

SENATE OF THE REPUBLIC

Sixteenth Parliamentary Session

RESOLUTION OF THE 12TH STANDING COMMITTEE

(Health and hygiene)

(Rapporteur: D'AMBROSIO LETTIERI)

Approved in 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 Article 144(1) and (6) of the Regulation

Communicated to the office of the Prime Minister on 5 August 2011

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The Committee,

having examined Community Act COM(2011) 353 Final, 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;

whereas the main objective of the Proposal for a Regulation is the need to harmonise, simplify and update the standards applicable to the composition and labelling of certain categories of food, so as to provide consumers with appropriate products in terms of nutrition and detailed information;

whereas that such an intervention would affect a wide range of products, including low-gluten or gluten-free food intended for those suffering from celiac disease;

recalling that celiac disease is "a permanent intolerance to gluten and is recognised as a disease affecting many members of society" (Article 1 of Act No 123 of 4 July 2005 containing standards for the protection of those affected by celiac disease), which means that those affected must eliminate all gluten from their diet;

whereas, in the document in question, the European Commission:

in Article 17(2) proposes the repeal of Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten, whose entry into force was planned for 1 January 2012 (Article 5 of Regulation (EC) No 41/2009);

in recital No 26 proposes, "for reasons of simplification", the inclusion of gluten-free products and those with a very low gluten content within the scope of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, with a consequent need to complete the technical adjustments needed to incorporate these details "prior to the entry into application of this Regulation";

also taking into account the fact that:

the objective of Regulation (EC) No 1924/2006 is to harmonise the national provisions on the (nutritional and health) information in commercial communications for and the labelling, presentation and advertising of food products (Article 1);

Regulation (EC) No 41/2009, on the other hand, relates specifically to the composition and labelling of food products geared to people with a gluten intolerance. It 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), in other words those which "must

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 to obtain special benefit from controlled consumption of certain substances in foodstuffs" (Article 2(2)(b) of Directive 89/398/EEC);

hereby expresses a reasoned opinion within the meaning of Protocol 2 of the Treaty on the Functioning of the European Union (TFEU) that the said Proposal for a Regulation does not comply with the principles of subsidiarity and proportionality – with specific reference to the standards applicable to celiac products – for the following reasons:

a) non-compliance with the principle of subsidiarity: the repeal of Regulation (EC) No 41/2009 is an action which is:

not necessary: the fact that the Regulation in question is still not in force makes it impossible to assess whether or not it would have achieved the desired effect. The need for specific rules on the wording "gluten-free" or "low-gluten" is evident because of the specific nature of the condition affecting celiac people;

not necessarily best dealt with at European Union level: it is debatable whether the use of nutritional indications such as those set out in Regulation (EC) No 1924/2006 would be more effective than those in Regulation (EC) No 41/2009 or those adopted by individual Member States. Thus, in Italy, the abolition of the concept of a "dietetic product" and the consequent treatment of gluten-free products in the same way as ordinary foods (bearing the indication "gluten-free", treated as a nutritional indication) would make it impossible for these products to be reimbursed by the National Health Service and would make it necessary to revise all the laws protecting celiac persons, given the prevalence of European Union law over national law.

The proposal therefore does not appear to comply with the principle of subsidiarity, in terms of either "necessity" – even though Regulation (EC) No 41/2009, which this proposal is intended to repeal, is indeed necessary – or of EU added-value, which cannot be claimed as it is clearly a step backwards in the protection of celiac persons, also with regard to the high protection standards provided for under Italian law. This makes it all the more important to keep Regulation (EC) No 41/2009;

b) non-compliance with the principle of proportionality: the limits of what is necessary to achieve the objectives set out in the Treaties are exceeded to the extent that, in a measure to harmonise legislation with the aim of establishing or ensuring the functioning of the internal market (Articles 26 and 114 TFEU), sufficient account is not taken of "a high level of protection [...] of human health" (Article 9 TFEU).

It should be noted, furthermore, that the first and second points of Article 168(1) of the TFEU also guarantee a "high level of human health protection" in the definition of all the Union's policies and that "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health".

The distinction between healthy persons and those with health

problems means that different treatments are required for each group. For the first group, the general consumer protection system is enough; however, the second group requires a specific system which, for celiac persons, as in this case, is already provided by the above-mentioned Regulation (EC) No 41/2009. Consequently, its repeal would constitute a major step backward in the protection of celiac persons, sufficient to exceed the harmonisation which the proposal intends to bring about pursuant to Article 114 TFEU.

From that point of view, the proposal does not appear to respect the principle of proportionality. On the contrary, the need to protect health should mean not only that Regulation (EC) No 41/2009 should be kept but also that its importance as a source of European Law should be raised.

Finally, it is also necessary to reconsider the issue of the exclusion of overweight people from the category of "vulnerable population groups" for which the proposed directive sets out a specific system. According to the World Health Organisation, being overweight or obese is one of the risk factors for a number of chronic diseases such as diabetes, cardiovascular conditions and neoplastic pathologies.

SIXTEENTH PARLIAMENTARY SESSION – DRAFT ACTS AND REPORTS -
DOCUMENTS

OPINION OF THE 14TH STANDING COMMITTEE

(EUROPEAN UNION POLICIES)

(Rapporteur: Aderenti)

19 July 2011

The Committee, having examined COM (2011) 353 Final,

Whereas:

the aim of the document in question is to harmonise, simplify and update the standards applicable to the composition and labelling of certain categories of food, so as to provide consumers with appropriate products in terms of nutrition and detailed information;

this aim should be achieved initially by the repeal of the current legislation (Article 17 of the Proposal for a Regulation) and then by the partial recast and restandardisation by the European Commission, by means of the adoption of delegated acts and implementing acts pursuant to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU) (Articles 2, 10 and 11 of the Proposal for a Regulation);

such an intervention would affect a wide range of products, including low-gluten or gluten-free food intended for those suffering from celiac disease;

recalling that celiac disease is "a permanent intolerance to gluten and is recognised as a disease affecting many members of society" (Article 1 of Act No 123 of 4 July 2005 containing standards for the protection of those affected by celiac disease), which means that those affected must eliminate gluten totally from their diet;

whereas, in the document in question, the European Commission:

in Article 17(2) proposes the repeal of Commission Regulation (EC) No 41/2009 of 20 January 2009, whose entry into force was planned for 1 January 2012 (Article 5 of Regulation (EC) No 41/2009);

in recital No 26 proposes, "for reasons of simplification", the inclusion of gluten-free products and those with a very low gluten content within the scope of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006, with a consequent need to complete the technical adjustments needed to incorporate these details "prior to the entry into application of this Regulation";

Also taking into account the fact that:

the objective of Regulation (EC) No 1924/2006 is to harmonise the national provisions on the (nutritional and health) information in commercial communications for, and the labelling, presentation and advertising of food products (Article 1);

Regulation (EC) No 41/2009, on the other hand, relates specifically to the composition and labelling of food products geared to people with a gluten intolerance. It 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), in other words those which "must 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 to obtain special benefit from controlled consumption of certain substances in foodstuffs" (Article 2(2)(b) of Directive 89/398/EEC);

hereby expresses the following criticisms, pursuant to Protocol 2 of the Treaty on the Functioning of the European Union (TFEU), concerning compliance with the principles of subsidiarity and proportionality – with specific reference to the standards applicable to celiac products – for the following reasons:

a) non-compliance with the principle of proportionality: the limits of what is necessary to achieve the objectives set out in the Treaties are exceeded to the extent that, in a measure to harmonise legislation with the aim of establishing or ensuring the functioning of the internal market (Articles 26 and 114 TFEU), sufficient account is not taken of "a high level of protection [...] of human health" (Article 9 TFEU).

It should be noted, furthermore, that the first and second points of Article 168(1) of the TFEU guarantee a "high level of human health protection" in the definition of all the Union's policies and that "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health".

The distinction between healthy persons and those with health problems warrants different treatment for each group. For the first group, the general consumer protection system is enough; however, the second group requires a specific system which, for celiac persons, as in this case, would appear to be already correctly set out in the above-mentioned Regulation (EC) No 41/2009. Consequently, its repeal would constitute a major step backward in the protection of celiac persons, sufficient to exceed the harmonisation which the proposal intends to bring about pursuant to Article 114 TFEU.

From that point of view, the proposal does not appear to respect the principle of proportionality. On the contrary, the need to protect health should mean not only that Regulation (EC) No 41/2009 should be kept but also that its importance as a source of European Law should be raised;

b) non-compliance with the principle of subsidiarity: the repeal of Regulation (EC) No 41/2009 is an action which is:

not necessary: the fact that the Regulation in question is still not in force makes it impossible to assess whether or not it would have achieved the desired effect. The need for a specific Regulation on the wording "gluten-free" or "low-gluten" is evident because of the specific

nature of the condition affecting celiac people;

not necessarily best dealt with at European Union level: it is debatable whether the use of nutritional indications such as those set out in Regulation (EC) No 1924/2006 would be more effective than those in Regulation (EC) No 41/2009 or those adopted by individual Member States. Thus, in Italy, the abolition of the concept of a "dietetic product" and the consequent treatment of gluten-free products in the same way as ordinary foods (bearing the indication "gluten-free", treated as a nutritional indication) would make it impossible for these products to be reimbursed by the National Health Service and would make it necessary to revise all the laws protecting celiac persons, given the prevalence of European Union law over national law.

The proposal therefore does not appear to comply with the principle of subsidiarity, in terms of either "necessity" – even though Regulation (EC) No 41/2009, which this proposal is intended to repeal, is indeed necessary – or of EU added-value, which cannot be claimed as it is clearly a step backwards in the protection of celiac persons, also with regard to the high standards provided for under Italian law. This makes it all the more important to keep Regulation (EC) No 41/2009;

Finally, it is also necessary to reconsider the issue of the exclusion of overweight people from the category of "vulnerable population groups" for which the proposed directive sets out a specific system. According to the World Health Organisation, being overweight or obese is a risk factor for a number of chronic diseases such as diabetes, cardiovascular conditions and cancer.