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NOTE

from: Presidency
to: Council

No. Cion prop.: 12099/11 DENLEG 98 AGRI 480 SAN 137 CODEC 1180

Subject: **Employment, Social Policy, Health and Consumer Affairs** Council meeting on
6 and 7 December 2012

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 (first reading)**
- Information from the Presidency
(Other business item)

Introduction

1. 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 purposes¹ (proposed Regulation) was submitted by the Commission on 24 June 2011 on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

¹ 12099/11 (COM(2011)353 final).

2. The proposal aims to replace Directive 2009/39/EC on foodstuffs intended for particular nutritional uses². It abolishes the concept of dietetic foods and provides for a new framework establishing general provisions only for a limited number of categories of food that are considered essential for certain vulnerable groups of the population.
2. The European Economic and Social Committee issued its opinion on 26 October 2011³.
3. Following an unsuccessful attempt to reach a first reading agreement with the European Parliament, the Council agreed on the general approach⁴ on 7 June 2012, under the Danish Presidency.
4. The European Parliament adopted its position at first reading on 14 June 2012⁵, voting on 83 amendments. The Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the examination of the proposal, Frédérique RIES (ALDE, BE) having been appointed Rapporteur.

State of play

7. The general approach was the negotiating mandate for the first two trilogues that took place on 19 September and 9 October 2012 under the Cyprus Presidency in the context of the negotiations for an *early second reading agreement* with the European Parliament.

² OJ L 124, 20.5.2009, p. 21.

³ NAT/518 – CESE 1604/2011.

⁴ 10086/12.

⁵ EP-PE_TC1-COD(2011)0156.

8. The agreement between the representatives of the Council, the European Parliament and the Commission was concluded at the third trilogue on 14 November 2012. The Coreper confirmed that agreement on 19 November 2012 subject to technical adjustments in the text in cooperation with the European Parliament and the Commission.

The agreement reached contains the following essential elements:

- the inclusion of total diet replacement for weight control foods within the scope of the proposed Regulation;
- the current rules on the use of the statements "gluten-free" and "very low gluten" will be regulated under the context of Regulation (EU) No 1169/2011 on the provision of food information to the consumers;
- the establishment of rules on the use of the statements indicating the absence or reduced presence of lactose in food will be regulated under the context of Regulation (EU) No 1169/2011 on the provision of food information to the consumers;
- the Commission shall, after consulting the European Food Safety Authority, submit reports on the necessity, if any, of special provisions on foods for sportsmen and for milk-based drinks;
- the conferral of powers on the Commission to adopt implementing acts to decide whether or not a food falls within the scope of the Regulation and to which category it belongs;
- the provision for taking into account the results of adequate test methods for engineered nanomaterials;

- the indication of the preference for breast-feeding and the prohibition of the use of pictures of infants on the labelling of follow-on formula;
- restrictions on the levels of residues of pesticides, especially in foods for infants and young children;
- the provision for technical guidance by the Commission for food business operators, and in particular small and medium enterprises;
- the inclusion, in an Annex to the Regulation to be updated by delegated acts, of the Union list of substances to be added to the foods covered by the Regulation;
- the deletion of provisions repeating EU legislation already in force;
- transitional measures avoiding legal gaps between the repeal of the previous legal framework and the entry into force of the new Regulation and respective implementing measures.

9. On 5 December 2012, Coreper agreed by qualified majority on the compromise text and on its submission, as an "A" item, to the Council AGRIFISH on 18-20 December 2012 in order to reach political agreement, subject to receiving an approval letter from the Chair of the European Parliament's ENVI Committee confirming the agreement reached between the institutions.

The text of the political agreement will then be adopted, subject to legal-linguistic revision, as the position of the Council at first reading. This will be transmitted to the European Parliament for final adoption of the Regulation according to Article 294(7)(a) of the TFEU, whereby the Council's position is adopted by the European Parliament.