

ROADMAP

Title of the initiative: **Revision of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for a particular nutritional uses (Framework Directive on dietetic foods).**

Lead DG: SANCO

Expected date of adoption of the initiative (month/year): December 2009

Initial IA screening & planning of further work

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Together with ensuring the proper functioning of the internal market, the specific objective of Directive 89/398/EEC (framework Directive) is to ensure product safety and appropriate consumer information through the definition of the characteristics/composition of foods that are suitable to fulfil the particular nutritional requirements of certain groups of the population and through specific labelling rules.

Directive 89/398/EEC was adopted in 1989 and subsequently issues with its implementation have come to light, a number due to the evolution of the EU Food legislation over the last 17 years. In particular with the adoption of Directive 2002/46/EC on foods supplements and, more recently, the adoption of Regulation 1925/2006 on the addition of vitamins and minerals of certain substances to foods (fortified foods) and Regulation 1924/2006 on nutrition and health claims made on food.

The need to consider revision of the framework Directive has been identified in two recent draft reports which have been prepared by the Commission Services and that will soon be sent to the Council and the European Parliament. The first covers the "notification procedure", that requires the manufacturer or the importer of certain dietetic foods to notify the competent authority where the product is being marketed. The second considers on the desirability of special provisions for foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

The reports take into account the views of Member States and other stakeholders and point to the need for a global revision of the framework Directive to achieve "strategic goals" such as to assure a better and simplified legal framework and to facilitate innovation.

What are the main problems identified?

Scope and definition

The report on the notification procedure shows that many difficulties in the implementation of Directive 89/398/EEC come from the different interpretations of the definition of "dietetic foods". Therefore, agreement on the scope of application needs to be sought. This would also help to clarify the different scopes of application of between diverse pieces of legislation, for example on food supplements and fortified foods to avoid further inconsistencies.

Notification procedure

Dietetic foods not belonging to categories for which specific provisions are laid down (for example infant formula and food for special medical purposes where there are specific directives) are required to undergo a notification procedure.

This requiring the manufacturer or the importer to notify the competent authority where the product is being marketed. The report notes that national competent authorities are not applying this procedure in the same way, leading to inconsistent implementation. To improve its functioning concretely, the procedures of notification and exchange of information between the Member States would benefit from clarification and streamlining.

Prior authorisation procedure of new ingredients

During the recent revision of the Directive on infant formulae and follow-on formulae, many Member States requested a system of prior authorisation to be introduced for the inclusion of new ingredients in infant formulae. This request merits further consideration, but would require changes to be made to the framework Directive.

Lactose-free

Information on the absence of gluten and/or lactose in a food product is of significant importance to those consumers who are celiac or lactose intolerant. A recital of the Regulation on claims indicates that conditions for the use of terms such as "gluten-free" and "lactose-free" should be dealt with within Directive 89/398/EEC. Although the current dietetic food legislation indicates that harmonised rules for the absence of gluten can be adopted by the Commission, changes to the framework Directive would be necessary to allow rules on the use of "lactose-free".

Diabetic Foods

In the draft report on diabetes concludes that there is no scientific basis on which to develop specific compositional requirements in a specific Directive. The Commission now needs to consider how best to reflect these conclusions in the framework Directive.

Sports foods

The framework Directive indicates that specific provisions will be laid down in a Directive to cover *foods intended to meet the expenditure of intense muscular effort especially sport people* ("sports foods"). However, although discussions on producing this Directive have started, minimal progress has been made as there are several issues that would make the adoption of legislation on sports foods difficult. For example, the scope of the Directive (sport food for elite athletes or amateur sports people), the establishment of a list of claims and the setting of compositional requirement reflecting the exact situation of this growing category of products. The revision of Directive 89/398/EEC would be the opportunity to reflect on different possibilities for dealing with sport foods, taking into account that a specific Directive does not anymore seem to be the best approach and that clarification on the potential interactions with the legislation on claims, food supplements and fortified foods are needed.

Conclusion

In the light of these considerations, it becomes clear that, after almost 20 years of application, the revision of Directive 89/398/EEC is required for a more effective and harmonised functioning of the dietetic foods sector.

Explain how EU action is justified on grounds of subsidiarity?

This sector is harmonised since 1989.

Different national legislation would create difficulties in EU trade and could not provide the same level of information and protection of consumers. Therefore, it is appropriate to maintain an update harmonisation of the dietetic food legislation.

B. Objectives of EU initiative

What are the main policy objectives?

To make sure there is consistency between the framework Directive with other pieces of food legislation (food supplements, fortified foods and nutrition and health claims).

To provide food business operators and Member States with clearer and simpler rules regarding the notification procedure for dietetic foods.

To clarify the situation with regard to whether or not a specific directive on diabetic foods is required.

To allow for the adoption of specific rules related to the absence of lactose in foods.

To consider the need, and practicality, of introducing prior authorisation for new ingredients in infant formulae and follow-on formulae.

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option A - Do nothing or act only through soft law instruments

Option B - Revise Directive 89/398/EEC

Option 1: Amend Directive 89/398/ECC only to the extent that a specific Directive on foods for diabetics does not need to be adopted but such products can still be marketed as dietetic foods.

Hard Law - Soft Law

Option 2: Global revision of Directive 89/398/EEC

Hard Law - Soft Law

Option C- Repeal Directive 89/398/EEC

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The evolution of the EU food legislation and in particular the adoption of the Directive on foods supplements and the recently adopted Regulations on fortified foods and on nutrition and health claims made on food are expected to have an impact on this sector.

The potential interactions between these pieces of legislation need to be identified and sorted out.

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Option A - Do nothing or act only through soft Law instruments

It would be a missed opportunity to provide legal certainty to Member States and stakeholders and to simplify procedures and administrative burden related to the placing on the market of these products in different Member States.

In addition, this would not fulfil a statutory requirement regarding foods intended for diabetics.

Soft law

Although some issues might be solved by making the use of soft Law (see below), it would not be sufficient to give the necessary legal framework to the majority of them.

Option B – Revise Directive 89/398/EEC

Option 1: Amend Directive 89/398/ECC only to the extent that a specific Directive on foods for diabetics does not need to be adopted but such products can still be marketed as dietetic foods.

Amending the Directive in this way would make clear that there is no benefit in providing a specific directive on diabetic foods. However it would be missing out the opportunity of improving at the same time the general functioning of the legislation, of clarifying its scope and application by the industry and the national authorities, as well as of supporting innovation in dietetic food production with a clear legal framework.

Soft Law

The use of soft Law is not considered suitable for diabetic foods, as these measures are non-binding and would not provide the needed harmonisation.

Option 2: a global revision of Directive 89/398/EEC

Scope and definition

Clarification of the definition and the scope would allow managing the so-called "borderline products", dietetic foods which may fall within the scope of different pieces of legislation, such as the Directive on food supplements and the Regulation on fortified foods.

It would also be the opportunity to clarify the situation with respect to the application of the Regulation on claims. The latter applies without prejudice to specific rules to dietetic foods but these rules on the use of claims, with the exception of infant formulae, are not defined in the Dietetic food legislation.

Soft Law

The use of soft law such as guideline may be considered as an option in this case. This possibility has to be further explored.

Notification procedure

A notification system is necessary to facilitate the official monitoring of the products for which specific rules cannot be laid down because they are innovative products or because they are not part of a generally recognised category of food. However the current notification procedure should be rationalised to ensure a more harmonised implementation across the EU.

Soft Law

At this stage we cannot exclude that the use of soft law such as guidelines may be an option in this case, although these measures are non-binding and will not provide harmonisation. This possibility has to be further explored, as well as the possibility of combining hard law and soft law measures..

Other issues

Prior authorisation procedure for new ingredients, for claims on lactose-free, for sport foods and for updating and clarifying other general articles of the Directive will have to be regulated through legal provisions. This has to be done in order to eliminate legal uncertainties and certain national rules, which may potentially not provide for the same level of consumer protection and create barrier to trade.

Soft Law

The use of soft law is not considered suitable for this option, as these measures are non-binding and would not provide the needed harmonisation.

Option C - Repeal Directive 89/398/EEC

Since 1989, the dietetic food area has become increasingly harmonised, notably with the adoption of specific EU Directives on a number of categories of such products. It is important to maintain specific rules for these categories of food and to provide for a harmonised approach and procedure for the other existing categories of dietetic foods as well as for the future ones resulting from scientific and technological progress.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Not yet identified.

Who is affected?

Specific groups of consumers, food business operators and national competent authorities

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The Commission services have prepared two draft reports for the Council and the European Parliament on the implementation of Article 9 (notification procedure) of Directive 89/398/EEC and on foods for persons suffering from carbohydrate metabolism disorders (diabetes).

There is a need for data regarding economic aspects and specific figures on dietetic foods and the different specific categories.

Work on collecting this information would be completed by an external contractor. However, input is expected from stakeholders and Member States.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Member States experts (working group)/ food business operators/ consumers (Advisory Group on the Food Chain)