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STATEMENT OF THE COUNCIL'S REASONS

Subject : Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

–Statement of the Council's reasons

Adopted by the Council on 22 April 2013

I. INTRODUCTION

1. On 24 June 2011, the European Commission submitted a 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[1] on the basis of Article 114 of the Treaty on the Functioning of the European Union (hereafter "TFEU").

2. In accordance with Article 114(1) of the TFEU, the Economic and Social Committee delivered its opinion on 26 October 2011[2].

3. Acting in accordance with Article 294(3) of the TFEU, the European Parliament adopted its position at first reading on 14 June 2012[3], approving 83 amendments to the original Commission proposal.

4. In accordance with Article 294(5) of the TFEU, the Council adopted its position at first reading by qualified majority on 22 April 2013.

II. OBJECTIVES

5. The proposed Regulation is aimed at replacing Directive 2009/39/EC on foodstuffs intended for particular nutritional uses[4] and a number of Commission acts implementing that Directive, while abolishing the concept of 'dietetic' foods.

   It provides for new general provisions for a limited number of categories of food that are considered essential for certain vulnerable population groups (infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and food for total diet replacement for weight control) and for a 'Union' list of substances (such as vitamins, minerals and some other substances) that may be added to the categories of foods referred in Article 1 of the proposed Regulation.

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1 12099/11 (COM(2011)353final).
2 NAT/518 – CESE 1604/2011.
3 EP-PE_TC1-COD(2011)0156.
4 OJ L 124, 20.5.2009, p. 21.

It seeks to clarify the legal framework by avoiding the overlap between the specific legislation applicable to such food and the legislation applicable to normal food, and by closing legal loopholes under the existing system.

It further aims at ensuring that the EU rules on such foods are applied in the same manner in all Member States, thereby helping to provide legal certainty in the interests of both consumers and producers whilst preventing distortions in the internal market.[5]

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

6. The Council's position introduces several changes to the Commission's proposal. Albeit with different drafting, the changes are mostly in line with the views expressed in the European Parliament's position at first reading.

7. The Council's position takes into account almost all of the substantive amendments suggested by the European Parliament, in particular:

   a) as regards the scope of the proposed Regulation:

      – the inclusion of the category of (total diet replacement for weight control) foods within the scope of the proposed Regulation (title, point (d) of Article 1(1), point (h) of Article 2(2) and recital 16 covering amendments 1, 11, 12, 20, 26, 36, 46);

[5] Currently, similar foods may be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption addressed to the population in general or to certain sub-groups such as pregnant women, older adults, growing children, adolescents and others. This situation undermines the functioning of the internal market, creates legal uncertainty for authorities, producers and consumers and carries the risk of marketing abuse and distortion of competition.

– the principle that people who are intolerant to gluten should be given at least the same level of protection as they receive under the current legal framework (recital 41); the rules on the use of the "gluten-free statements" should be transferred under Regulation (EU) No 1169/2011 on the provision of food information to consumers[6] (amendments 1, 11, 12, 20, 35, 44, 45, 70, 90);

– the importance of clarifying the legal status of "lactose-free" statements (recital 42 covering amendments 25, 80); rules on the use of such statements should be regulated under Regulation (EU) No 1169/2011;

– the need for Commission reports to assess if provisions regarding food for sportsmen (Article 13 and recitals 32, 33, covering amendment 6) and for milk-based drinks and similar products intended for young children (Article 12 and recital 31 related to amendments 21, 81) are necessary; the Commission reports should be submitted by 2 years after the entry into force of the proposed Regulation;

– the fact that 'low birth weight and pre-term infants foods' are within the scope of the proposed Regulation, as it is clarified in recitals 29, 30 covering amendments 13, 34, 43, 92;

b) the fact that substances injurious to health should be excluded from the composition of categories of food referred in Article 1 of the proposed Regulation (recital 3, covering amendment 3);

c) the need to regulate this sector and to clarify to which products the proposed Regulation is applicable (amendment 4, that was already covered by recitals 9 and 13 of the Commission proposal and is also covered by recital 10);

[6] OJ L 304, 22.11.2011, p. 18.

d) more emphasis on the need for Commission's technical guidance that may facilitate compliance of food business operators, in particular small and medium size enterprises (SMEs), with the proposed Regulation (Article 14 and recitals 10, 34 covering amendments 8, 29, 30, 31, 72);

e) the application of the precautionary principle, as referred to in Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[7], to the foods referred in Article 1 of the proposed Regulation (Article 5 covering amendments 9, 10, 53, 64, 69);

f) the need to restrict, as far as possible, pesticide residues in the foods covered by the proposed Regulation (points (b) and (g) of Article 11(1) and recitals 20, 21, 22 related to amendments 15, 16, 17, 62, 63);

g) the establishment of the Union list of substances, as set out in the Annex to the proposed Regulation, that may be added to one or more categories of food referred in Article 1 and its possible update by means of delegated acts (Articles 1(2), Articles 15 and 16, recitals 36, 37, 38, 39, and Annex covering amendments 22, 24, 37, 87, 88, 89);

i) the subjection of substances which are engineered nanomaterials to adequate test methods and, thus, the inclusion of a reference to the definition of engineered nanomaterials in Regulation (EU) 1169/2011 (Article 9(2) and point (b) of Article 2(1) and recital 23 covering amendments 23, 41, 87)

j) as regards the delegation of powers:

– the exclusion from the powers to be conferred on the Commission of adaptations to the definitions (Article 2(3) of the Commission proposal deleted by amendment 48) as both institutions consider them essential elements of the proposed Regulation, thus the changes could be done only by the ordinary legislative procedure;

[7] OJ L 31, 1.2.2002, p. 1.

– the procedure for adopting delegated acts (Article 18 covering amendment 77) and the list of delegated acts to be adopted (Article 18 covering amendments 78 and 79 and recitals 39 covering amendment 22).

k) the fact that the labelling, presentation and advertising of food should not attribute properties to food for the prevention, treatment or cure of human diseases (Article 9(5) and recital 25 covering amendment 58);

l) the importance of 'breast-feeding' and in order not to discourage it, the extension of the prohibition of pictures of infants in the labelling, presentation and advertising of infant formula to the labelling of follow-on formula (Article 10 and recital 26 covering amendment 59);

m) the information to be provided to health care professionals concerning the foods referred in Article 1 of the proposed Regulation (Article 9(6) covering amendment 60);

n) the information to be provided on recommendations for appropriate use of the food (amendment 67, already covered by Article 9(5)).

8. The Council's position also incorporates amendments 19, 39, 40, 49 (2nd part), 51, 52, which are of technical or editorial nature and aim at improving the clarity of the text.

9. The Council's position further introduces the possibility for the Commission to adopt implementing acts to decide whether or not a given food falls within the scope of the proposed Regulation and to which category of food under the scope it belongs (Article 3 and recital 40).

10. However, The Council's position does not include some amendments suggested in the European Parliament's position at first reading, for the following reasons:

a) Amendment 2 aimed at giving a particular emphasis to the safety of the food referred in Article 1 of the proposed Regulation, as the proposed Regulation is not limited to the safety of food. It should, if at all possible, be placed in the context of free movement of safe and wholesome food, as proposed by the Commission.

b) Amendment 5 on the Union's contribution to the application of appropriate practices for the marketing of breast-milk substitutes in third countries by Community based manufacturers, as the reference to the Council Resolution of 18 June 1992 is not totally adequate or accurate. In fact, Regulation (EC) No 178/2002 contains a more recent and specific position of the co-legislators in relation to the obligations of food business operators with regard to food imported into the Union and to food exported from the Union.

c) Amendment 7 on the food to be absorbed by persons suffering from carbohydrate metabolism disorder ("diabetes"), which is out of context, because "diabetes" is not specifically covered by the proposed Regulation as a disease.

d) Amendment 18 on the applicability of Regulation (EC) 178/2002, amendments 27, 28, and 54 on oversight, amendment 49 (1st part) referring to the import-export general provisions applicable to food and amendment 68 on post-market monitoring, as they repeat legislation in force.

e) Amendments 50 and 91, as providing a temporary authorisation through the same (rapid) procedure as the indefinite authorisation would entail an unnecessary supplementary administrative burden. Moreover, the power is delegated to the Commission to regularly update the requirements applying to the food referred in Article 1 of the proposed Regulation in order to enable consumers to benefit rapidly from technical an scientific progress, especially in relation to innovative products (Article 11(2) and recital 27).

f) Amendments 47 on the categories of foods for special medical purposes, amendment 61 on the elements to be notified for monitoring purposes and amendments 71 and 82 specifying the definitions of low calorie food and very low calorie food, which are too detailed to be considered in the context of a basic act and should rather be tackled, for instance, by delegated acts.

g) Amendment 56 on mentions prohibited on labelling of food to "normal consumption", which is no longer applicable, since the distinction between "dietetic food" and "food for normal consumption" has been abolished with the current revision.

h) Amendment 66, as the rules in force cannot be transferred automatically to delegated acts in the context of a new legislative framework.

i) Amendments 75 and 76 on information related to applications, as they were rendered obsolete by the changes in the legal text.

Amendments 14, 33, 38, 55 and 57 were also rejected due to the absence of any substantive change in the text.