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COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on food intended for infants and young children and on food for special medical purposes

[Previously known as the Impact Assessment accompanying document to the Proposal to revise the Dietetic Food Framework Legislation]

This document commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission

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TABLE OF CONTENT

Section 1: Procedural issues and consultation of interested parties

1.1. Consultations

Member States

The Commission wrote to the Member States on 12 April 2007 seeking their views and experience on the implementation of the Framework Directive on dietetic foods[1] in order to prepare the reports on 1) the implementation of the notification procedure of the Framework Directive on dietetic foods and 2) the desirability of special provisions for foods for persons suffering from carbohydrate-metabolism disorders. In addition, the Commission organised working groups with Member States in 2007 (27 June and 9 September) and 2008 (29 January, 13 May) to discuss the subsequent draft reports and to consider the need for a global revision of the dietetic food legislation. The two reports[2] were published in June 2008.

On 6 November 2008, the Commission sent to Member States a questionnaire in order to update the data on the implementation of the notification procedure (the report published in June 2008 contained data up to January 2005). Information was sent by the Member States on the notifications received in their country between January 2006 and June 2008.

Further meetings were organised in 2009 (6 April and 6 July) with the Member States in order to progress a general discussion on the revision of the Framework Directive. In order to gather further information on the problems with the current regime and potential options for rectifying the problems, the Commission sent a further questionnaire to Member States. The results of the questionnaire were discussed during a working group on 21 September 2009 along with the potential impacts revising the legislation would have. Member States were asked to gather qualitative and quantitative data, where possible, on the impact of each option to discuss further in November. On 23 November 2009 the Commission organised a final meeting to consider the data collected and to discuss the potential policy options.

Stakeholders

Stakeholders (industry association representatives and consumer's groups) were consulted on the revision of the dietetic food legislation within the framework of the Advisory Group on the Food Chain and Animal and Plant Health. Two meetings were organised on 17 July 2009 and 20 May 2010.

In the framework of the European Consumer Consultative Group (ECCG), the Commission explained on 25 March 2009 that an impact assessment on the revision of the dietetic food

[1] OJ L 124, 6.05.2009, p.21

[2] COM (2008) 393 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.

COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes).

legislation was ongoing. It presented the problem definition, objectives of the revision, options to consider and Stakeholders consultations and asked for input from consumers' associations.

In addition, between 2007 and 2009, several focused meetings were organised with the specialised dietetic food industry (mainly with IDACE which is the European Association of the Food Industries for Particular Nutritional Uses).

Summary of the consultation of the interested parties

Throughout the impact assessment and policy making process interested parties' (Member States and Stakeholders) views have been sought in order to design the policy option and assess their potential effectiveness and efficiency. Annex IV gives an overview of their positions and Annex VI lists all the stakeholders that have been consulted during the process.

1.2. Data collection on behalf of the Commission

The internal process to develop the Impact Assessment (IA) was supported by a contract with an external consultant[3]. In April 2009, a study on the economic, social and environment impact of potential policy options for the revision of the Framework Directive on dietetic foods was prepared by Agra CEAS Consulting. They were tasked with providing an *ex ante* assessment of the economic and wider social impacts of different situations. Due to the nature of the specialised food market the external consultant was unable to gather accurate detailed figures on the size of the dietetic foods market. However, as the policy options developed and further impacts were identified DG SANCO attempted to gather further information from the industry and the Member States to assess the key impacts the change in policy would have. These data are used and referenced throughout the impact assessment.

1.3. Inter-service Steering Group (ISSG)

A Commission Inter-Service Steering group on the Impact Assessment of the revision of the legislation was established. The group was led by DG SANCO with the participation of the following Commission Directorates General and Services: Agriculture and Rural Development, Industry and Entrepreneurship, Research and Innovation, Trade and the Secretariat General. The group met on 10 February 2009 (planned approach and the identified options were discussed), 26 March 2009 (report from the contractor on progress and collection of data were discussed) and 28 June 2010 (exchange of views on draft Impact Assessment report). On 9 August 2010, a final draft was sent to the ISSG whose members provided final comments beginning of September 2010 which have been incorporated

1.4. Follow-up to Impact Assessment Board recommendations

In its opinion of 20 December 2010, the Impact Assessment Board recommended that the problem issues should be better explained, in particular those linked to sports foods. The IAB also asked to discuss the expected impacts on national rules and to provide a more systematic

[3] Food Chain Evaluation Consortium (FCEC) Civic Consulting – Agra CEAS Consulting

assessment of administrative costs taking into account the interaction between different pieces of law.

In order to take these recommendations into account, the sections related to sports foods have been updated by using more systematically the information obtained from the external study and from focused consultations with the Member States and the industry representatives. As regards potential impacts on national rules, a summary table of the four options with regard the different categories of foods and rules that would apply to them under each option has been added and discussed. Finally, the impact assessment has clarified that administrative burden costs significantly vary between Member States and that applying EU Standard Cost Model would not reflect accurately the overall cost. Therefore, in order to appropriately demonstrate the impacts, a more qualitative approach was taken.

Section 2: Problem Definition

2.1. Background

The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens. In that context, EU Food legislation has been developed; its foundation being the General Food Law Regulation[4] which states that **food shall not be placed on the market if it is unsafe** (injurious to health or unfit for human consumption). As a general principle, more specific measures are introduced across the Union when a risk assessment or a market failure shows the need for further rules in order to harmonise trade and provide the same high level of consumer protection within the EU. It is the responsibility of the legislators to ensure that such rules are relevant and proportionate and do not unnecessarily add administrative burden and/or hinder innovation.

2.1.1. The Dietetic Food Framework Directive

The Dietetic Foods Framework Directive[5] (Directive on foodstuffs intended for particular nutritional uses, or "PARNUTS") was adopted in 1977 **to remove the differences between national laws relating to dietetic foods that impeded their free movement and had created unequal conditions of competition**. The Framework Directive was amended several times and a recast version was adopted in 2009 to include the rules of the new Comitology procedure.

To enable the consumer to be protected against fraud concerning the nature of these products, a **common definition on dietetic foods** was drawn up as well as **general provisions and common labelling rules**. The legal basis was former Article 100a of the EC Treaty, later replaced by Article 95, now Article 114 of the Treaty on the Functioning of the European Union (TFEU).

According to the legislation, dietetic foods have three major characteristics:

- they are special and distinguishable from normal foods (special composition or manufacturing process);
- they are intended for specific groups of the population and not for the general population;
- they satisfy the particular nutritional requirements of the persons for whom they are intended.

A particular nutritional use shall fulfil the particular nutritional requirements of certain categories of persons whose digestive processes or metabolism are disturbed; or of certain categories of persons who are in a special physiological condition and who are therefore able

[4] OJ L 31, 1.2.2002, p. 1–24
[5] OJ L 124, 6.05.2009, p.21

to obtain special benefit from controlled consumption of certain substances in foodstuffs; or of infants or young children in good health.

Examples of dietetic foods are *foods intended for infants and young children, foods for people suffering from intolerance to gluten, foods for special medical purposes (used under medical supervision) etc*.

The designation under which a dietetic food is sold shall be accompanied by an indication of its particular nutritional characteristics: **a suitability statement for the particular nutritional use.**

2.1.2. Application of the 'dietetic food' legislation

Dietetic foods covered by specific legislation

The Framework Directive lists in its Annex a series of groups of dietetic foods for which specific rules shall be set out by Commission Directives. For a number of these groups specific legislation (Directives/Regulation) has already been adopted laying down specific compositional and labelling rules. There is Commission legislation on:

- Infant formulae and follow-on formulae[6]: the specific Directive governing infant formula was introduced to ensure that formulae marketed as a substitute for breast milk were compositionally adequate and appropriately labelled and would not pose any threats to a child's health;

- Processed cereal-based foods and baby foods for infants and young children (baby foods)[7]: the specific legislation for baby foods focuses more on the substances that can and cannot be present or used in processed baby foods (e.g. maximum levels of pesticides residues, additives, minimum and maximum levels for certain nutrients etc.) in order to ensure nutritional quality for this category of foods used for convenience more than out of necessity;

- Foods intended for use in energy-restricted diets for weight reduction (slimming foods)[8]: the Directive on slimming foods was introduced to ensure adequate nutritional composition for this category of foods used as a convenient way to replace meals in order to control and/or lose weight;

- Foods for special medical purposes (medical foods)[9]: the Directive on medical foods includes basic compositional standards of foods but focuses more on the marketing and use of the products. It ensures that medical foods are appropriately labelled and is accompanied by sufficient conditions of use;

[6] OJ L 401, 30.12.2006, p.1.
[7] OJ L 339, 6.12.2006, p. 16.
[8] OJ L 55, 6.3.1996, p. 22.
[9] OJ L 91, 7.4.1999, p. 29.

- Foods for people intolerant to gluten (gluten-free foods)[10:] the recently adopted Regulation on foods for people intolerant to gluten lays down rules for the use of the term "gluten-free" not only for dietetic foods but also for 'normal foods'.

Dietetic foods with specific designation

There are two groups of foods that are covered by the Framework Directive and mentioned in its Annex but for which no specific rules have been elaborated so far: foods for persons suffering from carbohydrate metabolism disorders (diabetes) and foods intended to meet the expenditure of intense muscular effort, especially for sportsmen.

- Sports foods – The Framework Directive on dietetic foods indicates since 1989 that specific provisions will be laid down in a Directive to cover 'foods intended to meet the expenditure of intense muscular effort, especially for sportsmen'. Examples of sports foods include: *Protein bar supporting muscle building and fast recovery; Amino-acids supplements to meet the expenditure of intense muscular effort; Carbohydrate gel with extra sodium to compensate sweat loss.* Although discussions on preparing the Directive have already taken place[11], minimal progress has been made as there are several issues that would make the adoption of specific legislation on sports foods difficult (scope, number of categories, sports foods in a food supplement form, innovation etc.). The revision of the Framework Directive will provide the opportunity to reflect on different possibilities for dealing with sport foods.

- Foods for persons with diabetes – the Framework Directive outlines in its Article 6 the possibility of special provisions for foods for persons suffering from carbohydrate-metabolism disorder (diabetes). It requires that a decision is made on the desirability of a specific Directive for this category of foods. The Commission report[12] on diabetic foods concludes that there is no scientific basis on which to develop specific compositional requirements in a specific Directive for this group of foods.

- Foods for lactose intolerant people – the Nutrition and Health Claim Regulation foresees that *conditions for claims such as "lactose-free" addressed to group of consumers with specific disorders should be dealt with in the Framework Directive on Dietetic Foods*[13].

Dietetic foods without specific designation

Categories of foods not belonging to any of the abovementioned categories but complying with the definition of a dietetic food and for which no specific compositional and labelling rules have been laid down are required to undergo a notification procedure at national level to

[10] OJ L 14, 20.1.2009, p. 5.

[11] Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen, 28/2/2001

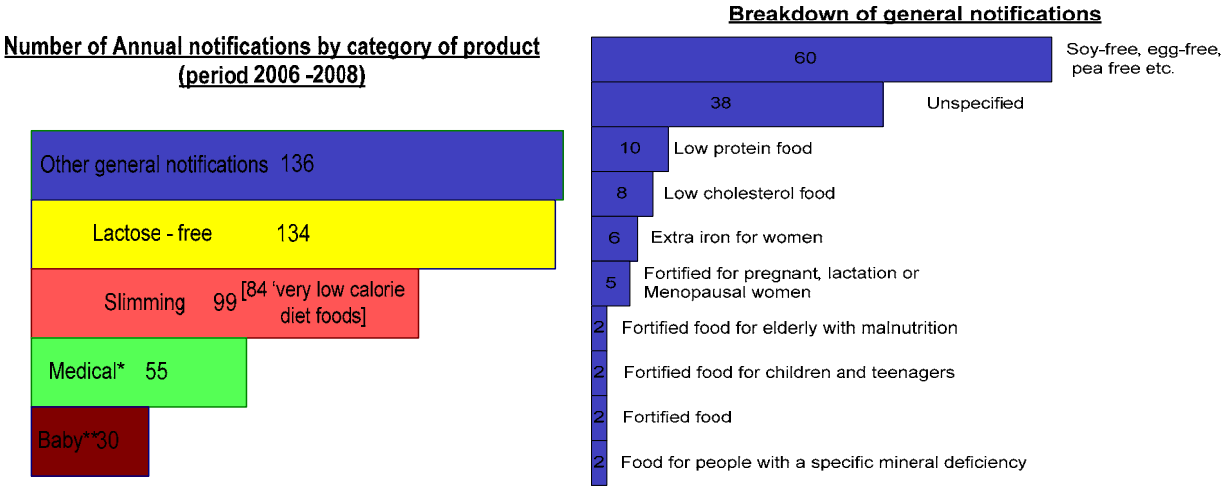
[12] COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes), Brussels, 26.6.2008

[13] Recital 22 of Regulation (EC) No 1924/2006

facilitate the official monitoring by the competent authorities and the placing on the market of innovative products. This requires the manufacturer or the importer to notify the competent authority of each Member State where the product is being marketed for the first time and to produce the scientific work proving the claimed suitability on request of the competent authorities.

The number of products notified[14] under the notification procedure as foreseen in Article 11 of the Framework Directive for 27 Member States is presented by category of products in the figure below.

Figure 1: Number of annual notifications by category of products



*Medical foods that were considered not to be covered by the specific Directive and therefore notified under the general notification procedure.

**Baby and infant foods that were considered not to be covered by the specific Directives and therefore notified under the general notification procedure.

NB: as no formal request for notifications on sports and diabetic foods is foreseen under the general notification procedure (Art.11) those groups of foods were not included in the figure above.

As regards gluten-free foods, given that a new Regulation has been adopted in 2009, there were not included either in figure 1 but a detailed situation of the gluten-free foods notifications in the Member States is given in figure 3.

[14] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting. p.139-142.

Figure 2: Number of annual notifications by Member States and by category of products (including sports foods and diabetic foods)

Country	AT	CZ	DE	DK	ES	EE	EL	FI	FR	HU	IE	IT	LT	LV	NL	PT	PL	RO	SE	SL	UK	EU Total
General Notifications	1	0.4	10	11	1	0	0	6	4	0	2	36	0.4	1	2	0	0.4	0	61	0	0	136
Lactose free foods	0	0	0	8	0	7	1	40	0	0	0	0	0	0	0	0	0	0	79	0	0	134
Slimming foods	0	1	0	12	0	0	0	7	2	0	44	0	0	0	0	0	0	0	0	0	33	99
Medicinal foods	10	0	8	0	0	0	7	0	4	0.4	0	0	0	0.4	0	0	0	2	1	22	0	55
Baby and infant foods	0	19	0	0	1	0	0	0	0	1	0	0	0	0	0	2	0	6	0	0	2	30

* **CY, MT** and **SK** had zero notifications.

Figure 3: Number of Annual Notifications on Gluten-free Foods by Member State

Country	AT	CZ	DK	ES	EE	EL	FI	FR	HU	IE	IT	PT	PL	SE	SK	SL	UK	EU Total
Gluten free foods	45	20	55	17	4	12	102	32	113	9	360	23	43	82	14	2	12	945

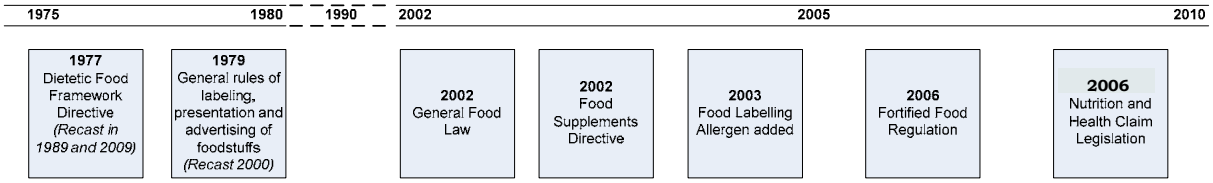
* **CY, DE, LT, LV, MT, NL** and **RO** had zero notifications.

2.1.3. Subsequent relevant measures in the area of food legislation

An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life (except for young infants when not breastfed). However, due to current economic, social and cultural situations, this ideal condition may not be achieved for all nutrients and by all groups of the population. Consequently, addition of nutrients and other substances to foods (fortified foods) and manufacturing of concentrated sources of nutrients (food supplements) has developed. In parallel, in order to advertise the added benefit of these (and other) foods to the relevant target groups of consumers and to promote them, nutrition and health claims have started to accompany food products.

As the food market evolved so did the EU legislation governing it, in order to ensure the functioning of the internal market and guarantee the same level of protection to citizens across Europe. The following figure illustrates the evolution of the EU food legislation in this field.

Figure 4: Evolution of the EU Food legislation



To understand the interaction of these pieces of legislation with the dietetic food legislation, it is important to understand their scope of application.

Of particular importance in this area is the adoption of the Food Supplements Directive[15], the Regulation on 'fortified foods'[16] (Regulation on the addition of vitamins and minerals and of certain other substances to foods) and the Nutrition and Health Claims Regulation[17].

Besides, the amendment of the general food labelling Directive in 2003[18] introduced rules on the indication of allergens or substances causing intolerances.

The Food Supplements Directive

The EU Food Supplements Directive was adopted in 2002 to ensure that food supplements that are placed on the internal market are safe and bear adequate and appropriate labelling. A food supplement is defined in the legislation as a foodstuff which supplements the normal diet. They are a concentrated source of nutrients (e.g. *vitamins, minerals*) or of other substances with a nutritional or physiological effect (e.g. botanical substances, fibres…). Food supplements are usually marketed in dose form such as capsules, pastilles, tablets, pills, powders or ampoules of liquids. Examples are *multi vitamin and minerals or mixture of herbals capsules; creatine and carbohydrate tablets; omega 3 fatty acid pills, etc.*

The Regulation on Fortified Foods

EU legislation on fortified foods was adopted in 2006 and provides for rules (conditions, labelling, positive lists etc.) concerning the addition of vitamins and minerals to foods for nutritional and/or physiological reasons (e.g. *fortified cereals with vitamins and minerals, fortified juices with vitamin C, margarine with added vitamin A etc.).* The Regulation also foresees the possibility, if certain conditions are fulfilled, to scrutinise and if necessary restrict the use or forbid substances with a nutritional or physiological effect.

Vitamins and minerals are added to foods by manufacturers for a number of purposes: for reasons dictated by public health considerations, restoration of their content where this has been reduced during manufacturing, storage or handling procedures or to provide a similar

[15] OJ L 183, 12.7.2002, p. 51–57
[16] OJ L 404, 30.12.2006, p. 26–38
[17] OJ L 404, 30.12.2006, p. 9–25
[18] Directive 2003/89/EC – OJ L 308,25-11-2003 p.15

nutritional value to foods for which they are intended as alternatives or to enrich foods in nutrient content.

The Regulation on Nutrition and Health Claims

The Regulation on nutrition and health claims was adopted in 2006 and lays down harmonised rules for the use of nutrition (*such as "low fat", "high fibre")* or health claims (*"helps lower cholesterol, calcium and vitamin D are needed for normal growth and development of bone in children" etc.)* made on foods. The Regulation aims at ensuring that any voluntary claim made on foods in the EU is clear, accurate, substantiated and not misleading, thus enabling consumers to make informed and meaningful choices when it comes to foods and drinks. Any nutrition claim made on food has to be present in an Annex to the Regulation and to comply with the requirements set down in the legislation and any health claim, whether a functional health claim or a disease risk reduction claim or a claim referring to children's development and health, made on food has to be prior-authorised by the Commission, in cooperation with Member States, after an evaluation of the substantiating science is given by the European Food Safety Authority (EFSA).

Use of nutrition and health claims is one way to pass information on to consumers and claims also contribute to supporting appropriate decision-making in relation to the purchasing of food and drinks. Only products offering substantiated health or nutritional benefits will be allowed to refer to those on their labels.

The Nutrition and Health Claim Regulation applies to all foods including dietetic foods without prejudice to further provisions included in specific legislation[19].

For health claims already authorised and nutrition claims a food business operator must be able to justify the use of the claim (post-market control).

General food labelling

At EU level, rules exist on food labelling which are mandatory for all foods. Mandatory food labelling, originally established by Directive 79/112/EEC[20] and recast as Directive 2000/13/EC, is currently under review. A proposal for a Regulation of the European Parliament and the Council on the provision of food information to consumers was adopted by the Commission in January 2008. The proposal introduces new rules to improve information to consumers; establishes the general principles of food information law; clarifies food business operators' responsibilities as regards the provision of food information to consumers; proposes basic rules on the legibility of labelling; proposes that mandatory information about substances causing allergies and intolerances listed in the legislation should be extended to non-prepacked foods. With respect to nutrition labelling, it is proposed that

[19] Rules for claims on infant formulae have been laid down in Annex IV of Directive 2006/141/EC, consequently Regulation on claims does not apply to infant formulae.

[20] OJ L 33, 8.2.1979, p. 1

there should be mandatory information on a number of key nutritional elements on the majority of processed foods. The European Parliament and the Council are expected to adopt the final Regulation by 2012.

2.1.4. International Standards

Apart from EU legislation, Codex Alimentarius standards exist on 'dietetic foods' which consist in a *"general standard for the labelling of and claims for prepacked foods for special dietary uses* (dated 1985)*"* and specific rules for a number of categories (See Annex I). These standards lay down general rules as well as specific composition and labelling rules for specific groups of foods.

2.2. Problem identification

The Dietetic Food legislation provides rules for foods that are different from 'normal' foods for the general public and it targets particular groups of the population with specific nutritional requirements.

EU food legislation has developed in parallel to the evolving food market to ensure a high level of consumer protection while guaranteeing the smooth functioning of the Internal Market. The Dietetic Food legislation was adopted over thirty years ago in order to ensure free movements of goods and prevent unequal conditions of competition. Nowadays due to the diversification and specialisation of foods, its interaction with the more recent pieces of EU legislation described in the background section is often being questioned.

The key problem identified in relation with the current application of the Framework legislation is distortions of trade in the internal market due to uneven interpretation and enforcement across Member States.

2.2.1. 'Dietetic' food or 'normal' food

As the development of food and its marketing is becoming more and more targeted to specific categories of consumers *(e.g. fortified foods for children, food supplements for pregnant women, fortified food to boost the immune system etc.)*, it could be argued that a vast number of products on the market today are developed for/aimed at a certain group of the population with specific nutritional needs. This consideration can lead to questions such as:

- How to deal with the following heath claim, recently positively assessed by EFSA: *"Folate contributes to normal maternal tissue growth during pregnancy"* which, once authorised under the claims Regulation, could be made on food containing folate in certain amounts and could be targeted to *women planning to become pregnant and pregnant women?* Would a product bearing that claim be considered as a dietetic food because targeted to women that plan to become pregnant or would that be considered as a 'normal' food bearing a health claim addressed to pregnant women?

o A margarine containing phytosterols which bears the authorised claim "*Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease*" is marketed as a normal food. However, some could argue that because it targets mainly hypercholesterolemic people, it could be considered as a dietetic food.

Added to this, is also the problem that according to the Dietetic Food legislation and the definition[21] of dietetic food, only "dietetic" foods (different from their normal food equivalent) are allowed to state suitability for a group of the population. This possibility is on the contrary not per se[22] given to normal foods.

Naturally, some foods are more appropriate than others for certain categories of people. A strict interpretation of the definition of dietetic food would, however, imply that such products could not be labelled as dietetic products. For example, a product naturally free of lactose (e.g. soy product) could not be labelled as suitable for lactose intolerant people because it is not a product that is different from its normal equivalent. On the contrary, a dairy product where lactose has been removed could be considered as a dietetic food and consequently state by definition its suitability for lactose intolerant people.

It is clearly difficult to see where that distinction between foods intended for the 'normal' population and foods intended for a 'specific group' of the population lies. This in turn is making interpretation, application and enforcement of current legislation difficult.

2.2.2. Legislation "shopping"

Member States have reported[23] that the legislation on dietetic foods is being used by some operators to circumvent the rules of subsequent legislation, distorting the notion of a food for particular nutritional uses, and resulting, in certain cases, in confusion over its application that creates unfair competition between businesses.

In other words, it appears that some operators notify under the dietetic food legislation a 'normal' food in order to be able to use a 'dietetic' suitability statement (mandatory according to the dietetic food legislation) instead of the equivalent voluntary claim and therefore avoid the requirements of the Regulation on claims. This situation distorts the market and results in an uneven playing field for food operators and unfair competition. This is particularly true for the potential dietetic foods for which no specific rules have been laid down and where the classification as dietetic foods, food supplements or fortified foods is not always obvious.

The following examples illustrate the situation:

- Foods for lactose intolerant people

[21] As noted in 2.1.2, dietetic foods are described by three major characteristics:
- they are special and distinguishable from normal foods (special composition or manufacturing process);
- they are intended for specific groups of the population and not for the general population;
- they satisfy the particular nutritional requirements of the persons for whom they are intended.

[22] A specific provision in the Framework Directive (Art.2.2.) allows under the comitology procedure 'normal' foods which are suitable for a particular nutritional use to indicate such suitability.

[23] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting

(Statement 1)"Lactose reduced milk for lactose intolerant people" and

(Statement 2) "Fermented dairy product, improves lactose digestion"

In both cases, the target population is individuals with symptomatic lactose maldigestion (lactose intolerance).

Are these 'dietetic' suitability statements or health claims? As highlighted before this is a question of importance in the context of food legislation as the requirements for using 'dietetic' suitability statements are not the same as the requirements for bearing nutrition or health claims – namely, notification procedure applied at national level versus EU prior-authorisation based on as scientific assessment by the European Food Safety Authority (EFSA) – and could result in unfair competition between food businesses.

- Foods for older adults (the elderly)

(Statement 1)"Fortified food in calcium and vitamin D suitable for elderly" and

(Statement 2)"Food fortified in calcium and vitamin D contribute to a reduction in the risk of bone fracture"

Similar foods could be sold as dietetic food in one Member State (using *Statement 1*) and as fortified food bearing a health claim in another (*Statement 2*). Bearing in mind that the respective legal requirements are not the same, this situation distorts the market.

- Sports foods

Branched chain amino acid products in a food supplement form: dietetic food or food supplement? Depending on the answer, differing rules may be applied by Member States distorting the market further.

2.2.3. Understanding the interaction – 'dietetic' suitability statement or claim?

When the Framework Directive on dietetic foods was adopted in 1977 the compulsory 'dietetic' suitability statement foreseen on the label was intended to cover broadly that category of foods with general rules rather than with specific rules. Following the adoption of the Nutrition and Health Claims Regulation in 2006, which covers all statements made on foods implying a nutritional and/or a health benefit, the interaction between the different pieces of legislation has become less clear. Moreover, it can be argued that, in cases where no further rules have been set in specific pieces of legislation, the indication of 'dietetic' suitability, as eroded by the Claims Regulation, would today be restricted to the indication of the group of the population to whom the food is intended.

Guidance from the dietetic food industry itself considers that *"mandatory or optional information required or allowed by the dietetic legislation related to their suitability, particular characteristics and composition, is not a claim under the nutrition and health*

claims (NHC) Regulation"[24]. These are considered as *claim-like* information and therefore outside the scope of the claims Regulation. The dietetic food industry guidance also suggests that *"information about dietetic foods which characterise their purpose, even if it includes nutrition or health information is principally not subject to the scope of application of the NHC Regulation".*

Industry's interpretation is problematic and potentially confuses the interaction of the dietetic food legislation with the claims Regulation, whose intention was to regulate the use of statements related to nutrition and health benefits made voluntarily on all foods (including dietetic foods). This demonstrates the need to clarify the interaction of these two pieces of legislation that were introduced at very different times and into very different food markets.

Example of complex interaction of sports foods with the claims Regulation:

The claim "*Vitamin C contributes to maintaining the normal function of the immune system during and after intense physical exercise".*

Would the fact that this claim refers to "intense physical exercise" lead to the classification of the product as a 'dietetic' product for sports people and consequently to consider such a statement as a suitability statement?

As a result of such classification, would it mean that such a claim cannot be used on foods for normal consumption, since, as mentioned earlier, following the dietetic food legislation, it is prohibited for foodstuffs for normal consumption to refer to 'dietary´ or any other impression that the product is covered by the dietetic food legislation?

2.3. Concrete drivers related to the management of foods currently covered by the Framework Directive

2.3.1. Non-uniform application of the notification procedure across Member States

Although a notification system facilitates the official monitoring of dietetic foods, the 2008 report on the notification procedure concludes that difficulties have arisen in relation to its correct and consistent application:

"The current notification procedure differs markedly as a result of both distinctly different national rules, but also as a result of different interpretations of the legislation. This results in differing burdens on both manufacturers and public authorities and provides consumers with uneven access to products. This implies that consumers in some Member States are denied a full product range while others may be insufficiently protected from products which typically carry a price premium, but may not offer the benefits implied through labelling and associated marketing."

[24] Diätverband Guideline, "Nutritionally incomplete FSMPs". IDACE Guidelines on the application of Reg. (EC) No 1924/2006 to PARNUT Foods and other relevant regulations/directives.

It is clear following the different categories that have been considered as dietetic foods between the Member States (see point 2.1.2 and Annex III for examples of notified products in the Member States) and the information received by some of them published in the study report (see summary in the next paragraph below) that Member States are not applying this procedure in the same way, in particular regarding the interpretation of the definition of dietetic food. The study report highlights for example that one Member State (Belgium) received no notifications under the general notification procedure whilst another Member State (Italy) receives 760 notifications on average per year (period covering January 2006 - June 2008; including the notifications on gluten-free foods).

The consequent outcome of the national decisions leads to differences and additional administrative burden for both Member States and industry. In addition, when the same product is subsequently placed on the market in another Member State, the operators have to provide the same information again and, theoretically, may have to do so 27 times if they wish to market the product across the EU. Below are examples of the differing approaches in Member States and the subsequent costs (Annex II includes further differences between Member States).

Germany – the notification procedure is accompanied by approximately €1500 fee and can take up to a year to be completed. The procedure is divided in four steps: formal assessment; legal assessment; scientific assessment; and, final report. It is estimated that a scientific assessment by the competent authority for each product takes 10 days. It therefore, almost amounts to a pre-market authorisation for all dietetic food.

In *Italy* the procedure involves the competent authority (CA) verifying the composition of a product against the listed contents and the nutritional properties claimed. Following this phase, the CA can ask the company to make changes to the label, or to provide the necessary scientific support for the substances used. Producers have to provide a copy of the product label to the CA (for each package and flavour when used) and have to specify the legislation under which they are notifying the product. There is an administrative fee of €160.20.

In *Poland* if a scientific assessment is considered necessary a fee of around €1200 is required from industry. Such assessment can take up to a year.

Furthermore, the notification procedure foreseen by the Directive does not give the power to the competent authorities to prevent/refuse the product being sold as dietetic product before it is placed on the market. In some Member States, there is extensive discussion and consultation between companies and Member States in order to ensure the legality of a product being sold as a dietetic food. In other Member States notification is more similar to a formal communication that the product is being sold as dietetic product.

This raises the question whether the administrative burden and different application across the Member States stemming from the notification system outweighs the control benefits.

The treatment of the two designated categories of dietetic foods without specific rules (sports foods and diabetic foods) in terms of placing on the market varies amongst Member States. Some have national rules, some have a national notification procedure, others request notification under the general procedure and others require nothing more than compliance with the general rules.

The variability in the application of the legislation has led to market distortions, differentiation in treatment of foods and is confusing to the European consumers.

2.3.2. Differing rules at Member State level on the management of dietetic foods with specific designation but without specific EU rules

Sports foods

The treatment of sports foods varies amongst Member States. As abovementioned, some have national rules in place, some have a national notification procedure, others request notification under the general procedure for dietetic foods and others require nothing more than compliance with the general rules.

Given the estimated size of the sports nutrition market in the EU (€2357 millions retail sales value) the existence of differing rules leads to potentially important market distortions. To have the category mentioned in the dietetic framework legislation results in Member States having to consider sports foods per se as dietetic foods intended for a particular group of the population. However, market research on the sector[25] splits consumers of sports nutrition into four groups[26] based on their individual characteristics and suggests that recreational user group makes up a larger market than bodybuilders and athletes, and its share is growing at a faster rate. The four groups are describes as follows:

- Bodybuilders: people who engaged in the sport of bodybuilding, which entails building up muscle through a combination of weight training and increased calorific intake;

- Athletes: all professional sportspeople, excluding bodybuilders;

- Recreational uses: who may be people who do sport at the weekend and fitness enthousiast;

- Lifestyle uses: people who do not use sport nutrition products for sports or exercise purposes. People within this group mainly consume sports nutrition products in order to provide a refreshing beverage, a quick meal replacement or simply as a snack. Consumers within this group may also use sports nutrition products to provide an energy boost during illness or even when feeling tired.

Therefore, Member States are concerned over the application of the dietetic food legislation to sports foods. Certain Member States consider sports foods to be dietetic foods; other Member States do not want to consider sports foods as dietetic foods. Some consider that some sports foods that currently fall under the dietetic food framework definition are more suitable to be marketed as a normal food with a claim (their reasoning being that they are sold in a food supplement form or sold in supermarkets[27], etc.). This clearly distorts the market as different Member States are applying different legal frameworks to the same foods.

[25] Datamonitor - How to attract new sports nutrition consumers. DMCM2980/published 08/2006

[27] The study report by Datamonitor mentions that a wide range of distribution outlets are used ranging from multiple retailers and health food shops to pharmacies, gyms/health clubs and vending machines. There are also Direct to Consumer (DTC) sales via the internet and through catalogues. Multiple retailers represent the largest share of the value of sales, although DTC sales are increasing in importance.

As mentioned earlier, *Sports nutrition* represents an important sector of the dietetic food industry in the EU with €2357 millions retail sales value. For example in Italy it represents €271 million; in the UK: €213 million; in France between €90 and €150 million; in Sweden €47 million.

Euromonitor figures suggest this sector represents 0.2% of the total food industry and to have an annual growth rate of 7%.

Management of sports foods in the Member States: concrete examples

a) National rules[28]:

In France, products designed to meet the expenditure of intense muscular effort are included in the "1977 Order on dietetic products". The French industry feels that the relative stagnation of the sports foods market in France results in part from the outdated national legal framework those products have to comply with. The French Competent Authority explains that under the current legislation it is very difficult to take legal actions when a product is not in compliance with the requirements of the legislation as these are not per se established on safety grounds but nutrition quality based.

In Italy, a circular defines six categories of products, their compositional requirements and labelling. Notification is required when a product is placed on the market. Sports foods in a food supplement form is the second category of food supplements sold in the supermarket in Italy in 2007. Difficult interaction between the food supplement Directive and the dietetic food legislation have been reported several times by sport foods manufacturers.

In Germany there are no specific national rules for sports foods and the German's Competent Authorities believe that they should not be considered as dietetic foods given their wide usage.

In Poland, there are no specific national rules either but they believe that EU legislation on sports foods would facilitate control of the market, particularly for products which currently enter the EU through Member States where there is little control over sports foods.

They are no national rules in Sweden and they believe they do not fit alongside with the other dietetic foods sector and seem to fit better within the Regulation on claims.

b) National notification procedure:

Hereafter, annualised data based over the period spanning January 2006 to the end of June 2008. It shows that around 1500 sports foods have been notified in the 11 Member States where notification is required.

[28] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting

Figure 5: Sports foods notifications in certain Member States

Country	CY	CZ	DK	ES	EE	EL	IT	LT	LV	PL	RO	EU Total
Number of Annual Notifications on "sports foods" by Member State	176	312	19	22	134	80	320	44	102	233	21	1463

*** AT, FI, FR, HU, IE, PT, SE, SK, SL** and **UK** had zero notifications. **BE** and **BG** reported not having such products on the market.

c) EU notification procedure (Article 11 of Directive 2009/39/EC):

Very little sports foods have been notified[29] annually between January 2006 and June 2008 under the general notification procedure. Only 22 notified sports foods among 5 Member States (EL, FR, IE, MT and SK). The products notified are mainly high protein products and low-calorie food, products for hydro-electrolytic regeneration, fast acting dextrose gel for people with an extra need for energy.

This shows how disparate the current situation is amongst the Member States when considering the legal management of sports foods.

As mentioned in the background, although discussions on preparing specific rules at EU level took place this last decade, several issues made the adoption of specific legislation on sports foods unsuccessful. In particular major difficulties were encountered as regards the scope of such specific directive as well as the set up of compositional requirements. The revision on the legislation on dietetic foods is the opportunity to consider other possibilities to manage more efficiently and consistently this group of foods.

Diabetic foods

Like sports foods, foods for diabetic people are also treated differently at the Member State level. The Commission report[30] on diabetic foods concludes that there is no scientific basis on which to develop specific compositional requirements for this group of foods. As they continue to be mentioned in the Dietetic Food Framework Directive they remain part of the scope and Member States are obliged to treat them as dietetic foods. This contradicts the scientific evidence that people with diabetes should be able to meet their dietary needs by appropriate selection from normal foods.

[29] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting. p.142.

[30] COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes). Brussels, 26.6.2008

Following the conclusions of the report abovementioned, the national rules on foods for diabetic people established in Germany for many years have been recently repealed.

Foods for people intolerant to lactose

Specially processed 'lactose-free' and 'low-lactose' milk products which are suitable for lactose intolerant people and/or galactosaemic individuals are considered as dietetic foods.

There are also 'normal' foods on the market, free of lactose by nature, which cannot automatically indicate their suitability for these specific groups of the population (e.g. soy drink) because they do not satisfy the definition of a dietetic food (specially processed and different form the normal food equivalent). In the light of what has been said already on lactose-free foods (section 2.2.1), this shows how grey the border between dietetic foods and normal foods can be and how the application of the legislation can distort the market unnecessarily.

2.3.3. Dietetic foods and normal foods intended for weight management

Commission Directive 96/8/EC under the Dietetic food Framework sets compositional rules and associated labelling rules for foods intended for use in energy-restricted diets for weight reduction, 'slimming foods'. These foods are defined under that legislation as specially formulated foods which replace the whole or part of the total diet (respectively sold as 'total diet replacement for weight control' and 'meal replacement for weight control').

Under the Regulation on claims there is also the ability to make health claims on normal foods related to "*slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet".*

So, on one hand there are 'dietetic foods' for weight control and, on the other hand 'normal foods' for weight control. There are questions as to whether these 'weight control' products should still be considered as dietetic foods and whether overweight and/or obese people are to be considered as a specific group of the population in the sense of the Framework legislation on dietetic foods or as a group of the general population.

2.4. How would the problem evolve, all things being equal?

There will be continued confusion with the application of different pieces of legislation which could result in increasing the differences in treatment of similar foods in Member States. This in turn would create unfair competition between businesses and not provide the same high level of protection for consumers across the EU.

2.5. Does the EU have the right to act (subsidiarity)?

The Framework Directive was based on Article 100 a of the EC Treaty, now Article 114 of the TFUE, which aims at establishing an internal market for dietetic foods while ensuring a high level of protection of consumers.

Prior to the adoption of the Framework Directive, the national measures in the Member States differed from one Member State to another. The differences between these laws obliged the dietetic food industry to vary their production according to the Member State for which the products were intended. To respond to this, general rules and a number of specific measures have been adopted at EU level.

In order to harmonise intra-community trade and trade with third countries the EU does have the right to act. However, this should be balanced against the proportionality of the measure and the added value European rules will have for citizens across all Member States.

On the other hand, there is a need to ensure that the measures are proportionate to the objectives to be achieved and are not a source of undue administrative burden for Member States and food businesses.

Section 3: Objectives

3.1. Overall objectives

The main aim of the revision is **to ensure appropriate consumer information and good functioning of the internal market** within the context of the Commission's commitment **to smart regulation** (proportionality, reduction of burden, legal clarity, and better enforcement) for Member States and businesses.

3.2. Specific objectives

Objective 1: Coherence

- To remove differences in interpretation and difficulties in applying the dietetic food legislation given the development of other food legislation.

- To coordinate and align appropriately rules for specific foods with other existing food legislation

Objective 2: Simplification

- To remove the rules that have become unnecessary, contradictory and potentially conflicting.

- To reduce the administrative burden associated with the implementation of the legislation.

Objective 3: Harmonisation

- To ensure that similar products are treated in the same way across the Union ensuring appropriate consumer information.

- To allow free movement and equal conditions of competition for goods.

Objective 4: Small Businesses and Innovation

- To ensure that any changes to the legislative management of foods currently covered by the Framework Directive do not impact disproportionately on small businesses (as they have limited capacities to invest additional resource in obtaining external legal expertise to understand the legislation) and/or place unnecessary additional burdens on food businesses operators.

- To ensure transparency and legal clarity in order not to hamper competitiveness or the opportunity to innovate appropriately.

3.3. Consistency with other EU policies and horizontal objectives

The general objectives identified above, especially regarding the EU action to ensure consumer protection and public health are compatible with the EU Charter of Fundamental Rights. They are also in line with the Lisbon Strategy (2005-2010) objectives stressing the consumer protection and confidence.

This initiative has been undertaken with the objectives of the Commission's Communication on Smart Regulation in the European Union. One of the aims of the review of the Dietetic Foods Framework legislation is to simplify legislative burdens in light of comments made by Member States and food business operators on the existing regime. Whilst this initiative does not form one of the wider 'fitness checks' it has used the principles to consider how a certain piece of legislation fits within the broader legislation context, exploring how existing legislation is working and what may need to be changed. It is also hoped that the policy will help SMEs develop in the market and removing unnecessary administrative burdens on businesses and Member States.

Section 4: Policy options

Different policy options can be identified in order to achieve each of the four objectives described in section 3.

In light of the problem identified in section 2 and the objectives outlined above it was considered that two approaches should be developed for the possible options:

(1) the notion of dietetic food is no longer needed to help the food market today and should be removed (options 1 and 2).

or,

(2) the notion of dietetic food needs to be strengthened to bring it more into line with today's food market (options 3 and 4).

The four options considered within this Impact Assessment have been developed to ensure that none of them would result in the removal of products from the market but may necessitate potential label changes and/or reformulation of products or have an impact on their market value. In other words, the options considered for the revision of the dietetic food legislation do not foresee any ban per se of foods currently sold as dietetic foods. The proposed rules within each option would allow for market adaptation and therefore a sufficient transitional period (two to three years) would be foreseen to help smooth transition of the change in legislation and minimise economic burden.

For example, under options 1 and 2 this means that as regards to "suitability dietetic statements", products labelled in conformity with existing rules will be allowed to remain during the transitional period under the control of national authorities, as usual practice. From that point on, it is expected that these "suitability dietetic statements" will disappear and products that wish to continue stating a similar benefit should ensure that they comply fully with the Regulation on Claims.

In addition, the Commission can help Member States and businesses to adjust to the new arrangements through working groups with the Member States and/or guidance/guidelines on implementation, as appropriate.

Besides, any of the four options would not preclude Member States to maintaining or adopting national rules for certain categories of foods as long as it is in line with the rules of the TFEU and in particular Articles 34 and 36 thereof.

- *Option1 - Repeal all the legislation on dietetic foods (Framework Directive and all the specific legislation adopted under that Framework)*

This option is based on the assumption that the maintenance of separate legislation on dietetic foods in addition to other existing rules of the food legislation (in particular in addition to the rules adopted for food supplements, fortified foods and nutrition and health claims) is no longer justified. It means consequently that rules for dietetic foods will not exist at EU level anymore and only other pieces of food legislation would apply.

- *Option 2 – Repeal the framework Directive on dietetic foods but maintain certain of the specific rules adopted under that Framework*

The analysis of option 1 remains valid for this option (the concept of dietetic foods would no longer exist and only other pieces of food legislation would apply). The difference would be that certain rules already established under specific pieces of dietetic food legislation would be maintained where added value at EU level could be demonstrated (as a reminder currently there is specific legislation for infant formulae & follow-on formulae, baby foods, slimming foods, medical foods and gluten-free foods).

Other potential categories of foods not covered by specific Directives and currently notified under the Dietetic Foods Framework would be entirely regulated by the other existing pieces of legislation governing food composition and labelling issues.

- *Option 3 – Revision of the Framework Directive establishing a positive list of dietetic foods with specific compositional and labelling rules*

The concept of dietetic foods would be maintained under this option but the scope of the Framework legislation would be restricted to a positive list of groups of foods with specific compositional and labelling rules. Other groups of foods would be entirely regulated by the existing pieces of legislation governing food composition and labelling issues

- *Option 4 – Amending the Framework Directive replacing the notification procedure with a EU centralised prior-authorisation procedure based on a scientific assessment*

The concept of dietetic foods and existing pieces of legislation would be maintained. For dietetic foods where standards exist (the five specific pieces of legislation) prior authorisation would not be required as these foods have to comply with set compositional and labelling requirements. For the other categories of foods currently covered by the Framework Directive the notification procedure would be replaced by a EU prior-authorisation system whereby prior authorisation of the product would be necessary before the product is placed on the EU market as dietetic food.

Discarded options

The following policy options were also considered but given their incompatibility with the objectives of the revision they have been excluded at an early stage and therefore they have not been analysed in detail.

- *No EU action – Status quo*

'No EU action' was not considered appropriate given the underlying objectives. If the legislation is not revised then it is anticipated that there would be a continued gradual increase in conflicting situations with other pieces of legislation. This option would not address the objectives as the scope of the legislation will not be clarified and interpretation difficulties for both Member States and Stakeholders will remain. The borderline situations between food supplements, fortified foods and dietetic foods will continue and same products could potentially still be classified differently in Member States.

This "No EU action" option has been taken as the baseline and therefore the potential positive and negative impacts associated with the other options will be measured against the status quo.

- *Adoption of informal guidelines at EU level*

This option would rely on "soft law instruments". It would be a flexible approach to addressing the changes needed with the current legislation but due to the non-binding status it may not be sufficient to tackle differences in the interpretation and implementation of the legislation. In particular the main problems with borderline products and the notification procedure cannot be adequately addressed through guidance as this tool does not provide legal certainty and cannot be used during judicial cases. Informal guidelines are also considered inappropriate to ensure the free movement of goods within the internal market and with third countries as they can be used or not by Member States, and in addition they can still be interpreted differently.

Besides, the difficulties with the implementation of the dietetic food legislation are not restricted to interpretation and concrete implementation issues. As highlighted in the section "problem identification", there is a need to consider the functioning of that legislation in depth and as part of the food legislation globally.

Figure 6: Summary table of the four options with regard to 1) the different groups of foods and 2) rules that would apply to them under each option

	Specific EU rules applying to specific groups of foods	**Notification procedure (Art.11)**	**Prior-Authorisation procedure for dietetic foods**	**National rules**
Baseline scenario	Infant and follow-on formula, baby food, slimming food, medical food and gluten-free food.	For the other groups of foods satisfying the definition of dietetic foods e.g. sports foods, lactose-free foods.	None (although few Member States apply "authorisation-like" notification procedure	Certain MS have adopted national rules on sports foods, lactose-free foods and diabetic foods in absence of EU specific rules.
Option 1	Removed	Removed	None	Potentially to replace the removed EU rules on food intended to infants and young children and medical foods (adopted under public heath grounds)
Option 2	Infant and follow-on formula, baby food, medical food. NB: statements related to gluten-free food and slimming food would be regulated under the Regulation on claims	Removed	None	Unlikely
Option 3	Infant and follow-on formula, baby food, slimming food, medical food and gluten-free food. New EU specific rules potentially for other dietetic food categories, e.g. sports foods, elderly foods, lactose-free foods	Removed	None	Unlikely
Option 4	Infant and follow-on formula, baby food, slimming food, medical food and gluten-free food.	Removed	EU approval for groups of foods such as sports foods, lactose-free foods, elderly foods, foods for pregnant women etc. before being sold on the market as "suitable for"	Unlikely

Section 5: Analysis of impacts

In accordance with the Commission's guidelines, this Impact Assessment analyses the likely social, economic and environmental impacts – be they direct or indirect – of the different policy options. Each option has been assessed against the theoretical baseline of 'do nothing' and therefore the impacts outlined are additional to the current status quo. The assessment of each option in terms of environmental impacts has not identified significant impacts (either negative or positive). As the Framework legislation on Dietetic Foods was established to ensure good functioning of the internal market the major focus of the analysis is on economic impacts (administrative burden, reformulation and labelling, innovation, competitiveness and price) of the options rather than social costs (e.g. public health). However, as in some areas there could be such potential social impacts - consumer protection and information and loss of employment– and, where possible, these have been assessed. The loss of employment has been identified under the economic impacts sections in particular when considering the impact on SMEs. The wider social analysis of the four options could not find any other significant impacts particularly on social wellbeing.

To help comparisons between options the impacts have been rated:

✓	**Small positive impact**	×	**Small negative impact**
✓✓	**Medium positive impact**	××	**Medium negative impact**
✓✓✓	**Large positive impact**	×××	**Large negative impact**

Methodology

When attributing the rating the overall impact on the market was considered and attempt was made to quantify it. However, obtaining exact data on the size of the dietetic food industry was not easy particularly as some data collecting sources consider that all 'specialised foods' (fortified foods, foods with claims, food supplements) are 'dietetic foods'.

Dietetic food sector

The dietetic food sector is relatively small, around 700 businesses and it generates around 2 billions euros added value each year. However, this is expected to be an underestimation as the Eurostat data only covers the key categories covered by the dietetic foods framework legislation. It does not include other dietetic products notified under the notification procedure of the Framework Directive.

Eurostat report suggests also that the sector is in growth. In the period between 2000 and 2007, the output of homogenized food preparations and dietetic food grew across the EU-27 by an average of 5.1 % per annum.[31]

[31] Eurostat publication *European business - facts and figures 2010*
http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-BW-09-001

Eurostat information suggests that the market share for SME is the same (approx. 99.5%)[32] as the overall European food market (99.1%). Information provided from the industry representative demonstrates that the market is quite diverse with both multi-national companies and small local producers depending on the country and the sub-sector of dietetic foods. E.g. the sector for baby nutrition appears to be dominated by a few large companies whilst the manufacturers of foods for diabetics and foods for people intolerant to gluten are mainly small businesses.

All the data collected do however suggest that the sector is relatively small in comparison to the overall food sector (*Eurostat estimation that the sector represent 0.2% of the total food manufacturing market*) and that the key sub-sectors within it are the infants and young children nutrition sector and the sports food sector.

See Annex III for a general overview of the EU's dietetic foods market including size, turnover and SME share.

Administrative burden

During the Impact Assessment process an attempt was made to estimate the administrative burden associated with the legislation (notification, record keeping, labelling, etc). Discussions with stakeholders and Member States highlighted that the level of administrative burden of the legislation varies significantly. For example, the UK's administrative burdens[33] measurement exercise suggests that the administrative burden stemming from the dietetic food legislation was approximately €45.00 per business. Whereas, the approach in Germany with a quasi "prior-authorisation" system of each notified dietetic products will give completely different figures (the fee on its own is €1500).

It was considered that applying the EU Standard Cost Model may not accurately reflect the overall cost; multiplying up the cost to an EU average might suggest cost savings that in reality would not be felt by all Member States or stakeholders. Therefore, in order to demonstrate the impacts appropriately, a more qualitative approach was taken.

5.0. Baseline scenario – No EU action

As mentioned before, the "No EU action" option has been taken as the baseline and therefore the potential positive and negative impacts associated with the other options will be measured against the status quo.

[32] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database
Annual detailed enterprise statistics on manufacturing subsections DA-DE and total manufacturing (NACE Rev.1.1 D) – Manufacture of other food products

[33] https://www.abcalculator.bis.gov.uk/

5.1. Option 1 - Repeal all the legislation on dietetic foods (Framework Directive and all the specific Directives adopted under that Framework)

5.1.1. Social impacts

The general and specific rules for products intended to particular groups of the population will be removed. This should not be of concern as regards foods for which no further specific rules have been laid down but subjected to the notification procedure as they would fall fully under other general rules (claims prior-authorisation procedure, general labelling rules, rules on fortification etc.). However, the loss of additional specific requirements that stipulate exact compositional and labelling rules to ensure a high harmonised standard of consumer protection for certain categories of foods (e.g. infant formulae, gluten-free foods) may have a negative impact. Removing these specific requirements at EU level could in certain cases lead to differing composition and labelling of products on the EU market. This could be of particular concern for certain vulnerable groups of the population for which the same high nutritional quality standards may not be ensured anymore for the food they rely on for their diet (e.g. infant formulae intended for young infants and cereal based foods).

Estimating the impact that removing some of the rules might have is not possible because various different factors may affect a person's diet (availability of alternatives, socio-economic factors, education, etc.) but for the reasons highlighted above it is considered that this option might have a negative impact on consumer protection for EU citizens.

The compulsory labelling requirements under the general Framework Directive and the specific pieces of legislation will be lost at EU level and therefore consumer information for these products (e.g. "to use under medical supervision", "age of use", "complete nutrients composition" etc.) may be reduced. Moreover, the rules establishing legal names -sales denominations- (e.g. infant formula, follow-on formula, gluten-free food, food for special medical purposes, meal replacement) would be lost at EU level. Whilst this is considered as a negative impact for dietetic foods with special denominations, it is considered as a positive impact for other potential categories of dietetic foods where no specific labelling rules have been laid down in terms of consistency with other food legislation.

By removing the concept of dietetic foods, the interpretation that mandatory and/or optional information required by the dietetic food legislation related to their suitability, particular characteristics and composition, is not a claim under the "nutrition and health claims (NHC) Regulation" would not be possible anymore. All foods on the market would be covered by the same legislation governing the information they bear. Consumer organisations consider that this will have a positive impact on consumer information allowing consumers to make equivalent product comparisons fairly and empowering them to make informed decisions about the food they consume.

5.1.2. Economic impacts

Simplification/legal clarity/Administrative burden

Repealing all the legislation will result in industry no longer having to comply with the additional set of dietetic food legislation and related costs such as specific labels,

compositional standards, etc. In addition, there would no longer be any confusion over whether a food on the market should be or not be in compliance with the dietetic food legislation. And consequently, that part of the legislation applying to foods would be simplified.

This simplification may not be felt by all sectors of the industry if by removing the dietetic framework legislation their products would then be covered by another piece of legislation that did not apply to them previously (e.g. a food that was considered under the scope of dietetic food due to fortification for a target population would fall under the fortified foods Regulation). However, it is considered that the costs stemming from the difficulty to understand if a product falls under the dietetic food legislation or not would be removed, which is likely to lead to a significant gain in time for businesses as well as for competent authorities.

A repeal of the legislation and consequently of the notification procedure will remove costs from industry and Member States. The evaluation of the Dietetic food Framework legislation[34] highlighted that the notification procedure varies from Member State to Member State (see table in annex II). For example a notification in Germany is accompanied by approximately €1500 fee (€1200 in Poland) and can take up to a year to be completed whilst in France and the UK there is no fee. Therefore the saving to industry could vary from minimal cost if a business notifies today only in the UK or France to €1200 - €1500 and potentially a gain of one year before placing on the market if they notify in Poland or Germany. These costs could be even greater if a business intends to place its products EU-wide.

Operating costs

No new rules are introduced so no reformulation costs are foreseen within this option. Some changes in the labels may be needed as the concept of 'dietetic' food would disappear and products bearing 'dietetic' suitability statement would be required to re-label but adapted transitional period should make the related potential costs less significant.

The Commission's Impact Assessment on food labelling carried out in 2008[35] estimated that there were 26.8 million product food labels (SKUs – Stock-Keeping Unit – the total number of products and different packaging sizes or types) in the EU covering 14.7 million products. Taking the assumption that between 0.2 -1% of these products also bear the label 'dietetic' or similar wording and considering that the cost of a label change is 225€ we can estimate that the cost for re-labelling is in the range of €6.6 - €33 million. By applying a two year transitional period (according to the report produced by RAND[36], over a 2 year period 60% of companies would introduce labelling changes as a normal part of their business operation) these costs are significantly reduced to €2.7 - €13.3 million.

[34] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting.

[35] Commission staff working document accompanying the proposal for a regulation of the European Parliament and of the Council on the provision of food information to consumers http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm

[36] http://www.rand.org/content/dam/rand/pubs/technical_reports/2008/RAND_TR532.pdf

Figure 7

Number of products (EU-27)	Percentage expected to have a dietetic reference on them	Cost of a label change (design only)	Total cost	Cost with transition period of two years [37]	Cost with transition period of three years [38]
14 755 458	147 555 (1%)	225 €	33 199 781€	13.279.912 €	6.639.956 €
14 755 458	29 511 (0.2%)	225 €	6 639 956 €	2.655.982 €	1.327.991 €

Another operating cost might be the need to comply with differing legal requirements in each Member State. With the removal of legislation at the European level, Member States may introduce their own rules for certain products at the National Level under the rules of the Treaty increasing the cost to industry. However, as it is not possible to gauge to what extent each Member States rules may vary it is not possible to attribute an estimation of costs that differing national rules may cause to industry. However, if we assume the worst case scenario – that all Member States adopt different rules – then the costs when businesses wish to trade within the single market could be significant. If we assume – more likely – that most Member States maintain the rules that existed already, the disruption to the internal market should be more limited.

Prices

Removing the denomination of 'dietetic' or similar wording from the label of foods may reduce the price of certain foods that are not substantially different from their normal food equivalent (e.g. suitable for diabetics' chocolate versus 'low sugar' chocolate). The figure below gives an example from France[39] -

Figure 8

Product	Price 'normal 'product	Price 'light 'product	Price 'dietetic' product	% difference ('normal' versus 'light')	% difference ('normal' versus 'dietetic')
Chocolate (80g)	€14.70 kg (average of 4 brands)	€17.00 kg "light chocolate"	€34.375/kg	+16%	+133%
Biscuits with muesli (290g)	€6.80/kg "normal";	€9.00/kg "light"	€10.20/kg	+32%	+50%
Jam (320g)	3.60/kg (average);	€7.00/kg "light jam"	€10.75/kg	+94%	+198%

Source: www.auchandirect.fr (April 2009)

[37] According to a study carried out by RAND over a 2 year period 60% of companies would introduce labelling changes as a normal part of their business operation. Calculation based on 40% of total cost to cover those businesses that would not have changed labels in that time.

[38] RAND Study - over a 3 year period 80% of companies would introduce labelling changes as a normal part of their business operation. Calculation based on 20% of total cost to cover those businesses that would not have changed labels in that time.

[39] Agra CEAS Consulting, study analysis IA.

In Germany, industry representatives[40] estimate that the price premium for foods for diabetic people is between 10% and 30%, similar to the premium paid for organic, lactose-free or gluten-free products. They consider that this premium is due to higher ingredient costs and the limited economies of scale available when making small batches. They have highlighted that without the ability to label the dietetic nature on the label these premiums would be lost. Therefore under this option it is likely that by repealing all the legislation including compositional and labelling standards, industry will no longer have the incentive to use higher quality ingredients in order to gain a sales and price advantage.

However, other tools would remain to market and promote the additional nutritional quality of product (use of claims) and pricing products accordingly. Moreover, repealing the denomination of 'dietetic' food does not prevent additional quality or standards being mentioned on the label and products being priced accordingly, as long as they comply with the general labelling requirements. Using the example of sports products - a particular formulation of a product with a nutritional or health benefit can be marketed as such using the claims legislation. It can also per se target the product to sports people as long as it is not misleading. It is therefore considered that the loss of the dietetic foods suitability statement will not have a significant negative effect on prices.

Trade and internal market

Repealing the legislation will result in industry no longer having to comply with EU legislation on dietetic foods. However, it cannot be excluded that Member States could maintain or adopt national rules for certain categories of foods in accordance with the rules of the Treaty on the Functioning of the European Union "TFEU" . Where such rules are established differently at national levels, trade between Member States may be disturbed as a company could have to comply with different rules. Similar difficulties would apply to non EU based companies. This option therefore may have a negative impact on intra community and third-country trade patterns.

Innovation

The food industry is quite an innovative sector that invests into research and development. According to Confederation of the Food and Drink Industries' (CIAA) publication on Data & Trends of the European Food and Drink Industry 2009 [41], within the EU, the key focus of these efforts relate to sophistication and variety of senses and then the specialist areas of medical foods and slimming foods. Industry reported that the role legislation plays on innovation is both positive and negative. On the one hand it can limit the possibilities to innovate; on the other hand it stimulates the sector to innovate further.

[40] Diätverband.

[41] Confederation of the Food and Drink Industries
Publication on Data & trends of the European Food and Drink Industry 2009 p.21 R&D and innovation worldwide trends

The main innovative area other than those outlined by CIAA is the sports food sector. IDACE reported that sports science is a rapidly evolving area of research and illustrates this by pointing out that there have been more than 1000 studies reported in peer reviewed journals during the last five years[42].

When asked, industry was unable to quantify the impact that relaxing or reinforcing rules on dietetic products would have. Some industry stakeholders considered that the removal of requirements would allow for greater flexibility to innovate whereas other believed it would remove the incentive to do so. It is therefore not possible to assess whether the removal of the dietetic food legislation will have a negative or positive impact on innovation.

SMEs

According to Eurostat statistics, the dietetic food sector has a total of 700 businesses within the sector although this sector does not include the producers of other potential food categories marketed as dietetic food but not mentioned in the legislation (the 'notified products'). The number of SMEs within this market is unknown. Industry representatives consider that the percentage could be large (depending on the sub-sector).

Repealing the legislation would mean that it would be easier for all food manufacturing SMEs to enter the market and this could result in opening up the sector to greater competition and making access easier for them. Removing additional requirements might also constitute a saving for SMEs as they may no longer have to invest additional resources in obtaining external legal expertise to understand and apply the dietetic food legislation before entering the market.

Balanced against the savings from simplification for all SMEs is the potential loss of niche market for extremely specialised SMEs in the dietetic food sector and therefore a loss of sales may be expected for them. Industry representatives were unable to quantify this impact but as Eurostat data highlights that total number of businesses in the sector is around 700 and therefore even taking the worst case scenario (100% are SMEs) this loss of niche market would only impact on 0.2%[43] of the total number of SME food manufacturers. The loss of niche market may also have a knock-on effect on employment in this sector potentially having a negative social impact on employment. This may be compensated by the growth of other SMEs.

It can therefore be considered that the negative impact on SMEs of removing the legislation is minimal and for most SMEs the overall impact would be positive. However, if Member States introduce their own national rules the impact for SMEs could be negative as new and different rules would apply.

[42] Report study IA, Agra CEAS Consulting, p. 53

[43] The total SMES in European food manufacturing market according to Eurostat figures is estimated to be 306,356.

Competitiveness and growth

Removing the legislation would increase competition for specialised dietetic food producers in more general markets. The dietetic food industry reported that consequently they may no longer be rewarded for the high quality ingredients they use if they are competing with the whole food industry.

While some products may disappear from the market (due to the loss of the dietetic food added value), the removal of the definition of dietetic food and the notification procedure would facilitate the marketing of other products currently not considered as dietetic foods.

More competitiveness in the general food sector by removing the 'dietetic' fragmentation could have a positive impact on economic growth in the long term, reducing market distortions.

Member States/Enforcement

The abolition of the notification procedure would reduce income for the Member States who have fees in place. Taking the example of Germany, as the national competent authority receives 80 notifications a year[44], the lost in revenue could be approx. €124 000 a year (see Annex II, fee €1533).

However, Member States would no longer have to devote time and resources to manage the notification procedure and assess whether a product is a dietetic food with a suitability statement, a fortified food or a dietary food supplement and to decide what piece of legislation applies to it. As indicated in the report on the notification procedure, Member States are not applying legislation in the same way (different interpretation of the definition and assessment procedure), thus creating unfair competition between businesses and important administrative burden without providing the expected harmonisation. Consequently, resources and time spent by Member States and food operators to apply the legislation could be reduced.

This option is therefore considered to have a positive impact on Member States as they will be able to focus primarily on food safety, ensuring adequate consumer information and not on multiple administrative procedures with little benefits as regards public health.

[44] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting.

→ Summary of the key impacts under option 1

Areas	**Impacts**
Social impacts (consumer protection and information)	×××
Economic impact - administrative burden	✓✓
Economic impact - reformulation and labelling	××
Economic impact - trade	××
Economic impact - innovation, competitiveness and price	✓
Economic impact - small businesses	✓

5.2. Option 2 – Repeal the Framework Directive on dietetic foods but maintain certain of the existing specific Directives adopted under that Framework

5.2.1. Social impacts

Under this option, general rules for dietetic foods adopted under the Framework Directive would be removed while existing specific rules would be maintained to ensure appropriate nutritional safety of products addressed to vulnerable groups of the population (e.g. infants and young children, people under medical supervision). Consequently, the nutritional quality of such foods will not be reduced under this option.

As the products notified under the Framework Directive do not have to satisfy specific compositional rules (they only are required to comply with labelling requirements), it is considered that removing the Framework Directive on dietetic foods should not have a negative impact on consumer protection.

The compulsory indication of a 'dietetic' suitability of the food foreseen by the general dietetic food Framework will be lost at EU level and therefore consumer information for these products might be perceived as reduced. However, contrary to option 1, this option ensures that certain additional information on certain groups of foods already established by the specific pieces of legislation[45] could be maintained if the general rules on labelling and nutrition and health claims are not sufficient to ensure adequate and sufficient consumer information (e.g. "to use under medical supervision", "age of use", "gluten-free" etc).

In addition, the indication of a 'dietetic' suitability has today become residual (restricted to the indication of the target group and compulsory defined labelling information) given the application of claims Regulation that foresees strict rules for the voluntary indication of nutrition and health benefits on the label of all foods (including dietetic foods). Therefore, the

[45] Infant formulae and follow-on formulae, baby foods, slimming foods, medical foods and gluten-free foods.

perceived reduction of consumer information by repealing the concept of dietetic foods would not be an issue under this option as specific rules will be maintained where necessary.

5.2.2. Economic Impacts

Simplification/legal certainty/Administrative burden

This option is not intended to introduce any new administrative requirements.

Repealing the Framework legislation will result in fewer rules to comply with. It is therefore considered that the benefits identified in option 1 also apply to this option, although these savings might be reduced by the maintenance of certain specific rules[46].

As for option 1, the repeal of the Framework Directive will consequently lead to the repeal of the notification procedure. This will remove costs for the industry.

As there would no longer be any confusion over whether a food on the market should be or not be in compliance with the dietetic food legislation it is considered that this option would have a positive impact on reducing burdens and simplifying legislation.

Operating costs

As for option 1, no new rules are introduced so no reformulation costs are foreseen within this option. Some changes in the labels will be needed as the concept of 'dietetic' food would disappear. However, given that the majority of the products covered by specific rules in practice are sold under their specific sales denomination (e.g. infant formulae and gluten-free foods) rather than the general 'dietetic' suitability statement, it is expected that the cost identified in option 1 (€2.4 - €12 million) would be reduced as specific rules would be maintained. A 2 year transitional period could be considered to alleviate theses costs.

Prices

Removing the denomination of 'dietetic' food may reduce the price of certain foods that are not substantially different from their normal food equivalents. This impact was also highlighted in option 1 but it is not considered to be significant.

Trade and internal market

Repealing the legislation will result in industry of third countries no longer having to comply with an additional set of EU food legislation except where specific legislation has been maintained.

[46] It has to be noted that, as the specific rules concerned are of a technical nature, and may apply to fairly innovative products, they have been adopted through the comitology procedure. It would be necessary to maintain a delegation of power to the Commission in view of the future management of those specific rules.

Under this option it is more unlikely, than with option 1, that Member States could maintain or adopt national rules for certain categories of foods as rules which are needed for nutritional purposes would be maintained at EU level.

It is therefore considered that this option - by maintaining what is required for cross-border trade but not imposing additional rules - should have a positive impact on intra-community and third-country trade patterns.

Innovation

Repealing the Framework Directive might have a negative impact on innovation given the fact that it may remove the incentive to innovate for the sectors where no specific rules exist. But as mentioned and developed in option 1, the role that legislation plays on innovation can be both positive and negative.

SMEs

As outlined in option 1, removing legislation reduces the burden on SMEs as they would have fewer rules to comply with and would therefore open up the sector to greater competition making it easier for them to access the market. The benefit of not having to invest additional resources in obtaining external legal expertise is also relevant here. So would be the potential negative impact of specialised SMEs losing sales and the social impacts on employment (but is expected to be minimal). As with this option it is less probable that Member States will adopt national rules it is considered that this option will have a more positive impact for SMEs.

Competitiveness and growth

As for option 1, removing the Framework legislation would increase competition for specialised producers in more general markets (except for producers of foods where specific rules are maintained) and consequently they may no longer be rewarded for the high quality ingredients they use if they are competing with the whole food industry. Therefore growth for specialised sectors may be limited at first. But this would not be the case for categories of foods where specific rules have been maintained which represents the majority of the current dietetic food sector.

While some products may disappear from the market (due to the loss of the dietetic food added value), the removal of the definition of dietetic food and of the notification procedure would facilitate the marketing of other products.

More competition in the general food sector by removing the 'dietetic' fragmentation should in the long term lead to economic growth.

Member States/Enforcement

As for option 1, the abolition of the notification procedure would reduce income for the Member States who have fees in place. However, Member States would no longer have to devote time and resources to manage that legislation and its interaction with others. The positive impact identified in option 1 is therefore valid under this option too.

→ Summary of the key impacts under option 2

Area	Impacts
Social impacts (consumer protection and information)	✓✓✓
Economic impact - administrative burden	✓✓
Economic impact - reformulation and labelling	x
Economic impact - trade	✓
Economic impact - innovation, competitiveness and price	✓
Economic impact - small businesses	✓✓

5.3. Option 3 – Revision of the Framework Directive limiting the scope of categories of dietetic foods to a positive list with specific compositional and labelling rules

5.3.1. Social impacts

Under this option, it is considered that consumer protection will not be changed as the specific existing rules would be maintained (As a reminder such rules exist for infant formulae & follow-on formulae, baby foods, slimming foods, medical foods and gluten-free foods) and for the other relevant 'dietetic' food categories specific rules could be established at EU level.

Establishing a positive list with specific compositional and labelling rules for product other than those covered by specific rules that are labelled as dietetic with suitability statements will ensure that the same rules apply for all products targeting certain specific groups of the population across the EU and the same level of nutritional food safety.

Consumers will be provided with specific labelling information for products that claim suitability for a particular group of the population. The dietetic food industry considers that suitability information is vital to ensure accurate information to consumers in need of special nutrition.

However, maintaining the definition of dietetic food could result in consumers becoming more and more confused about the information provided on food packages as highlighted in the problem definition.

Producers could still treat similar products in different ways:

- identify their products (e.g. sports drinks) as for a particular nutritional need for a specific group of the population and also accompany them with a general nutrition or health claim for the population at large, *e.g. electrolyte drink suitable for intense muscular effort especially for sportsmen, helps recovery*;

- market their products as products targeted to the general population and use a nutrition or health claim in order to widen their market, e.g. sports drink helps recovery.

It is therefore considered that this option may have a negative impact on consumer information.

5.3.2. Economic impacts

Legal clarity/simplification/ administrative burden

Maintaining harmonised compositional standards through a positive list at European level would provide legal certainty to industry across the EU and so there would no longer be confusion over whether a food is or not covered by the legislation on dietetic foods (positive list).

However, the administrative burdens exercise suggests that understanding and complying with legislation place a cost on industry. Estimates from other IAs on food labelling suggest the cost of familiarisation (including legal costs) to be on average € 1,408 per company. Every time new rules are introduced each company affected will have to incur these costs. It is therefore expected that introducing a new specific Regulation will introduce new administrative burdens. These may however be offset by the removal of the existing notification procedure.

Operating costs

Categories of foods that are currently notified could be subject to greater requirements (compositional standards and associated labelling) if they are placed on the positive list.

Establishing compositional standards for new categories might result in the need for industry to reformulate some products. As the rules for the specific categories already existing will remain the same, the impact would fall mainly on those products that are currently listed the Annex of the Framework Directive without compositional standards as well as other products that are notified under the notification procedure.

As mentioned in the background, there are around 400 dietetic products notified a year, that are not covered by specific dietetic food legislation and when including the estimation made for sports foods of 2550[47], it would amount to 3000 products.

[47] Using existing data where countries require national notification for sport foods (11 Member States) gives a rough indication that approximately 1500 sports products would have been notified annually (period 2006-2008). Multiplying this across all Member States could result in around 3600 notifications a year. Given the fact that we do have only factual information for 11 Member States, we could estimate that the number of notifications for the 27 EU Member States would be between 1500 and 3600, which average would be 2550.

Estimation on the potential costs if compositional standards are different to the current products on the market can be assessed using data above and UK research on reformulation[48]. Research carried out by UK when looking at the cost of reformulation to reduce saturated fat and salt in products has highlighted that reformulation cost can vary depending on the complexity of the reformulation required, subsequent problems with taste or texture, market share and coverage of product. Research suggested that the reformulation process can last between eight weeks to over a year and the cost can vary considerably depending on the complexity and other factors (type of product, existing production facilities, research and development undertaken by the company, number of sensory trials needed, capability of the business (in-house knowledge, frequency of reformulation work etc.)) Estimates provided by stakeholders suggest the impact to be as follows (see column 'estimates'):

Figure 9: Estimation of costs

Exercise	Main costs	Estimates
Producing a product brief / technical exploration	Labour costs	The initial scoping and discussions with technical team/suppliers can take up to 6 months
Creating the product for trial	Kitchen samples Failure rates Factory run	€120 - €7 200 % needed to repeat in the factory Opportunity cost of not running the factory €240 - €60 000 Industry production run €1 800 – €24 000
Sensory testing	Consumer panels	Varies widely €1200 – €432 000
Analytical testing	Nutritional analysis Shelf life evaluation	€300 – €1 800 €120 - €420
Labelling and packaging	Artwork and design Printer re-tooling and new plates	€240 - €720 €600

Figure based on UK assessment of reformulation for Saturated fats

The UK's Impact assessment assumes that the minimum cost of the reformulation process is equal to the cost attributed to analytical testing (€420 – €2220) and changes to the label and the package (€ 840 – €1320). They therefore estimated that the minimum cost for each product reformulated would be in the range of €1,260 – €3,540.

As highlighted above there are approximately 3000 products notified a year, therefore if compositional standards are established for all the categories currently notified then the cost of reformulation is expected to be in the range of €3.4 million to €9.6 million.

[48] http://www.food.gov.uk/multimedia/pdfs/consultation/consultsatfat.pdf

Figure 10: Detailed figure for certain categories where the dietetic foods industry would like to have new rules lay down at EU level:

Categories	**Product Notification (on a annual basis)**	**Cost of reformulation[49] (per sector)**
Sports foods	2550 (estimation)	€3.2 – €9million
Lactose free foods	134	€168.8 – €474.4 thousand
Food for infants and young children (e.g. growing milks, pre-term infant formula)	30	€37.8 – €106.2 thousand
Foods for pregnant and lactating women	5	€6.3- €17.7 thousand
Food for elderly with malnutrition	2	€2.5 – €7.1 thousand

It is therefore considered that this option will have a large impact on operating costs for businesses.

Prices

Categories of food currently notified and that will not be added to the list can still remain on the market but they might lose their sales advantage of being sold as a 'dietetic' product.

No change would occur for the existing categories covered by specific legislation. For other categories that may be added to the list, depending on the compositional requirements and the impacts these requirements may have on competition, prices might be increased and this may have a negative knock-on effect on sales. If consumers are able to pay more for a product because it has a "dietetic" status, this would lead to profit for the businesses.

Trade and internal market

Composition rules for foods would have to be compatible with WTO rules (e.g. the setting of additional EU rules for sports foods, foods for elderly, for pregnant and lactating women). The impact on international trade will depend on the rules and in particular their difference with rules prevailing in third countries.

By removing the notification procedure and providing a list of dietetic foods and the setting of specific rules, it is expected that this segment of the food production should be better harmonised (same rules would apply across the EU) having a positive impact on internal market and third country trade.

[49] Assumes cost of reformulation per product is constant €1,260.00 – €3,540.00.

Innovation

Establishing a positive list may have a negative impact on innovation as compositional rules may restrict the flexibility to develop new products. However, as mentioned in options 1 and 2 as supported by certain parts of the industry, the role that legislation plays on innovation can be both positive and negative. On the one hand it can limit the possibilities to innovate; on the other hand it stimulates the sector to innovate further.

SMEs

Additional compositional and labelling rules may provide a barrier to trade especially for SMEs and therefore some SMEs may no longer manufacture dietetic foods. This will have an effect on employment with the potential loss of jobs and the associated negative social impacts linked with unemployment.

The additional requirements to reformulate may have a significant impact on specialised SMEs as they may not have the resources necessary in-house to change products according to the new requirements whilst maintaining their specificity (e.g. taste and texture). As highlighted in the section above, the cost of the reformulation of an individual product line is estimated to be approx. €1,260 – €3,540 which will have a larger impact on SMEs than on large companies who can absorb the costs more easily. However, it should be noted that the dietetic food industry representatives consider that the benefits of establishing harmonised rules would outweigh the costs and simplify access to the market for SMEs.

Competitiveness and growth

Establishing a positive list with restricted rules would limit the number of manufacturers on the market, reduce competition between them and close the market to some other manufacturers. In effect, by having strict compositional rules, competitiveness between producers would be limited as the distinction between products would be minimal, e.g. by setting rules for isotonic drinks including specific compositional and labelling requirements, there would be limited possibility to differentiate the product and gain a competitive advantage over another isotonic producer. Oligopolies may arise if only one company has the expertise to meet the specific compositional standards. It is therefore considered that this option may have a rather negative impact on competitiveness and growth.

Whilst growth amongst limited competitors may be possible, general growth for the food sector might be limited.

Member States/Enforcement

A list of categories of foods will give clarity to Member States and food operators about the scope of the legislation. As for options 1 and 2, the abolition of the notification procedure would reduce income for the Member States who have fees in place (although it is considered a limited income). However, Member States would no longer have to devote time and

resources to manage that legislation and its interaction with others. Consequently, resources and time spent by Member States and food operators to apply the legislation could be reduced and primarily focused on the implementation of the specific rules.

→ Summary of the key impacts under option 3

Impacts	Dietetic food
Social impacts (consumer protection and information)	✓✓
Economic impact – additional administrative burden	✓
Economic impact - reformulation and labelling	×××
Economic impact - trade	×
Economic impact - innovation, competitiveness and price	×
Economic impact - small businesses	×

5.4. Option 4 – Amending the Framework Directive replacing the notification procedure with a EU centralised prior-authorisation procedure based on a scientific assessment

5.4.1. Social impacts

Establishing a prior-authorisation procedure for products not covered by specific legislation and that are labelled as dietetic food with suitability statements will ensure that the same conditions of use and labelling rules apply for all products targeting specific groups of the population across the EU. As the decision will be based on a scientific assessment, this would ensure a high level of consumer protection.

Products would not longer be able to be labelled as 'dietetic' indicating suitability for a certain group of the population without prior EU authorisation or specific compositional rules. This would also put an end to similar products being subjected to different levels of constraints and controls and therefore the level of consumer information would be the same. The EU requirements for the use of a suitability statement on the label would be the same as the one for the use of claims.

However, maintaining the definition of dietetic foods could result in consumers being confused about the information provided on food packages as highlighted in the problem definition. We would have still the situation where similar products could be sold as dietetic food intended for specific group of the population or as 'normal' food intended for the population in general (e.g. sports food). Having two similar sets of labelling on products either stating a particular suitability or making a claim may have a negative impact on consumer understanding.

5.4.2. Economic impacts

Legal clarity/simplification/Administrative burden

Industry would have to make an application to a Member State or to the European Commission and wait before marketing the product as 'dietetic' until 1) the European Food Safety Authority has assessed the product and 2) the legislators authorise the product as being allowed to be marketed as a 'dietetic' food. Estimates from industry suggest that the cost of preparing a dossier for prior authorisation for the health claim is around €20.000 – €50.000. It is likely that these costs will be similar for making an application to request a food to be labelled as 'dietetic'. Using the 3000 (400 Article 11 notifications + 2550 sports) notified products figure (see option 2 above) to make an estimate of the costs would suggest an annual cost in the region of €60 million – €150 million.

The Dietetic Industry stakeholders state that prior authorisation at European level could remove barriers to trade, as once a product is authorised at EU level all Member States would have to allow it on the market. Therefore there would be no requirement for a business to make multiple applications to various Member States in order to guarantee the same labelling of the product across the EU27 market. In addition, statements on foods (suitability and claims) will be treated by the same regulatory process resulting in a level playing field for industry. It will no longer be possible for some businesses to get a competitive advantage avoiding prior authorisation by making a suitability statement instead of a health or nutrition claim.

However, it is likely that some products may be required to obtain prior authorisation under the dietetic food legislation to indicate the suitability of the food and also to get prior-authorisation under the nutrition and health claims legislation to indicate a health benefit. This could result in the costs of prior authorisation being doubled for certain products.

Examples: an energy bar sold on the market might wish to target sports people under the dietetic food legislation due to its special formulated composition and be labelled as 'sports food for intense muscular effort especially for sportsmen'. The same product might also wish to bear the claim "supports fast recovery" and therefore may undergo two different authorisation procedures.

Therefore establishing a prior-authorisation process for products under the dietetic food legislation (with an assessment similar to nutrition and health claims) will maintain the burden on the industry. Negative impacts will include the need to submit a product to two procedures and the difficulty for both the Member States and industry in assessing whether a product is making a 'dietetic' suitability statement or a nutrition/health claim.

Prices

The need to prior-assess products and to submit a dossier before being allowed to use the requested 'dietetic' suitability statement would result in an increased cost for producers which will, if it is not easily absorbed, be passed onto the end consumer. It is therefore considered that prior authorisation could have a small negative impact on prices.

Trade and internal market

Third countries exporters will also be subjected to the new requirements and the need to prior-authorise their products before targeting them to a specific category of the population. The negative impact highlighted above might be somewhat compensated by the fact that the notification regime as foreseen on the Framework Directive will be removed and rules will be harmonised (same rules would apply across the EU). It is therefore considered that this policy could have both a positive and negative impact on trade.

SMEs

As with option 3, a compulsory prior-authorisation would impose an important cost to industry resulting in a barrier to trade for SMEs. Therefore some of them may no longer manufacture dietetic foods. This would be further exacerbated by the fact that SMEs would have to interact with the European Food Safety Authority, which many of them may not have the human and financial resources to do. This could also have an effect on employment with the potential loss of jobs and the associated negative social impacts linked with unemployment. This option is therefore considered to have a big negative impact for specialised SMEs.

Innovation

The most significant cost, which does not exist with the current notification procedure, would potentially be the impact that the prior-authorisation could have on innovation. According to industry figures, the potential delay between product innovation and access to market represents, according to the industry's estimation, a loss of €0.1mio each month (loss of sales).

Taking into consideration the industry's estimation, the cost would be, for the products notified under the Framework Directive, the following:

Figure 11: innovation cost

Products	**Notification (Article 11)**	**Prior authorisation cost (million €) (e.g. 20 000€ per dossier)**	**Innovation cost (million €) (assumes a year/12 months until place on the market)**
Slimming foods	99	1, 98	118.8
Lactose-free foods	134	2, 68	160.8
Baby and infant foods*	30	0,6	36
Medical foods**	55	1,1	66
Others	135	2,7	162
Sports foods***	2550	51,0	3 060
Total	**3003**	**60,0**	**3, 603**

However, under this option (as for the other options), the access to the market for the product is not denied. Only the labelling of the product as 'dietetic' would not be allowed before authorisation. Therefore, the cost for industry would result more from a loss of the price premium of being able to label a product with a specific status and not from the loss of sales, which is likely to represent a lower amount.

Competitiveness and growth

Requiring a prior-authorisation for the use of 'dietetic' suitability statement on the labels of products (without it being restricted to the benefit of the applicant) may take away their competitive advantage. Once the statement is authorised other products can use the same without incurring the initial cost of prior-authorisation providing they meet the same authorised compositional requirements and/or conditions of use.

As prior-authorisation is a lengthy process (around a year), which would result in growth in the market being slowed down/maybe stagnating.

Nevertheless, establishing prior-authorisation may give more clarity to the sector therefore growth amongst specialised producers might be possible under such legal framework.

Member States/Enforcement

Member States would no longer have a role in checking if the product complies with the definition of dietetic food e.g. is a protein concentrate in a capsule form a dietetic food for sports people or a food supplement? The burden would be transferred to the Commission.

The cost burden of carrying out prior-authorisation of food products would impact on the European Food Safety Authority. EFSA estimates the cost for the assessment of the suitability per dietetic food in the range of 80.000 to 90.000 €.

The amount can be broken down as follows: 75% of the amount corresponds to direct costs strictly related to the scientific assessment, 15% to service costs (interaction with applicant) and 10% to overheads (administration costs, management costs and scientific and cooperation assistance costs).

A positive aspect would be that Member States will not have to consider applications that have already been presented in other Member States (current multiple notifications). Also for Member States that already had a quasi 'prior-authorisation' system in place (e.g. Germany, Poland, Italy), they would no longer need to carry out their own scientific assessment.

→ Summary of the key impacts under option 4

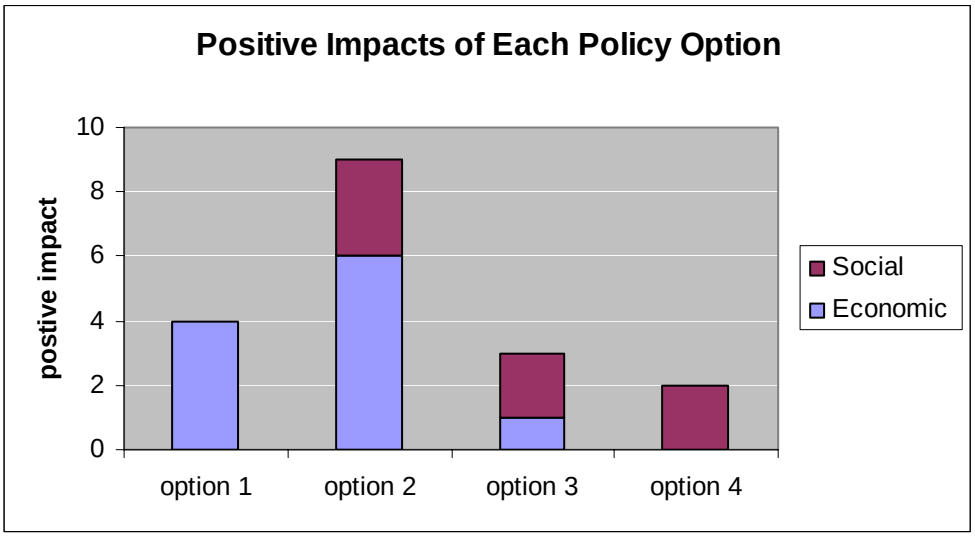
Impacts	Dietetic food
Social impacts (consumer protection and information)	✓✓
Economic impact – additional administrative burden	××
Economic impact - reformulation and labelling	××
Economic impact - trade	×
Economic impact - innovation, competitiveness and price	×××
Economic impact - small businesses	×××

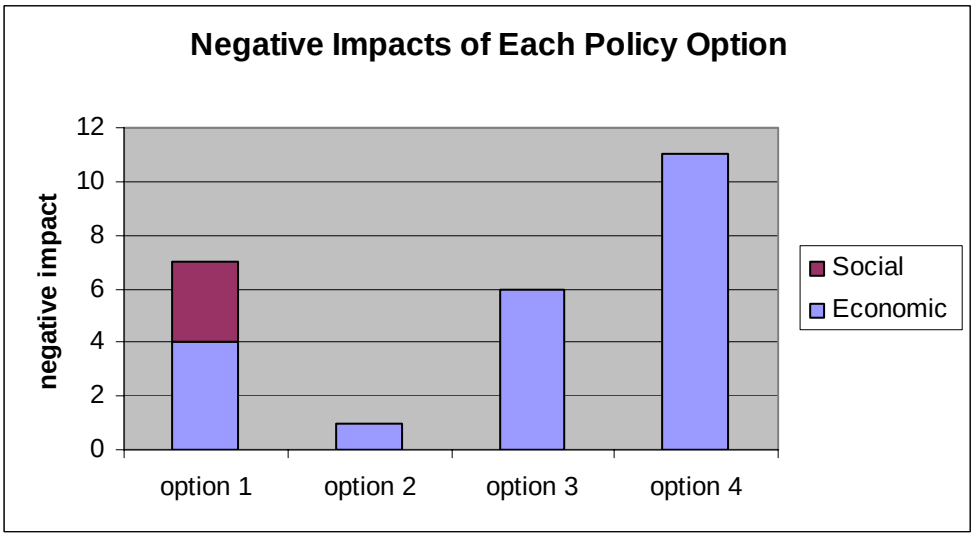
Section 6: Comparing the options

In order to evaluate the effectiveness and efficiency of the options identified in the impact assessment, consideration has to be given to their positive and negative impacts (efficiency) and how well each option will meet the objectives (effectiveness) outlined in section 3.

6.1. Comparing options in terms of social and economic impacts

To carry out the first analysis the summary tables for each option in section 5 have been used. Each impact (positive or negative) and its size have been added up to give an overall prediction of the policy options effect, allowing comparisons between options (see tables below).





Based on the comparisons of options above it appears that option 2 has the most benefits in terms of social and economical impacts and the least negative impacts (most efficient option).

6.2 Comparing the options in light of the objectives

In order to measure its effectiveness, each option has been rated against the initial objectives of the review to consider which option best met the aims of the review.

		Option 1	Option 2	Option 3	Option 4
General objectives	**Nutritional safety for the intended use** **Consumer Information** **Internal Market Function**	- - - -	+ + + + +	+ + + + +	+ + + + +
Specific Objectives	**Coherence** - remove difference in interpretation - coordinate and align with other rules	+ + + +	+ +	+ -	+ +
	Simplification - remove unnecessary rules - reduce administrative burden	+ + + +	+ + +	- - +	-- --
	Harmonisation - To ensure that similar products are treated in the same way across the Union	- -	+ +	++	+
	SMEs and Innovation - no disproportionate impact on SMEs - clear and simple rules to prevent barriers to innovate	+ +	+ + +	- + -	-- - -

Magnitude of impact of the criteria compared: ++ strongly positive; + positive, -- strongly negative, - negative

Based on the comparisons of options above against our initial objectives it appears that option 2 is the most effective policy option.

6.3 Highlight the trade-offs and synergies associated with each option

Option 1 - Repeal all

It is decided under this option that there is no need to maintain general rules for dietetic foods neither to maintain or develop harmonised specific rules (i.e. maintain rules for foods for infants and young children, medical foods, slimming foods, gluten-free foods or develop rules for e.g. sports foods, diabetic foods, very low calorie diets products and lactose-free foods).

Repealing the concept of dietetic food will prevent further distortions between dietetic foods and 'normal' foods with claims.

It will not longer be possible for businesses to gain a competitive advantage over other businesses by using the dietetic framework legislation to market a product instead of more appropriate legislation (i.e. claims when reference is made on nutrition or health benefits). This should remove market distortions (*legislation shopping*) and create equal levels of competition for operators across the 27 Member States. It should also help consumers to compare products more easily as all the products would be covered by the same legal measures. In addition, fewer rules would allow SMEs to gain easy access to the market and not hamper innovation and ensure better coordination between the requirements of different pieces of legislation.

However, whilst option 1 appears to be a good option in terms of simplification and reducing administrative burden the trade off in terms of the introduction of national legislation to compensate the repeal of the EU legislation may be significant. The advantages gained at the European level of the existing harmonisation for certain products intended to vulnerable groups of the population will be lost and most likely replaced by individual measures at Member State level.

Option 2 - Repeal but maintain certain existing rules

Option 2 provides the same simplification and administrative burden reduction benefits as option 1 but also gives the EU the possibility to maintain for certain categories of foods, rules the harmonisation of which has provided added value at European level (e.g. infant formulae and follow-on formulae). In terms of harmonisation, repealing the concept of dietetic foods would remove the distortion between dietetic foods and general foods bearing claims. It would maintain existing rules for certain products that are traded widely within the Union and where there is agreement amongst Member States for the continuing need for specific composition and labelling rules to ensure the free movement of these goods across the Union.

As with option 1, legal certainty would be given to businesses as regards the regulatory management at EU level of certain groups of foods for which no clear decision has been made until now i.e. sports foods, diabetic foods, very low calorie diets products and lactose-free foods; these foods will not be covered in the future by specific 'dietetic' rules at EU level but by the general rules applying to all foods.

Besides, having no general rules on dietetic foods anymore and clearer rules for other specific products should allow SMEs to gain easy access to the market and not hamper innovation and ensure better coordination between the requirements of different pieces of legislation.

Option 3- Revision with positive list of dietetic foods

The main advantage of setting a positive list for dietetic foods with specific compositional and labelling rules is that standardised rules would apply to the dietetic food sector ensuring harmonisation across the European Union. This option is considered to be the most conventional way to revise the Framework Directive. It was also considered at the beginning of the Impact Assessment process to be the most logic in line with the traditional legislative approach.

However, the number of foods that may be eligible under the broad definition of dietetic foods may be significant.

The categories of foods outlined in the problem definition – sports foods, very low calorie diets products and lactose-free foods – could potentially be covered in the future by specific EU rules, thus giving legal certainty to businesses by having specific rules on the composition and labelling being set for these foods. The burden that would fall on the industry and Member States for having to comply with additional specific dietetic food legislation (even if general and not detailed) to be able to target food to certain groups of the population may be considered disproportionate particularly taking into account the minimal additional public health and consumer information benefits.

Maintaining the definition would not fully address the interaction between normal foods with targeted claims and dietetic foods with suitability statements and therefore there may continue to be borderline products and difficult interaction between these pieces of legislation. It is therefore likely that Member States and industry may apply different pieces of legislation, in certain cases, to the same products. Therefore market distortions would remain.

Finally, establishing a definite scope and associated specific rules will introduce restrictions to innovation and create a close market.

Option 4 - Revision with prior-authorisation

Similarly as for option 3, the concept of dietetic food would be maintained and reinforced and positive and negative impacts identified above would be similar. Furthermore, the burden of prior-authorisation before using a 'dietetic' suitability statement on a product seems to be disproportionate in terms of consumers' protection and information and would be highly costly for the industry and especially for SMEs. It is also likely that a procedure to assess a suitability statement will overlap considerably with the procedure to assess a claim. It is considered that EFSA will have to carry out the same kind of assessment for the products under the legislation on dietetic foods and on nutrition and health claims. Whilst this may not create distortions in the market it is possible that having two similar regimes may create duplication, conflict and a significant amount of work. For example, the assessment of 'dietetic' suitability statements made on foods e.g. on sports foods, diabetic foods, very low calorie diets products and lactose-free foods would potentially overlap with the current ongoing assessment on nutrition and health claims requested on these products. This in turn may distort the market if some businesses only use the claims legislation, some use the dietetic food legislation and some use both. Similarly, the burden on Member States and the European Commission will increase. It can be argued that the additional work for EFSA, Member States and the European Commission would be enormous for little added EU benefit.

6.4. Preferred Option

In light of the assessment above, it is considered that option 2 provides the best way to achieve the objectives with the least trade-off or negative impacts (tables in section 6.1 and 6.2).

It offers the best approach to simplification, clarity, coherence and reduction of administrative burden without losing harmonisation that has proved beneficial at EU level in terms of consumer nutritional safety and internal market functioning.

As outlined in the problem definition section the benefit of having the current concept of dietetic food in the past is no longer sufficient given the evolution of the food market and the food legislation.

As highlighted in the analysis of impacts section removing the concept of dietetic food would prevent differences in interpretation, as all foods will be considered in the same way by general legislation. However, the analysis of option 2 demonstrates that certain rules established under the specific pieces of dietetic food legislation should be maintained when it is considered that the general labelling and safety rules are not sufficient to ensure adequate nutritional composition of the food to protect the most vulnerable consumers (infant and follow-on formulae, baby foods and medical foods) and appropriate consumer information across the Member States. The likelihood that national rules would be adopted for other specific categories of foods is reduced under this option in comparison with options 3 and 4 as it should be justified on ground of public heath protection in accordance with Art 36 TFUE and not because only because it falls into the definition of a food for particular nutritional uses provided by the framework Directive.

Section 7: Monitoring and evaluation

In the course of this impact assessment a series of actions have been assessed which should simplify the food legislation landscape and make existing rules easier to implement and enforce. It is considered that whichever option is taken forward will clarify the distinctions between food groups and make consumer understanding easier.

The general monitoring of the legislation on dietetic foods is included in the Regulation 882/2004 on official controls of food and feed. This Regulation foresees that the Member States implement efficiently the requirements of the food legislation. The Commission (Food and Veterinary Office) controls the correct enforcement by Member States.

Monitoring will be required not only to assess whether implementation is on track but also to review the evolution of the global context and to determine whether additional measures will be required. The monitoring would be done by the Commission and Member States for example through reports and inspections, laboratory tests and surveys. Self monitoring activities will also be carried out by the industry.

To assess the success of the measures introduced, several key indicators have been identified in line with the initial objectives of the policy action.

In order to evaluate the general objective of ensuring appropriate consumer information and the good functioning of the internal market, Commission's services conduct market studies for example under the consumer scoreboard initiative[50] to ensure good functioning of the internal market for consumers. We will be using the result of such studies in order to identify if the sector of specialised food products is shown to be an area of concerns.

As regards the four specific objectives, the following core progress indicators could be used:

Coherence

- Remove the difference in interpretation and difficulty in implementation of the dietetic food legislation given the development of other food legislation;

→ Indicator - Number of queries received by the Commission regarding the scope of the legislation by Member States and businesses

- To coordinate and align appropriately rules for specific foods with other existing food legislation;

→ Indicator - Number of products that have been classified or considered differently between Member States

[50] http://ec.europa.eu/consumers/strategy/facts_en.htp

Simplification

- Remove the rules that have become unnecessary, contradictory and potentially conflicting;

→ *Indicator - Number of pieces of EU level legislation applying per product*

- Reduce the administrative burden associated with the implementation of the legislation;

→ *Indicator - The reported change in the declared average administrative burden on industry and MS*

Harmonisation

- To ensure that similar products are treated in the same way across the Union;
- To facilitate free movement of goods;

→ *Indicators:*

- Evidence from the Consumer scoreboard or other market research studies on the functioning of the single market for specialised food products

- The number of national rules that have been maintained or newly adopted on products that used to be covered by the dietetic food legislation

SME and innovation

- To ensure that any changes to the management of foods currently covered by the framework Directive do not impact disproportionately on SMEs;

→ *Indicators:*

- Ease of access for SMEs to the market (time, cost)

- Survey on the number of SMEs (growth or reduction) manufacturing/selling products used to be covered by the dietetic food legislation

- To ensure transparency and legal clarity in order to not hamper competitiveness and innovation;

→ *Indicator - Number of innovations generated in the sector per year (new products)*

Once the proposal applies, the Commission will in discussion with Member States and stakeholders set up an appropriate monitoring system in order to establish the baseline situation and year on year progress against the initiatives objectives. These discussions will

also ensure that any monitoring system introduced will not place any significant additional administrative burdens.

ANNEXES

Annex I: Codex Alimentarius

Category	Codex Texts
Dietetic foods (general framework)	General Standard for the Labelling of and Claims for Pre-packed Foods for Special Dietary Uses (1985)
Infant & Follow-on Formula	Standard for Infant Formula and Formulas for Special Medical Purposes (1981, REV.2007) Standard for Follow-up Formula (1987)
Baby food	Standard for Processed Cereal-based Foods for Infants and Young Children (1981, REV.1-2006). Standard for Canned Baby Foods (1981)
Supplementary foods	Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (1991)
Gluten-free food	Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (1979 rev. 2008)
Medical food	Standard for the Labelling of and Claims for Foods for Special Medical Purposes (1991)
Slimming food	Standard for Formula Foods for use in Weight Control Diets (1991)
Very Low Energy Control Diets "VLCD"	Standard for Formula Foods for use in Very Low Energy Diets for Weight Reduction (1995)
Low sodium	Standard for Special Dietary Foods with Low-Sodium Content (including salt substitutes). (1981)

Annex II: Implementation of the notification procedure in certain Member States

(data Agra CEAS Consulting)

	Process	Competent Authority (CA)	Scientific dossier	Timescale	Fee
France	Notification with a copy of the label	Local: Department of the place of production/import	On request of the *préfet du département* Scientific publications to certify that it is a dietetic product, and additional data justifying the nutritional claims If the scientific work is part of an easily accessible publication, a reference to it is sufficient	No information	None
Germany	Notification; scientific assessment by the CA	Central (BVL): responsibility for running the process Local: responsibility for enforcement regarding composition and labelling	Scientific assessment made by the CA	Scientific assessment: 10 days (of only literature review) Total process: on average 4 months, but can be up to one year	€1,533, although this can be reduced by 25% if the application is not successful
Italy	Notification with a copy of the label	Central: Ministry of Labour, Health and Social Policies	On request of the CA Scientific publications to certify that it is a dietetic product, and additional data justifying the nutritional claims If the scientific work is part of an easily accessible publication, a reference to it is sufficient	Silent-assent process. If the CA does not contact the manufacturer within 90 days of receipt of the label the product is considered approved and can be left on the market	€160.20
Poland	Notification with a copy of the label	Central: responsibility for running the process Local: (voivodeship) final decision whether to allow the product on the market	On request of the CA A scientific assessment can be done by the CA (Office of Medicinal Products)	Response within 60 days Scientific assessment: 10 to 12 months	None at the first stage If scientific assessment is requested from Office of Medicinal Products: €1,170-€1,280
Sweden	Notification with a copy of the label	Central: formal check of the notification procedure only Local control authorities: they receive the label once checked by the CA	Technically on request of the CA, but since the CA stopped evaluating products in July 2008 there is no need for a scientific dossier	The CA responds by return to acknowledge receipt and the product can be placed from this point. The guide time for confirmation that the notification has been made correctly is one month for FSMPs	None
UK	Notification with a copy of the label	Central (FSA): checking of the label and that a product belongs to PARNUTS Local (Trading Standards Officers): enforcement of the law		Potentially lengthy if there is prior discussion with manufacturers, fairly quick once agreement on placement is reached	None

Annex III: Overview of the EU Dietetic Food Sector

(data Eurostat and Consultation responses)

European Food Manufacturing Sector

According to Eurostat's 2009 Publication European Business – Facts and Figures, the European food market has approximately 308.3 thousand food manufacturing businesses [51] of which 99% are small or medium enterprises[52]. As Eurostat's table highlights for 2006 the annual turnover is around €876 billion and the sector employees around 4.6 million people.

Table 3.2: Manufacture of food products, beverages and tobacco (NACE Subsection DA)
Structural profile, EU-27, 2006 (1)

	Enterprises		Turnover		Value added		Persons employed	
	(thousand)	(% of total)	(EUR million)	(% of total)	(EUR million)	(% of total)	(thousand)	(% of total)
Food products, beverages & tobacco	308.6	100.0	942 435	100.0	196 666	100.0	4 700.0	100.0
Food products and beverages	308.3	99.9	875 983	92.9	188 417	95.8	4 644.9	98.8
Meat and meat products (2)	44.0	14.3	175 613	19.1	30 000	15.3	1 000.0	21.3
Processed and preserved fish and fish products	4.0	1.3	22 833	2.4	3 955	2.0	129.4	2.8
Dairy products (3)	13.0	4.2	120 000	12.7	17 700	8.9	400.0	8.5
Bread, sugar, confectionery and other food products	192.4	62.3	233 013	24.7	71 951	36.6	2 059.0	43.8
Miscellaneous food products (4)	32.3	10.5	172 517	18.8	29 409	14.8	603.3	12.8
Beverages	22.0	7.1	133 000	14.1	34 000	17.3	460.0	9.8
Tobacco products (5)	0.3	0.1	66 452	7.1	8 250	4.2	64.0	1.4

(1) All data, except for tobacco products, rounded estimates based on non-confidential data.
(2) Turnover, 2005.
(3) Value added, 2005.
(4) Turnover and value added, 2005.
(5) Persons employed, 2005.

Source: Eurostat (SBS)

Eurostat's Business Facts and Figures 2009 publication highlights that the activity (at the NACE[53] group level of detail) within the food products and beverages manufacturing sector with the largest number of businesses was the manufacture of bread, sugar, confectionary and other food products (NACE Group 15.8); it contributed almost EUR 72.0 billion of value added and employed about 2.1 million people. It is under this sector that the dietetic food sector (NACE Group 15.88) sits (see next table).

[51] Eurostat Statistical books - European Business – Facts and Figures
http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-BW-09-001

[52] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database
Chart - Manufacturing subsections DA-DE and total manufacturing (NACE Rev.1.1 D) broken down by employment size classes - Reference year 2002 and onwards

[53] NACE is the statistical classification of economic activities in the European Community

Table 3.12: Manufacture of other food products (NACE Group 15.8)
Structural profile, EU-27, 2006

	Enterprises (thousand)	Turnover (EUR million)	Value added (EUR million)	Persons employed (thousand)	Share in total (%)	
					Value added	Persons employed
Bread, sugar, confectionery and other food products	192.4	233 013	71 951	2 059.0	100.0	100.0
Bread; fresh pastry goods and cakes	159.4	68 643	28 614	1 343.2	39.8	65.2
Rusks and biscuits; preserved pastry goods and cakes	5.6	21 537	6 529	157.3	9.1	7.6
Sugar	0.3	17 593	3 533	45.6	4.9	2.2
Cocoa; chocolate and sugar confectionery (1)	5.5	42 369	10 922	190.0	15.2	9.2
Macaroni, noodles, couscous and similar farinaceous products	7.9	8 980	2 225	58.4	3.1	2.8
Processing of tea and coffee (1)	2.8	18 154	4 899	56.6	6.8	2.7
Condiments and seasonings	1.6	11 964	2 724	53.3	3.8	2.6
Homogenized food preparations and dietetic food (2)	0.7	:	2 000	:	2.9	:
Other food products n.e.c.	8.5	:	:	128.3	:	6.2

(1) Rounded estimates based on non-confidential data.
(2) Value added, rounded estimate based on non-confidential data, 2005.

Source: Eurostat (SBS)

Eurostat's table above highlights the lack of segmented data for the dietetic foods industry. However, the data on homogenized food preparations and dietetic food only covers the key categories covered by the dietetic foods framework legislation (infant formulae and follow-up milk and other follow-up foods, baby foods, low-energy and energy-reduced foods intended for weight control, dietary foods for special medical purposes, low-sodium foods, including low-sodium or sodium-free dietary salts, gluten-free foods, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen and foods for persons suffering from carbohydrate metabolism disorders (diabetes)). It does not include other dietetic products notified under the notification procedure of the Framework Directive.

The figures in the table suggest that the sector is relatively small, around 700 businesses, and that it generates around 2 billions euros value added each year. This is expected to be an underestimation as the businesses manufacturing the dietetic products that are subject to notification only are not included.

Eurostat report suggests that the sector is in growth. In the shortened period between 2000 and 2007, the output of homogenized food preparations and dietetic food grew across the EU-27 by an average of 5.1 % per annum.[54]

Turnover:

Eurostat data also covers the turnover of the sector but data is limited as not all Member States have provided information.

[54] Eurostat publication *European business - facts and figures 2010*
http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-BW-09-001

Figure - Annual detailed enterprise statistics on manufacturing subsections NACE 15.88 Manufacture of homogenized food preparations and dietetic food Turnover (€ millions) for 2007

Member State	BE	BG	CZ	DK	DE	EE	IE	GR	ES	FR	IT	CY	LV
Turnover (€ millions)	86.1	7.5	48.5	-	1018.1	-	-	5.0	1812.2	1717.0	890.6	0	-

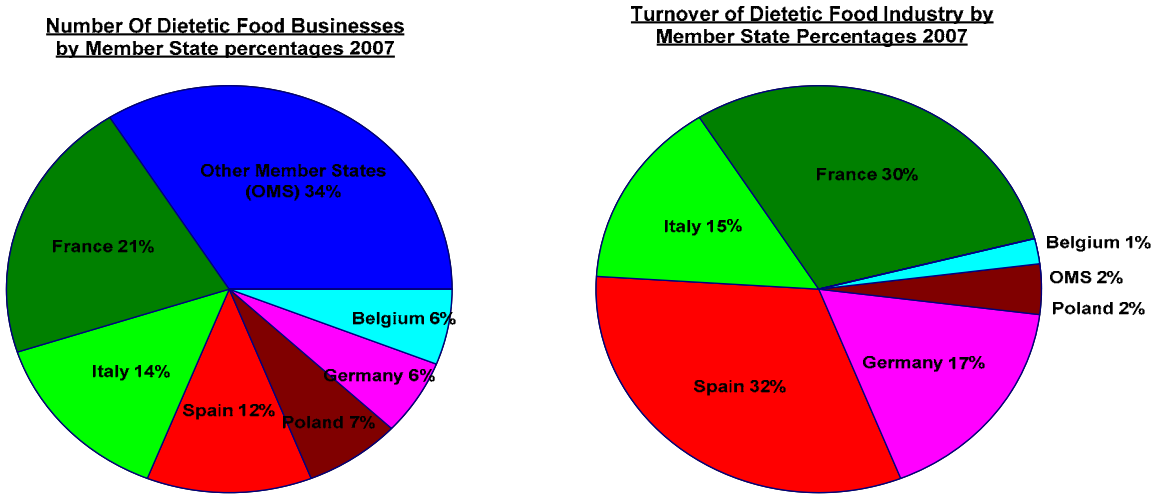
Member State	LT	LU	HU	MT	NL	AU	PL	PT	RO	SL	SK	FI	SE	UK
Turnover (€ millions)	-	-	35.9	-	-	-	134.1	-	5.5	5.9	20.3	0.5	54.3	19.9

Source: Eurostat data

The Commission attempted to gather further information on the turnover of the sector to fill the data gaps of Eurostat. However, information gathered during the consultation phase of the impact assessment process has provided incomplete data on the turnover of the various dietetic food sectors. The information provided by three Member States[55] (For the year 2007 - Italy 2.69 billion; Sweden 568 million; UK 1058 million) appears to be contradictory to that provided to Eurostat.

Member State Split:

Using Eurostat's annual detailed enterprise statistics on manufacturing subsections[56] suggests that the dietetic foods market is dominated by three main Member States: France, Spain and Italy (representing, on average, over 50% of the European total number of businesses, turnover and employees) with Germany, Poland and Belgium representing smaller shares.



Source: Eurostat data

[55] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting.

[56] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database
Annual detailed enterprise statistics on manufacturing subsections DA-DE and total manufacturing (NACE Rev.1.1 D) – Manufacture of Homogenized food preparations and dietetic food

SMEs in the sector:

Eurostat information on the number of SMEs in the "Manufacture of other food products" NACE Group 15.8 (the sector that covers dietetic foods – see table 3.12) suggest that the market share for SME is the same (approx. 99.5%)[57] as the overall European food market (99.1%). The dietetic food sector sits under the "Manufacture of other food products" (NACE Group 15.8) but as the number of businesses is estimated by Eurostat to be 700 it only represents 0.36% of the NACE Group. Therefore, extrapolation of this figure to the dietetic foods market may not be representative. Information provided from the industry representative demonstrates that the market is quite diverse with both multi-national companies and small local producers depending on the country and the sub-sector of dietetic foods. E.g. the sector for baby nutrition appears to be dominated by a few large companies whilst the manufacturers of foods for diabetics and foods for people intolerant to gluten are mainly small businesses.

Trade

Figures on the trade of these products are not readily available as the data is not collected at the European level. Even data on specific categories of food trade cannot be obtained through the EU customs database.

Data on sub-sectors within the Dietetic Foods Framework

Member States provided segregated data on the magnitudes of size of the different categories of dietetic foods across the EU. According to the data extracted from the study report[58]:

Sports nutrition represents an important sector of the dietetic food industry in the EU with €2357 millions retail sales value (Italy: €271 million, the UK: €213 million, France between €90 and €150 million, Sweden €47 million). Euromonitor figures suggest this sector represents 0.2% of the total food industry and to have an annual growth rate of 7%.

The Infants and young children nutrition sector, based on the information provided by four Member States, appears to represents the biggest dietetic food sector in terms of turnover with France: €750 million; Germany: €561 million; the UK: €485 million and Sweden: €86 million.

The Commission received limited information on the other sector's turnover and based on this information estimations on the size across the whole EU is not possible (*Slimming foods* represent €100 million in France and €19 million in Sweden; *Medical foods* represent €200 million in France; €22 million in Germany and €23 in Sweden. *Foods for diabetics* represent €200 million in Germany but only €0.3 million in Italy.)

[57] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database
Annual detailed enterprise statistics on manufacturing subsections DA-DE and total manufacturing (NACE Rev.1.1 D) – Manufacture of other food products

[58] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting

Annex IV: Summary of Stakeholders' opinions

Consumers

Consumers' organisations' main concern is that certain foods are getting special designation/status under the current Framework Directive which could result in them avoiding to complying with other important provisions – e.g. Regulation on Nutrition and Health Claims. These stakeholders have highlighted that where there are no compositional or labelling requirements justified by public health risk there is no need to provide a specific status to foods. This is especially the case when this status allows the food to indicate a suitability statement that could be confused with a claim or make it appear more appropriate than a similar normal food.

Consumer's organisations are in favour of repealing the framework legislation but maintaining some of the existing specific rules governing specific categories for infants and young children, medical foods and gluten-free foods. They have, however, reservations about the need for a specific legislation on slimming foods and have asked the Commission to consider its application and use.

Industry

All industry stakeholders agreed that quantifying the exact impacts in terms of operating costs or loss of sales for each option was not possible. However it was considered that the main impact would be on the way these foods are treated on the market and what legislation they would fall under rather than economic impacts. Industry stakeholders believe the most important aspect for choosing the preferred option should be that trade would not be hampered and harmonisation across Member States is assured.

The dietetic food industry believes that clear and transparent legislation governing the composition of products for the dietetic food sector is crucial. It is needed to maintain the protection of vulnerable groups of the population and those with special nutritional needs from a public health and food safety perspective. In that context and to ensure advantage to SMEs and no barriers to free movements of goods, they suggest to strengthen the current legislation and to include in a positive list at least the following groups of products:

- ‘Foods for infants and young children up to the age of three’ - including Low Birth Weight Formula, Hospital Discharge Formula, Breast Milk Fortifier and Growing Up Milks;
- ‘Foods for pregnant and lactating women’
- ‘Foods for the elderly in good health’
- ‘‘Foods for weight management’
- ‘Foods for special medical purposes’
- ‘Foods for sportspeople’
- ‘Dietary foods for people with gluten intolerance’
- ‘Lactose-free foods’.

In addition, the dietetic food industry emphasise the need for a transparent, efficient and effective procedure for the expansion of the Community list. They argue that science still emerges in this area and therefore a flexible procedure must be preserved to promote innovations.

Nevertheless, this position is not shared by all stakeholders of the industry; certain others believe that the same rules should apply to all foods and that there is no reason to foresee different rules except in very limited cases, where nutritional food safety issues are concerned.

Differences in views between stakeholders exist for example for sports foods:

One group of stakeholders believes that sports foods clearly fit the definition of dietetic foods in that they meet particular nutritional needs and are distinguishable from food products intended for general consumption. Another stakeholder group does not think that specific sports nutrition rules are needed for the protection of public health and adds that it becomes increasingly difficult to maintain that sports nutrition is clearly distinguishable from general foods as the sector is moving more into mainstream.

Member States

Member States agree that harmonisation is important to ensure that 'legislation shopping' is not possible when applying the EU legislation. Member States underline that the most important aspect to maintain would be consumer safety. During consultation some Member States highlighted that the benefit of having a definition for dietetic foods was still important, given the uniqueness of the products, to ensure that they are considered different from their normal food equivalents. However that position was not shared by other Member States that considered that certain specific rules could be maintained without the definition and that the general notified products could be more appropriately regulated through other pieces of legislation.

ANNEX V: List of consulted stakeholders

AIIPA	Associazione Italiana Industrie Prodotti Alimentari (Italian Association Producers of Food products)
BEUC	European Consumers' Organisation
BMELV	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (German Federal Ministry of Food, Agriculture and Consumer Protection)
BVL	Bundesamt für Verbraucherverschutz und Lebensmittelsicherheit (German Federal Office for Consumer Protection and Food Safety)
CAOBISCO	Association of the Chocolates, Biscuits and Confectionary Industries of the European Union
CHC	Consumers for health Choice
CIAA	Confederation of the Food and Drink Industries of the EU
DGCCRF	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (French Directorate General of Competition, Consumers and Fraud Repression)
DiaetV	Diätetisches Lebensmittel Verordnung (German National Law on Dietetic Foods)
DDB	Deutscher Diabetikerbund (German Association People with Diabetes)
EDA	European Dairy Association
ENSA	European Natural Soy food Manufacturers Association
ESSNA	European Union the European Specialist Sports Nutrition Alliance
EUROCOMMERCE	Retail, wholesale and international trade representation to the EU
EUROCOOP	EU Community of Consumer Co-operatives
Federsalus	Federazione Nazionale Aziende Prodotti Salutistici (Italian Federation of Health Products Manufacturers)
FK	Federacja Konsumentow (The Polish Consumer Federation)
FSA	Food Standards Agency (UK)
GIS	Główny Inspektorat Sanitarny (Polish Main Health Inspector's Office)
HFMA	The Health Food Manufacturers' Association
ICGA	International Chewing Gum Association

IDACE	Association of the Food Industries for Particular Nutritional Uses of the European Union
IDF	International Diabetes Federation
IDFA	Infant and Dietetic Food Organisation (UK)
IFOAM	Federation of Organic Agriculture Movements
KIGPR	Krajowa Izba Gospodarcza (Polish National Chamber of Commerce for Drinks)
MNI	Medical Nutrition International Industry
PFPZ	Polska Federacja Producentów Zywnosci (The Polish Food Producer's Federation)
PSD	Polskie Stowarzyszenie Diabetyków (Polish Association of People with Diabetes)
SDCA	Syndicat de la Diététique et des Compléments Alimentaires (French Dietetic and Supplements Manufacturers Union)
UEAPME	European Association of Craft, Small and Medium-sized Enterprises
UNESDA	European Soft Drink Association
VLCD	Very Low Calorie Diet Industry Group
VZBV	Verbraucherzentrale Bundesverband (German Federation of Consumer Organisations)
WAFG	Wirtschaftsvereinigung alkoholfreie Getränke (Germany industry Association for alcoholfree drinks)