods for persons suffering from diabetes are not currently subject to the notification procedure laid down in Article 9.

2.1.3. *Cyprus*

No notification has been received by the competent authority of the Republic of Cyprus.

2.1.4. *Czech Republic*

No notification has been received by the competent authority of the Czech Republic.

2.1.5. *Denmark*

A total of 36 notifications have been received by the Danish competent authority. The notified foods are described as:

- low-protein foods (19),

- very low-calorie diet foods (9),
- lactose-free foods (5),
- gluten-free foods (3).

2.1.6. *Estonia*

A total of 19 notifications have been received by the Estonian competent authority. The notified foods have been described as:

- gluten-free foods (18),
- low-sodium foods (1).

Placing on the market: The marketing of three of these foods had already been notified in other Member States before notification in Estonia.

2.1.7. *Finland*

A total of 350 notifications have been received by the Finnish competent authority. The notified foods are described as:

- low-lactose or lactose-free foods (201),
- gluten-free foods (131),
- cholesterol-lowering foods (17),
- low-protein foods (1).

Note: Around 17% of the Finnish population suffer from lactose intolerance. For that reason the dairy industry has developed several milk products that are suitable for this population group.

Placing on the market: All the notified products were placed on the market for the first time in Finland.

2.1.8. *France*

A total of 92 notifications have been received by the French competent authority. The notified foods are described as:

- low-calorie food, not covered by specific legislation on weight reduction (34),
- high-protein and low-calorie foods (8),
- fortified foods for children and adolescents (cereals, biscuits and milk drinks) (46),
- fortified foods for seniors (milk drinks and biscuits) (2),

- powder milk-based food for convalescents (1),
- gluten-free foods (1).

Note: No information has been received for the period 2002-2005.

Placing on the market: The French authority states that in general, no information is provided about whether or not the product has been notified in another Member State.

2.1.9. Germany

A total of 338 notifications have been received by the German competent authority.

Out of that total, 119 notifications (35%) were found to be suitable for dietary purposes and in conformity with the legal provisions. The notified foods (including 27 products for which the procedure is still ongoing) are described as:

- Foods for hypercholesterolemics and/or persons requiring fat-modified food (46)
- Foods for pregnant women and/or breastfeeding mothers (30)
- Foods for persons suffering from an absorption or digestion disorder and diet-related nutrient deficiency (20)
- Foods for persons with an iron deficiency (14)
- Foods for persons requiring protein-modified food (in particular phenylalanine-low foodstuffs) (12)
- Foods for persons with a deficiency in specific amino acids (11)
- Foods for persons with a deficiency in certain mineral substances (other than iron) (7)
- Other (6)

128 notifications (38%) were not accepted because of, for example, the absence of an objective designation of a particular consumer group, the mention of conditions not requiring nourishment with specially formulated dietary foods (climacterium, migraine, age, stress, need to build up resistance, etc.) and/or a lack of marked differences compared with foodstuffs for normal consumption, such as food supplements⁸ or foods to which vitamins, minerals or other substances have been added⁹ ("fortified foods"). In addition some products were mainly intended for non-nutritive purposes, so that classification as a medicinal product could not be ruled out.

For 49 notifications the procedure is still ongoing, e.g. due to court proceedings pending or the not yet completed examination. Furthermore, 42 products were unnecessarily notified as they belong to categories of food included in Annex I of 89/398/EEC.

Notes: National provisions exempt the following groups of dietetic foods from the notification procedure laid down in Article 9:

- low-sodium foods including low-sodium or sodium-free dietary salts,
- gluten-free foods.

Placing on the market: For 15 of the notified products it was stated that the products had already been on the market in another EU Member State before placement on the German market. Four of those products were found to be suitable for dietary purposes.

2.1.10. Greece

A total of 15 notifications have been received and accepted by the Greek competent authority. An example of a notified product for particular nutritional uses is:

- a product partially covering the needs of certain persons that present peptic disturbances because of dietary excesses.

Note: Another four notifications regarding dietetic food for partial coverage of the nutritional needs of women during pregnancy and breastfeeding were not accepted, because there was no substantiation of the nutritional need.

⁸ "Food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities". They are regulated by Directive 2002/46/EC on food supplements. *OJ L 183, 12.7.2002, p. 51–57.*

⁹ Foods to which vitamins, minerals or other substances have been added are regulated by Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. *OJ L 404, 30.12.2006, p. 26–38.*

2.1.11. Hungary

A total of 174 notifications have been received by the Hungarian competent authority. The notified foods are all described as:

- gluten-free foods (174).

Note: Four of these products can be used by patients with phenylketonuria as well.

2.1.12. Ireland

One product has been notified to the Irish competent authority. It is described as:

- foods for people with lactose intolerance or lactase deficiency (1).

Note: The specific legislation passed into law in Ireland in 2002, and no formal notification procedure was in place before that date.

2.1.13. Italy

A total of 12000 notifications have been received by the Italian competent authority. Examples of notified foods for particular nutritional uses are:

- growth milk for infants,
- lactose-free milk,
- products for hydro-electrolytic regeneration in case of diarrhoea,
- food based on carbohydrates and group B vitamins to counteract ketose.

Note: In the Italian legislation, notification is required also for food supplements and fortified foods. The Italian competent authority states that a significant proportion of the notifications is constituted by food supplements, but it was not possible to extract the number of dietetic foods from the total number of notifications.

No information has been received for the period 2002-2005.

2.1.14. Latvia

A total of four notifications have been received by the Latvian competent authority. The notified foods are described as:

- dietetic waters suitable for different purposes (4). For example, for persons with an intensive amount of intellectual work, or for persons over 40, and who have a high radioactive environment and food pollution background.

2.1.15. *Lithuania*

No notification has been received by the Lithuanian competent authority.

2.1.16. *Luxembourg*

No notification had been received by the Luxembourg competent authority until 2001. No information has been received for the period 2002-2005.

2.1.17. *Malta*

No notification has been received by the Maltese competent authority.

2.1.18. *The Netherlands*

A total of five notifications have been received by the Dutch competent authority. The notified foods are described as:

- foods low in sodium and marketed as suitable for low sodium diets (5).

2.1.19. *Poland*

A total of 985 notifications have been received by the Polish competent authority. A substantial part of those (around 88%) concerned foodstuffs intended for particular nutritional uses belonging to the groups of foodstuffs listed in Annex 1 of the Directive.

The remaining 119 notifications relate to food described as:

- gluten-free foods (113),
- products with plant sterols (fat spreads and yoghurt drinks) (3),
- others: probiotics (2), growing up milk (1).

2.1.20. *Portugal*

A total of 66 notifications have been received by the Portuguese competent authority. The notified foods have all been described as:

- gluten-free foods (66).

Note: The Portuguese authority reports on the notifications received from November 2000, which is the date of the Decree-Law for transposition of Directive 1999/41/EC into national legislation.

No information has been received for the period 2002-2005.

Placing on the market: The marketing of these products had already been notified in other Member States before notification in Portugal.

2.1.21. *Slovak Republic*

No notification has been received by the Slovak Republic's competent authority.

2.1.22. *Slovenia*

A total of 63 notifications have been received by the Slovenian competent authority. The notified foods are all described as:

- gluten-free foods (63).

Placing on the market: The marketing of 62 of these products had already been notified in other EU Member States before notification was given to Slovenia.

2.1.23. *Spain*

A total of 544 notifications have been received by the Spanish competent authority. A substantial part of those (around 50%) concerned foodstuffs intended for particular nutritional uses belonging to the groups of foodstuffs listed in Annex 1 of the Directive, and therefore they are not included in this analysis.

A total of 273 notifications have been accepted by the Spanish competent authority. The notified foods are described as:

- gluten-free foods (215),
- low-sodium foods (56),
- foods for premature or low-birthweight babies (2).

2.1.24. *Sweden*

A total of 1680 notifications have been received by the Swedish competent authority. The notified foods are described as:

- gluten-reduced foods or naturally gluten-free foods (1128),
- foods reduced in or free from lactose, milk or milk protein (556),
- egg-free foods (160),
- soy-free foods (124),
- foods reduced in or free from protein/pea protein (89),
- phenylalanine-low foods (28),
- others: foods for adults with an extra need for calcium, such as women after menopause and older women (6), cholesterol-lowering foods and foods for extra input of energy or proteins (4), foods for adults with an extra need for iron (1) and other nutrients (2).

Note: The total of these notifications is higher than 1680 as each product can belong to more than one category (for example, a food that is both gluten-free and milk-free).

Placing on the market: Most products have not been notified in other Member States before placement on the Swedish market.

2.1.25. United Kingdom

A total of 114 notifications have been received by the UK competent authority. The notified foods are described as:

- gluten-free foods (103),
- others: breastmilk fortifiers (3), growing up milk (3) and foods for low-birth weight infants (2), dietetic salt (1), lactase deficiency management foods (1), weight management foods (1).

Note: The specific legislation passed into UK law in 2002, and no formal notification procedure was in place before that date.

Placing on the market: The UK does not have any information about whether these products have been notified for the first time in the UK, or if they have been notified previously in other Member States.

3. DISCUSSION

In the following discussion the Commission has highlighted the main issues put forward by Member States regarding the implementation of Article 9, grouping together relevant suggestions and examples from different Member States.

1. Concerning information on the first-time placing of a product on the market, several Member States expressed the view that it is often difficult to ascertain whether a food has been previously notified in another EU Member State. This can be due to the fact that importers often do not specify this information. Moreover, when there is knowledge that the food has been placed on the market in the Community, the importer often does not know in which Member State.

One Member State suggested simplifying the notification system and limiting it to the first notification, which could be disseminated electronically between Member States.

2. Some Member States commented that manufacturers or importers rarely notify modifications of the composition or of the labelling of dietetic foods that have been previously notified. Manufacturers and distributors sometimes change to a certain extent the composition, the claimed nutritional purpose, or the category of persons for whom the dietetic food is intended, so that a re-examination of compliance of the product with the legislation may become necessary.

One Member State underlined the fact that there is no obligation to inform the competent authority when a product is taken off the market, which makes it difficult to have an updated overview of what is on the market. Another Member State suggested creating the obligation for notifiers to communicate any changes made to an already notified product.

3. The provisions of Article 9(3) empower Member States, where necessary, to require the manufacturer or the importer to produce the scientific work and the data establishing the product's compliance with Article 1(2).

One Member State suggested exchanging practices and specialist knowledge among Member States on this issue.

4. There are discrepancies in the implementation of Article 9. Several Member States have received notifications for foods that belong to one of the groups listed in Annex I, which normally do not require notification under Article 9; even foods that are not covered by Directive 89/398/EEC have been notified. One explanation is that in some Member States notification is required for a wider range of foods, and the authorities do not differentiate between the different types of notifications.

On the other hand, an analysis of the notifications shows that there can be a number of reasons why it is difficult to apply the existing legislation. There are many so-called "borderline products", dietetic foods which may fall within the scope of different pieces of legislation. There can be uncertainties about dietetic foods being covered by a specific Directive or subject to the provisions of Article 9 as well as whether products are dietetic foods or normal foods.

Article 9 vs. specific Directives

Some Member States have taken the view that foods for people suffering from phenylketonuria are dietetic foods within the scope of Article 9, while others consider them as dietary foods for special medical purposes. The same kind of problem has occurred with "very low-energy products".

Dietetic foods vs. foods for the general population

Regarding the borderline with normal foodstuffs, the most frequent cases are summarised in the following examples:

Some Member States consider foods with added plant sterols as dietetic foods, intended for people suffering from hypercholesterolemia, while other Member States consider these as foods for the general population.

A similar issue arises when distinguishing between dietetic foods and food supplements. For example, some Member States view tablets with added vitamins for seniors as dietetic food, while others have treated them as food supplements. The Commission has noted that it is not possible for a food to be considered as both a dietetic food and a food supplement. In fact, according to the definition set out in Article 2 (a) of Directive 2002/46/EC on the approximation of laws of Member States relating to foods supplement, the purpose of a food supplement is to supplement the normal diet. On the contrary dietetic foods are foods which owing to their special composition or manufacturing process are suitable for a specific population group. As a general rule, if a food is presented in a dose form, as referred to in the definition of food supplements in Directive 2002/46/EC, it will be considered as a food supplement; but if a case-by-case examination of the nutritional purpose of the food shows that it is intended for a certain category of persons who are in a special physiological condition (and not for the general population), this product might be considered as a dietetic food.

There are also classification concerns regarding fortified foods and dietetic foods. In the report, for example, fortified cereals for children and adolescents have been notified as dietetic foods but, because of the recent entry into force of Regulation 1925/2006 on fortified foods (1 July 2007), such products could now be considered as fortified foods.

Some categories of normal foods were considered as dietetic foods by certain Member States because of the use of claims such as "soy-free" or "milk-free". This was based on the reasoning that these foods were intended specially for persons with intolerances or allergies to specific ingredients. It should be noted that, in the case of "allergen labelling", the indications concerning the presence of allergens are already covered by Directive 2000/13/EC on general food labelling¹⁰. The objective of that legislation is to provide consumers with comprehensive information on foodstuffs. To ensure that consumers suffering from an allergy or intolerance have information on the ingredients to which they are sensitive, there is a requirement to indicate on the label a reference to the name of the allergenic ingredients identified in the legislation. It is generally accepted that people who are sensitive to specific substances look at the list of ingredients for relevant information. In addition, foods which do not contain potentially allergenic ingredients cannot be automatically considered as dietetic foods.

¹⁰ Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L 109, 6.5.2000, p. 29–42, last amended by Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. OJ L 310, 28.11.2007, p. 11-14.

It should be noted that the report concerns relevant notifications made to Member States before some of the recent food legislation was in place. The evolution of EU legislation, such as the adoption of Directive 2002/46/EC on food supplements, is already having an effect on the notification system. Moreover, the recent entry into force of the Regulations on fortified foods and on nutrition and health claims is expected to have an impact on the category of foods notified under the Article 9 procedure.

5. Looking at the summary table that presents an overview of the notifications received (see Annex), it appears that a good percentage of the total of 3689 notifications (57%, 2107 notifications) refers to gluten-free products, and a second significant proportion (21%, 764 notifications) refers to lactose-free products. It can thus be seen that there are, among the high number of notifications, some generally accepted categories common to many of the Member States.

4. CONCLUSION

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.