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

**ON FOODS FOR PERSONS SUFFERING FROM CARBOHYDRATE
METABOLISM DISORDERS (DIABETES)**

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

ON FOODS FOR PERSONS SUFFERING FROM CARBOHYDRATE METABOLISM DISORDERS (DIABETES)

1. PURPOSE OF THE REPORT

Directive 89/398/EEC relating to foods for particular nutritional uses¹, otherwise called dietetic foods, provides that the Commission would report on the desirability of special provisions for foods for people with carbohydrate-metabolism disorders (diabetes). This report summarises the dietary recommendations for people with diabetes and the current European legislation on foods intended for them so that the desirability of special provisions for foods for people with diabetes can be assessed.

2. DIABETES MELLITUS

Diabetes mellitus is a group of metabolic disorders characterised by chronic hyperglycaemia (high level of blood glucose) and glucose intolerance due to insulin deficiency, impaired effectiveness of insulin action or both. Normally the hormone insulin, produced by the pancreas, controls the level of glucose in the blood through the movement of glucose from the blood into the body's cells where it is used as an energy source.

The World Health Organisation has defined two main classifications for diabetes mellitus¹:

Type 1 diabetes (formerly known as insulin dependent diabetes mellitus (IDDM) or juvenile onset diabetes), in which the pancreas fails to produce the insulin that is essential for survival. This form of diabetes develops most frequently in children and adolescents, but is being increasingly noted later in life. It is treated by insulin injections and dietary management.

Type 2 diabetes (formerly known as non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes), which results from the body's inability to respond properly to the action of insulin produced by the pancreas. Type 2 diabetes accounts for around 90% of all diabetes cases worldwide. It occurs most frequently in adults, but is being increasingly seen in younger adults and children. This form of diabetes is usually treated by changes in lifestyle such as diet and physical activity alone or together with oral hypoglycaemic agents, although sometimes insulin injections may be required.

¹ 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. OJ L 186, 30.6.1989, p. 27.

There are other classifications of diabetes arising from genetic defects, disease of the pancreas, and drug or chemical-induced disorders. There is also *gestational diabetes*, which affects women during pregnancy and usually disappears after delivery of the baby. Women who have had gestational diabetes are at higher risk of developing diabetes in later life.

2.1. Metabolic disorder

The metabolic effect of diabetes mellitus is more than a disorder of carbohydrate metabolism as it also includes disturbances in protein and fat metabolism that are due to the deficient action of insulin on target tissues resulting from insensitivity to or lack of insulin. As a result, the body's ability to convert glucose to energy is reduced.

Diabetes usually manifests itself as hyperglycaemia, which is the result of glucose entering the circulation at a rate greater than it can be removed. Blood glucose levels during fasting and after eating (postprandial) are regulated by mechanisms that are, to some extent, different. Postprandial blood glucose levels are largely dependent on meal composition, whereas fasting blood glucose levels mainly reflect the rate of glucose production by the liver.

There are various dietary parameters that influence blood glucose, such as the amount and types of foods consumed and their properties. It has been observed that some common foods containing the same type and amount of carbohydrates can have different effects on blood glucose levels (glycaemic response). The different glycaemic responses to foods containing the same amount of carbohydrates depend mainly on the rate of absorption from the small intestine. The type of carbohydrate is a major factor affecting absorption. Other influences on the rate of absorption are cooking and food processing.

Alcohol affects blood glucose levels as it suppresses the production of glucose in the liver, leading to a lowering of plasma glucose levels. but, if habitually consumed in large amounts, alcohol impairs insulin sensitivity, leading to increased plasma glucose levels.

Poorly treated diabetes increases the risk of vascular and neurological diseases and shortens life. There are also complications, such as loss of sight, associated with damage to the blood vessels and nerves caused by persistently raised levels of blood glucose. The maintenance of tight control over blood glucose (and blood pressure) can reduce the likelihood of complications.

3. TREATMENT OF DIABETES

The aim of the treatment of people with diabetes is to normalise blood glucose levels and also to minimise the complications arising from diabetes. The treatment needs to be tailored to the individual, who has to learn to integrate blood glucose monitoring with dietary management and physical activity and, if needed, oral hypoglycaemic agents or insulin injections.

4. DIETARY ADVICE

Historically, the recommended diet for people with diabetes focused on carbohydrate intake. Prior to the 1980s it was thought that blood glucose control could not be achieved without carbohydrate restriction. The advice was to restrict carbohydrate intake, especially sucrose intake, and that carbohydrates should therefore provide less than 40% of energy intake. Research since the 1970s has shown that a more liberal carbohydrate intake is not detrimental to good blood glucose control and, according to the theory developed in the early 1980s, it was total energy intake, rather than carbohydrate intake, that had an impact on glucose levels. In addition, a high-fat diet contributed to the development of complications of diabetes such as vascular damage leading to heart disease. In the 1980s the dietary advice changed to increasing the contribution of carbohydrates to energy intake and decreasing the proportion of energy from fat, especially saturated fat, and protein. It was recommended that the diet should be higher in fibre and that the amount of fruit and vegetables eaten should be increased. Currently, the dietary advice for people with diabetes is based on the same healthy eating advice as is given to the general population, tailored to their individual needs.

4.1. Scientific basis for dietary advice

In 2004, on behalf of the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes (DNSG of the EASD), Mannⁱⁱ reviewed the evidence for dietary advice for people with diabetes and made recommendations. Annex I summarises the main points noted in the review.

In 2002 a team led by Franzⁱⁱⁱ published a technical review of the evidence base for the nutrition principles and recommendations for the treatment and prevention of diabetes and related complications, which formed the basis of the American Diabetes Association position statement^{iv} on this issue. The overall conclusions of the Franzⁱⁱⁱ technical review were similar to those of Mannⁱⁱ.

4.2. European Dietary Recommendations

4.2.1. *Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes Recommendations*

In many EU countries, for example Denmark, Finland, Greece, Germany, Sweden, Hungary and Slovenia, the dietary advice to people with diabetes is based on the recommendations of the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes (DNSG of the EASD).

The 2004 DNSG recommendations took into account evidence on the roles of different unsaturated fatty acids, the value of low glycaemic index foods, the potential cardioprotective effects of antioxidant nutrients, the need to avoid excessive intakes of protein and the benefits of physical activity. The DNSG stresses that the dietary recommendations for people with diabetes are very similar to those aimed at the population as a whole for the promotion of good health. A summary of the recommendations and dietary advice is given in Annex II.

4.2.2. *Member States' National Diabetes Organisation Recommendations*

Some national diabetes organisations have their own guidelines for the overall nutrient profile of diets for diabetics. For example, France, Sweden and the United Kingdom provide their own dietary advice to people with diabetes. The recommendations on macronutrients are similar, i.e. carbohydrates contributing around 45-60% of total energy, fats providing <30-35% of energy, and protein providing 10-15% of energy intake. The contribution of the different types of fatty acids to energy intake is also similar: saturated or *trans* fatty acids providing <10% energy; polyunsaturated fatty acids also providing <10% energy intake; and monounsaturated fatty acids providing around 10-20% of energy. These recommendations are also in line with the advice of the DNSG of the EASD.

Annex II summarises the specific advice for the dietary management of diabetes from various organisations within Europe.

4.3. **Summary of dietary advice**

Diabetes is a disorder of macronutrient metabolism. The main objective of treatment is to control blood glucose levels and to reduce the risk of complications such as vascular or neurological damage. It may also be necessary for people with diabetes to aim to achieve optimal blood lipid status. These objectives can be achieved by different means, including eating an appropriate diet.

Two technical reviews on the evidence for the nutritional management of patients with diabetes, one produced on behalf of the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes (DNSG of the EASD), and the other produced for the American Diabetes Association, indicate that in the light of the scientific evidence the overall dietary advice to people with diabetes is that they should choose a healthy diet and should be able to do so from normal foods.

The dietary recommendations to people with diabetes within the different Member States are similar. In general, the dietary advice to people with diabetes is the same as the healthy eating advice to the general population. There is no need to exclude particular foods or nutrients from the diet but the balance of the diet overall is important. Individuals with diabetes need to plan their meals in such a way as to minimise changes in blood glucose concentrations and need to choose a diet to match their individual needs, taking into consideration the macronutrient composition of the foods eaten and their rate of absorption. The overall advice is that individuals should achieve or maintain an optimal body weight. Carbohydrate-rich foods should provide the major part of the diet. Foods rich in dietary fibre or with a low glycaemic index (for example pulses, wholegrain cereals and pasta) are especially recommended. The fat content of the diet should be less than 35% of energy, with monounsaturated fatty acids (found in olive oil and rapeseed oil, for example) providing 10-20% of energy. Both saturated fatty acids (found in animal products and hard edible fats, for example) and polyunsaturated fatty acids (found in vegetable oils, soft edible fats and fish, for example) should each provide less than 10% of energy intake, and protein intake should meet the requirements of the individual.

The overall advice is:

- choose a variety of foods;
- base meals and snacks on starchy foods such as wholegrain cereals, breads, potatoes and other starch vegetables;
- eat plenty of fruit and vegetables, at least five portions a day;
- have moderate intakes of dairy products and meat, fish or their alternatives (soy products, nuts, etc.); and
- limit intakes of fatty or sugary foods and alcohol.

Annex I gives a more detailed summary of the dietary advice.

5. INFORMATION PROVIDED BY MEMBER STATES AND OTHER INTERESTED PARTIES ON FOOD FOR PEOPLE WITH DIABETES

The Commission sought information from Member States on the current situation with regard to dietary advice, regulation of foods marketed as suitable for diabetics, the use of the claim “suitable for diabetics”, and the main products available on their market. Information was received from eighteen Member States.

5.1. Current regulatory position in some EU Member States

Below is a brief summary of the information provided by Member States concerning their national provisions. Annex III provides a more detailed summary.

Dietary advice – In general, dietary advice for people with diabetes is in line with the healthy eating recommendations for the population as a whole but tailored as

necessary to meet the needs of the individual. In many countries the advice is based on the recommendations of the DNSG of the EASD.

Regulations on foods intended for people with diabetes – Five Member States have compositional standards. In France there are compositional standards for “low-carbohydrate foods”; in Hungary for food that "can be consumed by diabetics" or with the indication "Diabetic (name of the product)" or "for diabetic"; in Germany, Spain and Slovakia there are certain compositional requirements for foods that can make a claim that they are “suitable for diabetics”.

The French regulation (Decree No 91-827 as amended) stipulates that in products intended as low-carbohydrate foods the total weight of assimilable carbohydrates must be less than 50% of the content of corresponding normal foods. However, under certain specified conditions, the percentage can rise to 70% for starch products and foods containing fructose or sorbitol. The foods must be sold with descriptions that include the terms “low in carbohydrates” or “reduced carbohydrate content”. In addition, the assimilable carbohydrate content must be indicated, followed by the statement “to be included in the daily quantity prescribed by the doctor”.

The regulations in Germany (Verordnung über diätetische Lebensmittel § 12) governing foods produced specifically for people with diabetes include details of the sugars that may be added and under what conditions. In addition there are restrictions on the energy content of bread and the carbohydrate content of beer. Following advice from the scientific community these regulations are under review.

The Spanish regulations include restrictions on the carbohydrate content of foods, sugars that may be added, and the fat content. There are certain labelling requirements for products containing sorbitol or aspartame.

The Hungarian regulation includes restrictions on the carbohydrate content of foods as well as restrictions on the use of mono- and disaccharides carbohydrate including fructose.

The Slovak regulation includes restrictions on the carbohydrate content of foods, the energy value, and the fat, animal protein, cholesterol and salt content.

Provisions for making the claim “suitable for diabetics” – In Hungary, the Slovak Republic, Germany and Spain products have to comply with the compositional requirements specified in their national legislation. In the majority of other reporting Member States, the claim should be in line with the rules on labelling of foods for particular nutritional purposes. Some Member States discourage the use of such claims in the light of the conclusion of the DNSG of the EASD that specific diabetic products are not scientifically justified.

5.2. Foods marketed as suitable for diabetics currently on the European market

The examples given by Member States as types of products specifically marketed for people with diabetes were chocolate, confectionery, drinks, biscuits and jams with fructose, polyols or artificial sweeteners in place of sucrose. As noted above, in France “low-carbohydrate foods” have to comply with the compositional requirements specified in the national legislation. It is permissible to indicate that

they can be advised by a doctor for use as part of the diet of certain diabetics. Pure fructose, aqueous fructose and sorbitol are also included in the French regulation as products for low-carbohydrate diets when intended to be used as sweeteners. In Germany, the national legislation on foods for diabetics includes specific provisions for bread and beer. Products that comply with the labelling provisions include bakery products, jams, chocolate, sweets, desserts and milk products containing fructose and/or sugar alcohols instead of sucrose. In Portugal there are some foods intended for enteral nutrition that are foods for special medical purposes and are suitable for people with diabetes. In addition, some ordinary foodstuffs with reduced energy content and with sucrose replaced by fructose, polyols or artificial sweeteners are marketed as “suitable for diabetics”. However, none of these ordinary foodstuffs have gone through the foreseen procedure that allows foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.

5.3. Views of other interested parties

From the information provided by Member States and interested parties it appears that many diabetes research and patient support organisations are not in favour of foods specifically produced or marketed for people with diabetes. They consider that the promotion of these foods can detract from the general dietary advice to people with diabetes, their reasons being that the overall dietary recommendations for diabetics are the same as the healthy eating recommendations for the population as a whole. Some Member States note that ordinary foods with reduced fat, sugar and/or energy content may make it easier for people with diabetes to comply with the dietary recommendations.

On the other hand, some patients and manufacturer organisations believe that new food products with proven benefit could be developed and used as part of an improved diet. This may include products that differ from commonly eaten alternative products in, for example, the amount and type of fat or the fibre content, or which may have a low glycaemic index. The organisations view industrially pre-prepared and fast food as an important area for development. They believe that, if developed, such foods might also be suitable for the population as a whole since they may be beneficial in helping people to achieve a lifestyle that would reduce the risk of developing diabetes.

6. LEGISLATION

6.1. Current legislative framework

Dietetic foods are defined in Article 1(2) of Directive 89/398/EEC (framework Directive) by three major characteristics:

- they are clearly distinguishable from normal foods (special composition or manufacturing process);
- they are intended for specific groups of people and not for the general population;

- they satisfy the particular nutritional requirements of the persons for whom they are intended. This should be supported by generally accepted scientific data.

Certain groups of products for particular nutritional uses, listed in the Annex of the above-mentioned Directive, are regulated by specific Directives which lay down compositional criteria and/or labelling provisions in order to ensure that the products are used appropriately and that they provide minimum and/or maximum levels of certain nutrients. Some of these are products that might be the sole source of nutrition, for example infant formula and some foods for special medical purposes. Such products have to satisfy the complete nutritional requirements of the individual as in certain circumstances there might not be an alternative source of nutrition. Other products such as cereal-based foods and baby foods, and foods intended for weight reduction could be viewed as "convenience products" because the particular nutritional needs of the persons for whom they are intended may also be covered by a careful selection of normal foods.

Foods for particular nutritional uses that are not listed in the Annex may be marketed under the provisions of Article 9 of the framework Directive. Under these provisions manufacturers or importers have to fulfil two procedural obligations when marketing these products:

- They must notify the competent authority of the Member State concerned that the product is being placed on the market and must, at the same time, forward a model of the label used. When the same product is subsequently placed on the market in another Member State, they must repeat the notification procedure.
- They must keep at the disposal of the competent authorities a file containing the scientific work and the data establishing that the product is in compliance with the definition of foods for particular nutritional uses, in other words, that the product fulfils particular nutritional requirements of the group of persons for whom it is intended.

Products that comply with the provisions of the framework Directive and the relevant specific Directives may circulate freely in the Community. Controls carried out by the competent authorities must be in conformity with relevant Community legislation and should be post-market ones. Member States are also responsible for ensuring that products marketed under the rules laid down in Article 9 of Directive 89/398/EEC are indeed dietetic foods.

The labelling of dietetic foods, as in the case of all foods, should comply with the provisions laid down in Directive 2000/13/EC on labelling of foodstuffs. In addition, according to the framework Directive, their labelling should indicate:

- the particular nutritional characteristics of the product;
- the particular qualitative or quantitative elements of the composition with regard to the intended use; and
- the energy, protein, carbohydrate and fat content of the product.

6.2. Possible legislative options

The Commission has at this stage identified three possible legislative options for dealing with foods intended for persons with carbohydrate-metabolism disorders (diabetes):

- A. Adopt a Commission Directive laying down specific compositional requirements for such products.
- B. Amend the framework Directive 89/398/EEC so that these products are deleted from Annex I, i.e. they will not be the subject of a specific Directive but may be marketed under the provisions of Article 9.
- C. Amend the framework Directive 89/398/EEC so that foods intended for persons with diabetes are excluded from the scope of that Directive, i.e. they cannot be marketed as foods for particular nutritional uses.

7. CONCLUSIONS

Two technical reviews^{ii & iii} on the evidence for the nutritional management of patients with diabetes have been considered in this report. Both reviews indicate that people with diabetes should choose a healthy diet and should be able to do so from normal foods. In the light of these reviews there are no grounds for developing specific compositional requirements for foods intended for people with diabetes.

The Scientific Committee on Food was asked to comment on the scientific conclusions of this report, in particular with regard to the scientific basis for defining specific compositional criteria for foods for persons suffering from diabetes mellitus. The Committee supports the following: *Dietary choices by people with diabetes can affect their long term health risks associated with the disease. The desirable dietary composition for people with diabetes is similar to that recommended for the population as a whole. Therefore, people with diabetes should be able to meet their dietary needs by appropriate selection from normal foods. There are no scientific grounds for specific compositional criteria for foods for particular nutritional uses in people with diabetes. However, people with diabetes should have information on dietary needs in diabetes, and on composition of foods, to enable them to choose a balanced diet that meets their individual requirements*^v.

Consequently, in the light of these considerations, the Commission would propose that Directive 89/398/EEC be amended in order that no specific Directive is required for that category of foods. The most appropriate and balanced solution for dealing with foods intended for persons with carbohydrate-metabolism disorders (diabetes) would be elaborated and presented in the framework of the revision of that Directive. In this context, the various policy options will be carefully examined and assessed taking into account the potential scientific and technological developments and other relevant legitimate factors such as e.g. the legal situations in the Member States and the health and socio-economic impacts.

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