EUROPEAN COMMISSION

Brussels, 20.6.2011
SEC(2011) 763 final

COMMISSION STAFF WORKING PAPER

SUMMARY OF THE 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 Summary of the Impact Assessment accompanying document to the Proposal to revise the Dietetic Food Framework Legislation]

{COM(2011) 353 final}
{SEC(2011) 762 final}

1. PROBLEM DEFINITION

Foods for particular nutritional uses or 'dietetic' foods are foods that are different from foods for normal consumption and are specially manufactured products intended to satisfy the particular nutritional requirements of specific categories of the population e.g. foods for infants and young children, medical foods, foods for weight reduction, gluten-free foods etc. The dietetic food legislation was implemented since 1977 in order to ensure free movements of goods and prevent unequal conditions of competition.

It consists of a Framework Directive[1] and specific measures adopted for certain categories of foods:

- Infant formulae and follow-on formulae[2];

- Processed cereal-based foods and baby foods for infants and young children (baby foods)[3];

- Foods intended for use in energy-restricted diets for weight reduction (slimming foods)[4];

- Foods for special medical purposes (medical foods)[5];

- Foods for people intolerant to gluten (gluten-free foods)[6].

Due to diversification and specialisation of foods over the last decades, new pieces of legislation have been adopted. Of particular importance in this context are the legislation on food supplements[7], fortified foods[8] and nutrition and health claims[9].

Discussions with Member States and stakeholders have highlighted difficulties relating to the implementation of the dietetic food legislation and its interaction with more recent pieces of legislation. The main problems identified relate to the following issues.

'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/aimed for a certain group of the population with specific nutritional needs. It is sometimes more and more difficult to see where that distinction between 'normal' foods intended for the 'general' population and 'dietetic' foods intended for a 'specific' group of the population lies.

1 OJ L 124, 6.5.2009, p. 21.
2 OJ L 401, 30.12.2006, p. 1.
3 OJ L 339, 6.12.2006, p. 16.
4 OJ L 55, 6.3.1996, p. 22.
5 OJ L 91, 7.4.1999, p. 29.
6 OJ L 16, 21.1.2009, p. 5.
7 OJ L 183, 12.7.2002, p. 51–57.
8 OJ L 404, 30.12.2006, p. 26–38.
9 OJ L 404, 30.12.2006, p. 9–25.

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

When the framework legislation was adopted, in December 1976, the compulsory 'dietetic' suitability statement foreseen on the label of dietetic foods was intended to cover a large scope and was not limited to defined information. Following the adoption of the Nutrition and Health Claims Regulation in 2006, which covers all statements made on foods implying a nutrition and/or a health benefit, the interaction between the different pieces of legislation becomes less clear. Today, 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 be restricted to the indication of the group of the population to whom the food is intended.

Legislation shopping

Member States have reported[10] that the legislation on dietetic foods is being used by some operators to circumvent the rules of legislation adopted subsequently to it, thus distorting the notion of a food for particular nutritional uses and resulting in certain cases in confusion over its application.

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 claim and therefore avoid the requirements of the claims Regulation (EU prior-authorisation with scientific assessment). This possibility distorts the market and results in an uneven playing field for food operators and unfair competition, as some businesses can gain an unfair advantage over a competitor by using a dietetic food statement instead of having the same claim authorized. This is particularly true for the potential dietetic foods that are subject to the notification procedure or for which no specific rules have been laid down.

Concrete examples of distortions:

Between Member States and businesses

- Some Member States will consider that a food marketed as 'food suitable for people with digestion disorders' is a 'normal' food bearing a claim under the Nutrition and Health Claims legislation and request it be subject to EU prior-authorisation. Other Member States will consider it as a 'dietetic' food that should be notified at national level. A business operating in different Member States may therefore have to comply for the same product with different rules depending on the competent authorities' interpretation of the legislation

For consumers

- A consumer might pay more for a 'dietetic chocolate suitable for diabetic people' considered as being specially formulated for diabetic people than for a similar 'normal' chocolate bearing a nutrition claim "low in sugar".

[10] 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.

Stakeholders most affected

The proposal will have a direct impact on specialised dietetic food producers and Member States competent authorities and an indirect impact on general EU food producers and consumers.

Intervention necessary

After more than 30 years of existence of the Framework Directive on dietetic foods, this revision is also an opportunity to simplify the legal framework, reduce administrative burden whenever possible and to facilitate innovation as well as to only intervene when EU action provides substantial added value over individual Member States action.

2. ANALYSIS OF SUBSIDIARITY

The Framework Directive was based on Article 100a of the EC Treaty, now become Article 114 of the Treaty on the Functioning of the European Union (TFEU) and aims at establishing an internal market for dietetic foods products 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 were adopted at EU level.

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

3. POLICY OBJECTIVES

Overall objectives:

The main aim of the revision is **to ensure appropriate consumer information for specific foods 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.

Specific objectives:

- Objective 1: **Coherence –** To remove the difference in interpretation and difficulty in implementation of the dietetic food legislation given the development of other food legislation and to appropriately coordinate and align rules for specific foods with other food legislation

- Objective 2: **Simplification –** To remove the rules that have become unnecessary, contradictory and potentially conflicting and 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 and to allow the free movement and equal conditions of competitions for goods.

- Objective 4: **Small Businesses and Innovation –** To ensure that any change to the management of foods currently covered by the Framework Directive does not impact disproportionately on small businesses (as they have limited capacities to invest additional resources in obtaining external legal expertise to understand the legislation) or place unnecessary additional burdens on food businesses operators that may hinder innovation.

4. POLICY OPTIONS

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

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

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

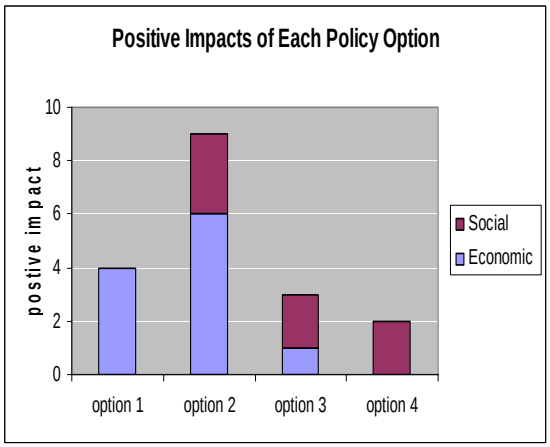
- Option 3 – Revise the Framework Directive establishing a positive list of dietetic foods with specific compositional and/or labelling rules

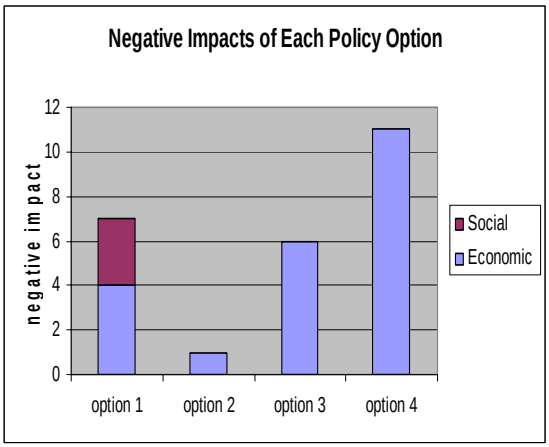
- Option 4 – Amend the Framework Directive replacing the notification procedure with EU centralised prior-authorisation procedure based on a scientific assessment.

5. ASSESSMENT OF IMPACTS

In order to undertake the impact assessment a range of potential impacts were identified through consultation with Member States and stakeholders. This Impact Assessment analyses the likely social, economic and environmental impacts – be they direct or indirect – of the different policy options. As the Framework legislation on dietetic food was established to ensure good functioning of the internal market the major focus of the analysis is on economic impacts of the options (administrative burden, reformulation and labelling, innovation, competitiveness and price) 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, these have been where possible 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. The assessment of each option in terms of environmental impacts has not identified significant impacts (either negative or positive).

Summary of impacts:





Option 1

Abolishing the concept of dietetic food will prevent further distortions between dietetic foods and 'normal' foods with claims. However, whilst this 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 certain EU legislation related for example to foods intended to infants and young children may be significant.

Option 2

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. Having no general rules on dietetic foods anymore and clearer rules for certain specific products should ensure better coordination between the requirements of different pieces of legislation.

Option 3

The main advantage of setting a positive list for dietetic foods with specific compositional and labelling requirements is that standardised rules would apply to the dietetic foods sector ensuring harmonisation across the European Union. However, the burden that would fall on the industry and Member States for having to comply with additional specific dietetic foods legislation to be able to target foods to certain groups of the population may be considered disproportionate particularly taking into account the minimal additional public health and consumer information benefits.

Option 4

The application of a standard prior-authorisation procedure would ensure more harmonisation across the European Union than the general notification procedure currently in place. However, the burden of obtaining 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.

6. COMPARISON OF OPTIONS

		Option 1	Option 2	Option 3	Option 4
General Objectives	**Nutritional quality 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

The impacts of the options considering the repeal of the dietetic food legislation (options 1 and 2) were estimated mainly as being positive with regard to the objectives of the revision - coherence and simplification of the legislation, harmonised intra-union trade and growth of the markets and taking into account SMEs. However, these positive impacts would be counter-balanced by the loss of harmonised rules for products intended to vulnerable groups of the population. Therefore, specific legislation for categories of foods for which the lack of additional compositional and labelling rules to the general rules could compromise nutritional safety should be maintained.

The options of maintaining and reinforcing the legislation on dietetic foods (option 3: by maintaining and establishing specific rules or option 4: by imposing a prior-authorisation regime to all dietetic foods) were considered as placing on industry, Member States and the Commission disproportionate burdens (administrative, operational, enforcement) in comparison to the benefit to public health and consumer information. In addition, third country trade might be affected by additional requirements and such approach would close the sector and restrict competitiveness (especially for SMEs).

Preferred option

It is concluded that the revision of the legislation should be done in accordance with option 2 assuming that the maintenance of separate legislation on dietetic foods in addition to other existing rules of food legislation is no longer justified in the current food market.

In line with the Commission's Smart Regulation policy, option 2 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.

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 foods 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 and appropriate consumer information across the Member States (e.g. foods intended to infants and young children and medical foods).

7. MONITORING AND EVALUATION

A set of indicators and data to be collected was proposed to enable future measurement of the economic and social impact of initiative.