



EUROPEAN COMMISSION  
Impact Assessment Board

Brussels,  
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## Opinion

### Title

**Impact assessment on Proposal to revise the Dietetic Food Framework Legislation**

**(draft version of 16 November 2010)**

### **(A) Context**

The Dietetic Foods Framework Directive (Directive on foodstuffs intended for particular nutritional uses, or "PARNUTS") was adopted in 1977 to harmonise national laws relating to dietetic foods that impeded their free movement and had created unequal conditions of competition. It has since been amended and a recast version was adopted in 2009. The Directive defines dietetic food as being distinguishable from normal food, aimed at a specific population group and able to meet their particular nutritional requirements. Specific labelling and composition requirements are set for certain categories of dietetic food by associated EU laws; these being infant formulae milk, baby food, slimming food, medical food and gluten-free food. The general EU dietetic rules cover food in sport, diabetic and lactose-free categories, and other foods that meet the dietetic definition. The general EU dietetic rules require a food to be labelled with a general dietetic suitability statement and to be notified to a national body.

Discussions with Member States and stakeholders have highlighted difficulties with the definition of 'dietetic' and problematic interactions with more recent pieces of legislation, such as the Regulation on Nutrition and Health Claims. This initiative's aims include legal simplification and better enforcement.

### **(B) Overall assessment**

**While the report is of acceptable quality and sums up a thorough assessment process it should be improved in certain regards. The problem issues should be better explained, especially those linked to sports food. The report should present its options in an easily comparable way and the planned transition arrangements should be discussed. To ensure the preferred option is clearly justified, a more systematic assessment of total administrative costs should be provided that takes some account of interactions between different pieces of law. Finally, the expected impact on national rules should be discussed.**

## **(C) Main recommendations for improvements**

### **(1) Better explain the problem issues and the baseline, especially for sports food.**

The IA report should more fully discuss the problem of regulating sport foods, clarifying how national rules on their management and marketing differ within the Community and explaining more clearly why it is difficult to establish a useful definition. It should also explain which Member States and stakeholders support harmonised EU rules on some or all sports food products. The number of general notifications of dietetic food by Member State should be stated, for example in the Annexes, split into categories that include sport food. The problem section should also present key statistics more clearly, so the annual number of dietetic food notifications across the EU and the highest and lowest number of notifications per Member State are evident. The problem section should also briefly describe the dietetic food industry, summarising the details given in the Annexes.

### **(2) Provide details about the options' content and their transition periods.**

To avoid misunderstanding, the report should further clarify what each option entails in terms of EU rules on food composition, labelling and notification or prior-authorisation. A summary table of the options should be added to show which types of rules will affect which food categories. It should be noted that option 3 is assessed because it is the approach that is most often used when revising law and is preferred by certain groups. The length of the planned transitional periods should be stated, and impact calculations should take them into account if this is not already the case. The report should also indicate how the Commission will help Member States and businesses to adapt, in order to achieve a relatively consistent application of the various relevant EU laws.

### **(3) Provide a more systematic assessment of administrative costs.**

The report should provide a more systematic and comparable assessment of total administrative costs and burdens. It should assess option 2 in some depth and should indicate cost ranges if necessary. It should also discuss if any option is likely to lead to the EU-origin administrative costs of this law being substituted by national-origin costs or costs linked to other EU laws or vice versa (e.g. due to fragmentation or consolidation of national rules). It should aim to indicate which option would have lowest overall burden on businesses, and should comment on the significance of administrative costs compared to costs on businesses of substantive compliance and costs on supervisory authorities. The report should explain the difficulties faced in assessing this issue and should give the underlying assumptions for any estimates, particularly about what firms would do if not regulated ('business as usual'). An annex on this subject is strongly recommended.

### **(4) Discuss expected impact on national rules.**

The report should discuss the expected impact of each option on national specific rules, indicating if these are likely to fragment further or to consolidate. The options which are most likely to minimise fragmentation should be identified.

**(D) Procedure and presentation**

The standard disclaimer should be added to the front page of the report. The Annex containing IASG meeting minutes should be removed. The executive summary should briefly discuss the main impacts of each policy option.

**(E) IAB scrutiny process**

Reference number	2009/SANCO/004
External expertise used	No
Date of IAB meeting	Written procedure