



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 19 December 2012
(OR. de,en)**

**Interinstitutional File:
2011/0156 (COD)**

**16961/12
ADD 2**

**DENLEG 114
AGRI 820
SAN 300
CODEC 2850**

ADDENDUM TO THE "A" ITEM NOTE

from: General Secretariat of the Council

to: Council

No. prev. doc.: 16958/12 DENLEG 113 AGRI 819 SAN 299 CODEC 2849 + COR 1

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

Subject: 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) (Legislative deliberation)**

- Statement by Germany

Delegations will find in the Annex a statement by Germany on the abovementioned subject.

Statement by the Federal Republic of Germany**"Proposal for a Regulation on food intended for infants and young children and on food for special medical purposes"**

"Germany is opposed to the current proposal for a Regulation on food intended for infants and young children and on food for special medical purposes.

Germany has always supported revision of the European legislation on dietetic foods in principle. The desired objectives of simpler and better regulation and more far-reaching harmonisation of this area of law are not, in Germany's view, adequately achieved by the proposed Regulation.

In particular, Germany considers that the new Regulation does not take adequate account of the special level of protection required for highly vulnerable target groups. The German view is that, for reasons of preventive health protection, it is problematic to allow the unrestricted addition of various substances added, because of their nutritional or physiological effect, to foodstuffs within the scope of the Regulation.

In this context, Germany observes *inter alia* an irreconcilable discrepancy between the stringent requirements of the Health Claims Regulation on the scientific verifiability of nutrition and health claims in food advertising on the one hand, and the clearly less stringent safety requirements with regard to preventive consumer health protection in relation to foods for special medical purposes on the other.

Furthermore, the proposed Regulation no longer contains the procedure for approving an extension of the positive list that was originally included, so that the addition of substances not hitherto covered in the positive list is now left to the sole initiative of the European Commission. Food producers are thereby deprived of the possibility of obtaining European approval for a substance by a clearly regulated procedure and thus securing legal certainty for innovations. The new Regulation consequently does not meet the requirement to promote innovation."