EUROPEAN
COMMISSION

Brussels, 23.4.2013
COM(2013) 241 final

2011/0156 (COD)

**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

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

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1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document COM (2011) 353 final – 2011/0156 COD):	24 June 2011
Date of the opinion of the European Economic and Social Committee:	26 October 2011
Date of the position of the European Parliament, first reading:	14 June 2012
Date of transmission of the amended proposal:	[*]
Date of adoption of the position of the Council:	22 April 2013.

* Taking into account the developments in the informal discussions between the Council and the European Parliament following the European Parliament first reading, the Commission did not prepare an amended proposal but expressed its views on the Parliament amendments in the "*Communication de la Commission sur les suites données aux avis et résolutions adoptés par le Parlement eropéen lors de la session de juin 2012*" (document SP (2012)540) sent to the European Parliament on 12 July 2012.

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The proposal revises the framework legislation applying to foodstuffs for particular nutritional uses, so-called 'dietetic foods', as set out in Directive 2009/39/EC[1].

Taking into account the evolution of the food market and the corresponding evolution of EU food law over the last decades, the proposal for a Regulation abolishes the broad concept of 'foodstuffs for particular nutritional uses', which dates back to 1977 and has led to problems for stakeholders and controlling authorities in an evolved market and legal context. It provides for a new framework establishing general provisions only for a limited number of categories of foods that are considered as essential for certain vulnerable groups of the population i.e. infants and young children and people under medical supervision.

The proposal also foresees the establishment of a single Union list of certain categories of substances (e.g. vitamins, minerals, amino acids …) that may be added to the categories of food covered by the proposal. This Union list consolidates different lists currently foreseen by different measures adopted by the Commission under the existing legal framework for foodstuffs for particular nutritional uses.

The proposal pursues the objectives of better regulation, since it maintains specific rules for products only where these are necessary to protect vulnerable groups of the population, and simplifies the current legislation by removing rules that have become unnecessary or contradictory and by bringing together the different lists of substances that may be added to these products.

3. COMMENTS ON THE POSITION OF THE COUNCIL

3.1. General comments

The Commission's proposal was transmitted to the European Parliament and to the Council on 24 June 2011. The European Parliament adopted its position at first reading on 14 June 2012 and supported the main goals of the Commission's proposal. In particular, the European Parliament agreed on the need to abolish the concept of food for particular nutritional uses itself as well as on the need to limit the scope of the legislation only to certain categories of foods intended for vulnerable groups of the population. The position of the European Parliament included 83 amendments to the original Commission's proposal.

No modified Commission's proposal was issued. In the "*Communication de la Commission sur les suites données aux avis et résolutions adoptés par le Parlement européen lors de la session de juin 2012*" (document SP (2012) 540) sent to the

[1] Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21–29). Under that framework legislation, a series of specific measures were adopted by the Commission. More specifically, Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1–33); Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16–35); Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22–26); Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29–36); Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16, 21.1.2009, p. 3–5); Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (OJ L 269, 14.10.2009, p. 9–19); Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries (OJ L 179, 1.7.1992, p. 129–130).

European Parliament on 12 July 2012, the Commission indicated that it could accept in full, in part, in principle or subject to rewriting 53 of the 83 amendments, as it considered that these amendments could clarify or improve the Commission's proposal and were consistent with its general aims.

Following adoption of the European Parliament's first reading position, informal discussions continued between the delegations of the European Parliament, the Council Presidency and the Commission, with a view to concluding an agreement at the common position stage ('early second reading agreement').

These discussions proved successful and are reflected in the common position of the Council, which was adopted with qualified majority. The Commission considers that the common position of the Council reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament. Although on certain elements, the common position differs from the Commission's original proposal, the Commission considers that it represents a carefully balanced compromise and is satisfied that it covers all issues considered essential by the Commission when adopting its proposal.

3.2. Amendments of the European Parliament accepted by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

Foods for weight reduction: the European Parliament agreed with the Commission's proposal to transfer the existing rules on meal replacement products for weight control under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. However, it adopted amendments to include in the scope of the Regulation total diet replacement products for weight control, including Very Low Calorie Diet products (VLCDs), which also replace the totality of the daily diet but have a lower energy content (amendments 1, 11, 12, 20, 22, 26, 36, 46). The European Parliament also set detailed rules for these products in the basic act (amendments 71, 82).

In its Communication on the European Parliament's position at first reading, the Commission accepted the principle of including such products in the scope of the Regulation, in a spirit of compromise. However, it explained that detailed rules should not be included in the basic act. They should on the contrary be established by a delegated act adopted in the framework of the Regulation as it is the case for all other foods in the scope.

The Council's position is in line with the Commission's, since meal replacements are left out of the scope, total diet replacement products, including VLCDs, are in the scope, and it is foreseen that specific rules for these products will be adopted by delegated acts. A clear description of VLCDs is provided in the recitals, and that goes in the direction of the European Parliament's concerns as represented in its amendments. The Council's position is acceptable by the Commission.

Milk-based drinks and similar products intended for young children: in its first reading position the European Parliament adopted amendments 21 and 81 requiring the Commission to adopt a report on milks intended for young children (so-called 'growing up milks'). The report, to be based on the advice of the European Food Safety Authority, should assess the need for special provisions for these products.

The Commission agreed with the European Parliament on the usefulness of a report based on the scientific advice of the European Food Safety Authority, especially

taking into account that different views exist on whether these products are needed or not to satisfy the nutritional requirements of young children. The Council also agrees with the European Parliament and proposes a drafting which requires the Commission to draft a report on these products as required by the European Parliament, within two years from the entry into force of the Regulation. The Council requests the Commission to consider in the report, among others, the nutritional requirements of young children, the role of these products in the diet of young children and whether these products have any nutritional benefits when compared to a normal diet for a child who is being weaned.

The request for a report, as drafted by the Council, is acceptable for the Commission.

Pesticides: the European Parliament proposed in its first reading position amendments to introduce in the basic act detailed provisions on the use of pesticides, in particular as regards food intended for infants and young children (amendments 15, 16, 17, 62, 63). These provisions focused, among others, on the importance, when implementing the legislation, to restrict as far as possible use of pesticides in products intended for the production of food covered by the Regulation, to update measures in the area regularly and to pay particular attention to certain pesticides containing dangerous active substances, safeners or synergists, with the objective to ultimately avoid their use.

The Council introduces similar amendments going in the direction of those by the European Parliament. However, the Council did not include in its amendments reference to the fact that, when implementing the legislation, the objective should be to ultimately avoid the use of certain pesticides containing dangerous active substances, safeners or synergists.

The Commission had accepted partly, in principle or subject to rewording, the amendments of the European Parliament. In this context, it should be noted that the Commission's proposal foresaw the possibility for the Commission to set where necessary specific rules on pesticides in the delegated acts covering products in the scope of the Regulation, and that legislation on pesticides has been recently reviewed and takes into account vulnerable groups (including children, foetuses and embryos). Therefore the Commission could be flexible to refer to the use of pesticides as long as it is consistent with the existing rules on pesticides. The Commission supports the Council's position on the subject, and considers that it represents a good compromise accommodating the major concerns of the European Parliament. In addition, the Commission also refers to the statement made in attachment.

Use of pictures in labelling of follow-on formula: the Commission had accepted in principle amendment 59 by the European Parliament to extend to the labelling of follow-on formulae the existing restrictions on labelling of infant formula as regards the prohibition to use pictures of babies, text, etc. idealising the use of the product. The Commission underlined however that such rules would sit better in the context of the relevant delegated act.

The Council, in its position, agrees with the European Parliament and proposes amendments in this direction. Further, it proposes to accompany this requirement with the general principle that the labelling, presentation and advertising of infant formula and follow-on formula shall be designed not to discourage breast-feeding.

The Commission acknowledges that due to the political importance of this provision, it is opportune to include it in the basic act, as proposed by both co-legislators, and considers the Council's position acceptable.

Technical guidance: the European Parliament had introduced amendments 30 and 72 requiring the Commission to adopt guidelines through delegated acts to facilitate compliance of food business operators, in particular SMEs, with the requirements of the Regulation. The Commission accepted these amendments in principle.

The Council position foresees the possibility for the Commission to adopt technical guidance but does not require this to be done by delegated acts. The Commission accepts the position of the Council.

Precautionary principle: the European Parliament had introduced amendments 9, 10, 53, 64, 69 to reiterate that the precautionary principle, as set out in the General Food Law Regulation (EC) No 178/2002[2], is applicable when taking risk management measures relevant for the food covered by this Regulation. The Commission accepted some of the amendments in principle, in a spirit of compromise. In order to accommodate the European Parliament's concerns, the Council introduces in its position a cross-reference to the relevant requirements in Regulation (EC) No 178/2002. Considering the horizontal nature of Regulation (EC) No 178/2002, the Commission prefers a cross-reference that would guarantee better consistency of EU rules and therefore supports the Council's position.

Access to documents: the European Parliament, in its position, introduced amendment 76 to guarantee fair access to documents in line with the rules of Regulation (EC) No 1049/2001[3]. This amendment was partly accepted by the Commission and is accepted with redrafting by the Council. The Council's position is acceptable as it cross-refers to Regulation (EC) No 1049/2001 thus ensuring consistency of EU rules.

3.3. Amendments of the European Parliament rejected by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

Union list of substances: the Commission's proposal foresaw the establishment of a Union list of certain categories of substances (e.g. vitamins, minerals, amino acids…) that may be added to the categories of food covered by the Regulation. In the Commission's proposal this list had to be established and updated by implementing acts on the basis of established criteria set in the basic act.

In its position, the European Parliament proposed that this Union list of substances should constitute an Annex to the Regulation and that it should be established and updated by delegated acts (amendments 22, 87, 88, 89). The European Parliament's amendments left the Annex empty and to be filled in by the Commission after adoption of the Regulation. These amendments were rejected by the Commission, since it was considered that, in accordance with the rules of the Treaty on the Functioning of the European Union, the establishment and update of a list of well-

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48.

defined categories of substances on the basis of criteria set in the basic act should be done by implementing acts.

In its position, the Council accepts the European Parliament's position that the Union list should constitute an Annex of the Regulation. However, the Council does not leave the Annex empty for future adoption by the Commission, but establishes the Union list by itself, including in this Annex all the substances belonging to certain categories of substances (e.g. vitamins, minerals, amino acids…) that may be added to the categories of food covered by the Regulation. Furthermore, the Council agrees with the European Parliament that amendments to the Union list (in terms of categories covered or substances included) should be done by delegated acts, but redrafts the relevant Articles of the Regulation in light of the change in the nature of powers delegated to the Commission.

The Commission understands that, given the vulnerability of the categories of the population that are the consumers of the food covered by the Regulation, the legislator wants to decide by itself what substances should be included in the Union list. The Commission can therefore accept that the Union list of substances is established by the legislator in Annex to the Regulation. The Commission can also accept that modifications to the Annex should be done by delegated acts, since the drafting in the Council's position leaves the necessary large discretion to the Commission when adopting such measures, in line with the nature of delegated acts as set out in the Treaty on the Functioning of the European Union.

Nano-materials: the European Parliament adopted amendment 87 requiring specific criteria for the evaluation and inclusion of substances that are engineered nano-materials in the Union list, in particular with respect to the test methods for evaluating their safety. The European Parliament also introduced a cross-reference to the definition of 'engineered nanomaterial' provided in Regulation (EU) No 1169/2011 on the provision of food information to consumers[4] (amendment 41). The Commission rejected these amendments considering that the European Parliament's concerns were adequately addressed by the Commission's proposal and that these amendments were therefore not necessary.

The Council, in its position, includes, with different drafting, the amendments of the European Parliament. It also redrafts the proposal to clarify the interaction between the Regulation and Regulation (EC) No 258/97 on novel foods[5]. The Council's position can be accepted by the Commission, in the spirit of compromise, and taking into account that consistency is ensured with other pieces of EU legislation.

Amendment of definitions: the Commission's proposal foresaw the possibility to adapt the definitions of food covered by the Regulation on the basis of delegated acts, taking into account technical and scientific progress and relevant developments at international level, as appropriate. This was also proposed in order to facilitate the resolution of future possible borderline cases with respect to food covered by this Regulation. Both the European Parliament and Council agree that definitions are

4 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18–63.

5 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1–6.

essential elements of the proposed Regulation and therefore cannot be modified by delegated acts.

While the Commission had originally rejected amendment 48 by the European Parliament, it can now accept the one by the Council, in the spirit of compromise and taking into account the introduction by the Council of a new Article in the proposal on interpretation decisions (see below under 3.6).

Delegation of powers to the Commission: the European Parliament's (amendment 77) and Council's positions foresee that the power to adopt delegated acts is conferred on to the Commission for a period of five years which is tacitly extended in absence of opposition, instead of an indefinite period as originally proposed by the Commission. The Commission can accept this in a spirit of compromise and considering that both co-legislators are requiring it.

3.4. Amendments of the European Parliament accepted by the Commission in full, in part or in principle, but not incorporated in the position of the Council at first reading

Different categories of food for special medical purposes: the European Parliament had adopted amendment 47 which clarified that food for special medical purposes can fall into three different categories (i.e. nutritionally complete food with standard nutrient formulation; nutritionally complete food with a nutrient-adapted formulation; nutritionally incomplete food with a standard or nutrient adapted formulation). While the Commission had accepted this amendment in principle, the Council did not include it in its position.

The Council's position is however acceptable for the Commission, since the distinction between the three different categories of food for special medical purposes is already present in the existing legislation and will be established in the relevant delegated act. Inclusion of this level of detail into delegated acts will also ensure the necessary flexibility if such categories would need modification in the future.

3.5. Amendments of the European Parliament rejected by the Commission and not incorporated in the position of the Council at first reading

'Gluten-free' and 'very-low gluten' foods: the Commission originally proposed that rules on these products, currently included in a specific Regulation adopted under the existing Framework Directive on 'dietetic foods', should be kept as such but transferred under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[6]. The European Parliament proposed in its position (amendments 1, 11, 12, 20, 35, 44, 45, 70, 90) to add food for people intolerant to gluten to the scope of the Regulation and included specific rules in the basic act. This was rejected by the Commission since it would be unnecessary and would not be in line with the objective of better Regulation and simplification.

The Council did not incorporate the European Parliament's amendments and established, on the contrary, that existing rules applicable to these products should be transferred under Regulation (EU) No 1169/2011 on the provision of food information to consumers, through specific procedures described therein. In a recital, the Council specifies that this transfer should ensure at least the same level of

[6] 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, OJ L 404, 30.12.2006, p. 9–25.

protection for people who are intolerant to gluten as currently provided for under the existing rules and that it should be completed prior to the application of the Regulation. Furthermore, the Council foresees that the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between food that is specially produced, prepared and/or processed to reduce the gluten content of one or more gluten-containing ingredients and other food that is naturally free of gluten.

The Commission supports the Council's position that will not only guarantee the maintenance of the same level of protection for consumers, but will also allow extending the existing rules to non pre-packed foods, thus increasing consumers' protection. Furthermore, the transfer of the rules under Regulation (EU) No 1169/2011, that already contains rules on the mandatory indication of the presence of gluten-containing ingredients, will be consistent with the principles of better Regulation and guarantee that all rules related to gluten are covered by the same legal framework.

Formula for low birth weight and pre-term infants: the Commission did not accept the position of the European Parliament (amendments 34, 43 and 92) that formulae for low birth weight and pre-term infants should be included in the scope of the Regulation as a sub-category of food for special medical purposes and that, in all cases, such formulae should comply both with the requirements applicable to food for special medical purposes and those applicable to standard infant formulae. The Council acknowledged in its position that a reflection should be carried out on what rules applicable to standard infant formulae and follow-on formulae should also apply to foods for special medical purposes for infants, with a view to a possible extension of the rules applicable. However, it adopted amendments leaving it for the Commission to do so in the context of delegated acts.

The Council's position is acceptable for the Commission. Indeed, not all low birth weight and pre-term infants need food for special medical purposes, and a decision on the nutritional requirements of low birth weight or pre-term infants needs to be taken on a case by case basis. Similarly, not all rules applicable to infant formula should apply to formula for low birth weight and pre-term infants, as a certain degree of flexibility is needed.

When adopting specific rules for food for special medical purposes via delegated acts, the Commission will have the possibility to consider what rules should apply to food for special medical purposes for infants, taking into account the developments in the market and the notable increase of the offer related to such products. The Commission considers that the Council's drafting takes into account the European Parliament's concerns, since it clearly foresees that the Commission will have to consider the issue when adopting delegated acts.

Innovation: the Council does not incorporate in its position amendments 31, 50 and 91 of the European Parliament that relate to a temporary authorisation procedure for innovative products. The European Parliament's amendments aimed at allowing innovative products not complying with the composition requirements as laid down in the delegated acts adopted under the Regulation to be placed on the market for two years.

The Council considers the Commission's proposal in this respect sufficient, since the latter foresees the possibility to modify by delegated acts composition requirements for products covered by the Regulation. However, the Council modifies the proposal

by stressing that amendments to such requirements should take into account all relevant data, including data provided by interested parties in relation, among others, to innovative products. The Commission accepts the Council's position which strikes a fair balance between the support to innovation and the opportunity to eliminate unnecessary rules and excessive administrative burden.

'Lactose-free' foods: the European Parliament proposed in its first reading position amendment 80 requesting the Commission to draft a report to clarify the status of indications of "lactose free" and "very low lactose" together with a legislative proposal if necessary. The Council, in its position, suggests that these statements could be harmonised, if necessary, under the rules of Regulation (EU) No 1169/2011 on the provision of food information to consumers, as it is the case for gluten. A recital also makes reference to the existing scientific advice provided by the European Food Safety Authority on the subject[7].

The Commission considers that a report would not be needed since the status of these indications is clear under general food law, and scientific advice on the subject already exists. The Commission accepts the Council's position which ensures consistency both with the management of the rules on 'gluten-free' foods, and with the rules on the mandatory indication of the presence of ingredients containing lactose, which are also already required under Regulation (EU) No 1169/2011.

3.6. New provisions introduced by the Council

Foods intended for sportsmen: the Commission originally proposed to leave sports foods out of the scope of the proposed Regulation and to have them covered exclusively by general food legislation (and in particular the Regulation on claims). The European Parliament, in its first reading position, agreed with the Commission that these products should fall out of the scope of the Regulation but called on the Commission to "*assess, not later than 1 July 2015, the need to review general food law in this regard*" (amendment 6).

The Council agreed in its position to leave these products out of the scope of the proposed Regulation but introduced amendments requiring the Commission to draft a report on the necessity, if any, of specific rules for these products with the possibility to accompany this report with a legislative proposal. The Council's request for a report can be accepted in the spirit of final compromise, and especially taking into account that the co-legislators agree that, in the meantime, these products should remain out of the scope of the Regulation.

Interpretation decisions: the Council introduced in its position an Article allowing the Commission to adopt implementing measures to decide whether a food falls within the scope of the Regulation and under what category. The Commission considers the Council's amendment to be a useful improvement of the proposal, which will facilitate the implementation of the Regulation and will reduce the difficulties related to borderline cases. Indeed, the difficult borderline between foods currently considered as foods for particular nutritional uses and 'normal foods' was one of the reasons that convinced the Commission to present the proposal.

Transition periods and repeal of existing measures: the Council's position foresees a transition period of three years plus exhaustion of stocks, instead of two

[7] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010; 8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777.

years plus exhaustion of stocks as proposed by the Commission. The Council also proposes to extend this transition period for specific products in case the Commission is late in adopting the relevant delegated acts. The Council's position is acceptable in the context of the general compromise and also taking into account the revised draft that improves clarity for operators and controlling authorities.

Deletion of rules on emergency measures: the Council in its position deletes rules on emergency measures since these are already included in Regulation (EC) No 178/2002 on general food law. The Council's position is acceptable by the Commission.

4. CONCLUSION

The Commission considers that the common position adopted by the Council with qualified majority reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament. Although on certain elements, the common position differs from the Commission's original proposal, the Commission considers that it represents a carefully balanced compromise and is satisfied that it covers all issues considered essential by the Commission when adopting its proposal.

For the reasons outlined above the Commission supports the common position adopted on 22 April 2013.

5. STATEMENT BY THE COMMISSION ON PESTICIDES

In implementing Article 11(1)(b), the Commission will pay particular attention to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) No 1272/2008[8] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, or considered to have endocrine disrupting properties that may cause adverse effects in humans, or which are very toxic, or which cause critical effects such as developmental neurotoxic or immunotoxic effects, with the objective to ultimately avoid their use.

[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1–1355.