



30.9.2011

## **NOTICE TO MEMBERS**

**(74/2011)**

**Subject:** Reasoned opinion by the Senate of the Republic of Italy on the 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 (COM(2011)0353 – C7–0169/2011 – 2011/0156(COD))

Under Article 6 of the Protocol No 2 on the application of the principles of subsidiarity and proportionality, any national parliament may, within eight weeks from the date of transmission of a draft legislative act, send the Presidents of the European Parliament, the Council and the Commission a reasoned opinion stating why it considers that the draft in question does not comply with the principle of subsidiarity.

Under Parliament's Rules of Procedure the Committee on Legal Affairs is responsible for compliance with the subsidiarity principle.

Please find attached, for information, a reasoned opinion by the Senate of the Republic of Italy on the above-mentioned proposal.

Senate of the Republic

16th term

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## RESOLUTION OF THE 12TH STANDING COMMITTEE

(Health and hygiene)

(Rapporteur: D'Ambrosio Lettieri)

Adopted at the morning session of 2 August 2011 on the 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 (COM (2011) 353 final)

Pursuant to Senate Rule 144(1) and (6)

Forwarded to the Presidency on 5 August 2011

The 12th Standing Committee,

- having considered the Union act COM(2011) 353 final – 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,
- appreciating that the main aim of the proposal for a regulation is the need to harmonise, simplify and update the rules governing the composition and labelling of specific categories of foods in order to provide consumers with appropriate products from a nutritional point of view, together with detailed information,
- whereas such measures would concern a broad category of products, including gluten-free or low-gluten food, intended for people with coeliac disease,
- whereas coeliac disease 'is a permanent intolerance to gluten and is recognised as a social disease' (Article 1 of Law No 123 of 4 July 2005, laying down rules for the protection of persons suffering from coeliac disease), resulting in the need for sufferers to totally eliminate gluten from their diet,
- noting that in Article 17(2) of the proposal, the Commission repeals Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten, which was due to come into force on 1 January 1, 2012 (Article 5 of Regulation (EC ) No 41/2009); whereas, moreover, in Recital 26 it argues that 'for the sake of simplification', gluten-free and very low gluten products should be included within the scope of Regulation (EC) No

1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods, resulting in the need to complete the technical adaptations to incorporate those claims into the text 'prior to the entry into application of this Regulation',

- whereas, furthermore, the aim of Regulation (EC) No 1924/2006 is to harmonise national provisions concerning nutrition and health claims made in commercial communications, on labelling and in the presentation and advertising of everyday foods (Article 1),
- whereas Regulation (EC) No 41/2009, however, specifically regulates the composition and labelling of foodstuffs suitable for people intolerant to gluten; whereas that regulation was adopted on the basis 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 particular nutritional uses (Article 1), namely that they 'must fulfil the particular nutritional requirements: (i) of certain categories of persons whose digestive processes or metabolism are disturbed; or (ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs' (Article 1(2)(b) of Directive 89/398/EEC),
- Expresses, pursuant to Protocol 2 to the Treaty on the Functioning of the European Union (TFEU), a negative reasoned opinion for non-compliance with the principles of subsidiarity and proportionality – with specific reference to the rules applicable to gluten-free products – for the following reasons:
  - a) infringement of the principle of subsidiarity: the repeal of Regulation (EC) No 41/2009 action is:
    - unnecessary: the failure of the regulation in question to be implemented to date makes it impossible to assess whether or not it has achieved its intended effect. The need for specific rules regarding 'gluten-free' or 'low gluten' products is, however, obvious, given the specificity of coeliac disease;
    - not necessarily a sign of added value at EU level: it is questionable whether the nutrition claims as defined in Regulation (EC) No 1924/2006 are more effective than those of Regulation (EC) No 41/2009 or than any rules that may be adopted by individual Member States. On the contrary, in Italy, abolishing the concept of 'dietary product', placing gluten-free foods on the same level as everyday foods (with the words 'gluten free' treated as a nutrition claim) would mean that the national health service would not be able to reimburse these products and, given the prevalence of EU law over domestic law, all legislation providing greater protection for people suffering from coeliac disease would have to be reviewed.

From this point of view, therefore, the proposal does not appear to be consistent with the principle of subsidiarity, with regard to both the 'necessity' criterion – conversely, it is precisely Regulation (EC) No 41/2009, which the proposal seeks to repeal, that is necessary – and to the 'EU added value' criterion; the proposal cannot be regarded as adding value when the measure will clearly constitute a step backwards in the protection of people with coeliac

disease, also in relation to the high standards of protection provided by Italian law. Accordingly, the need to retain Regulation (EC) No 41/2009 appears to be even more obvious;

b) infringement of the principle of proportionality: the proposal goes beyond what is necessary for achieving the objectives of the treaties, insofar as a measure to approximate laws, with the aim of establishing or ensuring the functioning of the internal market (Articles 26 and 114 TFEU), does not take sufficient account of the 'requirements linked to the [...] protection of human health' under Article 9 TFEU.

It should be noted, moreover, that Article 168(1), first and second paragraphs of the TFEU also provides for a 'high level of human health protection' in the definition of all Union policies and stipulates that 'Union action, which shall complement national policies, shall be directed towards [...] preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health'.

However, the distinction between healthy people and people with health problems calls for different sets of rules. For the former, general consumer protection laws may suffice, while for the latter, there needs to be a specific set of rules which, as far as people with coeliac disease are concerned, appear to have already been correctly laid down in the aforementioned Regulation (EC) No 41/2009. Accordingly, its repeal would result in a substantial setback for the protection of people suffering from coeliac disease, such as to overstep the bounds of the harmonisation objective that the proposal seeks to pursue under Article 114 TFEU.

From this point of view, the proposal does not appear to be consistent with the principle of proportionality. On the contrary, the requirements to protect health should involve not only retaining Regulation (EC) No 41/2009, but even – possibly – having its status raised within the European Union sources of law.

Lastly, the Standing Committee takes the view that additional thought should be given to the exclusion of overweight people from the category of 'vulnerable groups of the population', to which the proposed regulation devotes specific rules. The World Health Organisation considers being overweight or obese to be among the greatest risk factors for a significant number of chronic diseases, such as diabetes, cardiovascular disease and cancer.