



EUROPEAN COMMISSION

Brussels, 23.5.2012
C(2012) 3072 final

Sen. Renato SCHIFANI
Presidente
Senato della Repubblica
Palazzo Madama
IT – 00100 ROMA

Dear President,

The Commission thanks the Senato della Repubblica for its reasoned opinion 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 purpose {COM(2011) 353 final}¹.

The Senato della Repubblica concluded that the intended repeal, in Article 17(2) of the proposal, of Commission Regulation (EC) No 41/2009 of 20 January 2009² concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten is in breach with the principle of subsidiarity.

The Commission proposes to continue to regulate at EU level the indication of the absence of gluten in foodstuffs. This would be done either in the framework of Regulation (EC) No 1924/2006³ of the European Parliament and the Council on nutrition and health claims made on foods (as initially proposed by the Commission) or as currently discussed in the Council, in the framework of Regulation (EU) No 1169/2011⁴ of the European Parliament and the Council on the provision on foods information to consumers. Depending on the result of the discussions, the Commission shall incorporate the statements "gluten-free" and "very low gluten" and their associated conditions of use under one of those frameworks prior to the entry into application of the new proposed Regulation.

The Commission can therefore not consider the invocation of a breach of the principle of subsidiarity in this case as founded.

The Senato della Repubblica further considers that the intended repeal of Regulation (EC) No 41/2009 would breach the principle of proportionality, insofar as it would not sufficiently take the protection of public health into account.

The Commission fully recognises that people with celiac disease need clear information about the gluten content of foods. For this reason, it adopted specific rules harmonising

¹ http://ec.europa.eu/food/food/labellingnutrition/nutritional/docs/sanco_11224_2011_rev5_it.pdf

² OJ L 16, 21.1.2009. p.5.

³ OJ L 404, 30.12.2006. p. 26.

⁴ OJ L 304, 22.1.2011, p.18.

the indication of the absence of gluten in January 2009 through Commission Regulation (EC) No 41/2009.

The Regulation establishes specific requirements to be met for foods to be voluntarily labelled as "gluten-free" (when the gluten content is not higher than 20 mg/kg) or "very low gluten" (when the gluten content is not higher than 100 mg/kg).

It is important to note that according to Regulation (EC) No 41/2009 the statement "gluten-free" may already be used for foods intended for particular nutritional uses and for foods for normal consumption. Therefore, the Proposal, though it abolishes the concept of dietetic food, will simplify the application of these rules and maintain the same level of protection of people intolerant to gluten.

The same high level of protection of human health will be maintained at EU level as the conditions of use stipulated by Regulation (EC) No 41/2009 will continue to apply without discontinuity, but under a different legislative framework.

Moreover, the Commission would like to note that the current and proposed rules do not concern the reimbursement nor the subsidy of products by the national health services. This is an issue that falls within the competence of Member States.

The proposed Regulation would not prevent a Member State from maintaining or introducing a system of reimbursement or subsidy of certain categories of products regardless of the fact that such categories are covered or not by this proposal.

It should also be noted that the Commission adopted in 1996⁵ specific rules applying to products presented as "meal replacement for weight control" and "total diet replacement for weight control". Regulation (EC) No 1924/2006 then recognised the possibility for operators to make health claims on foods related to "slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to a reduction of the available energy from the diet".

Therefore, in the interest of legal certainty, simplification and legal coherence of Union legislation, such statements should be regulated solely by Regulation (EC) No 1924/2006.

I hope that these clarifications help to address the concerns raised in the Senato della Repubblica's reasoned Opinion and I look forward to continuing our political dialogue on these important issues in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*

⁵ OJ L 55,6.3.1996, p.22