COUNCIL OF THE EUROPEAN UNION

Brussels, 17 April 2013

8351/1/13 REV 1 ADD 1

Interinstitutional File: 2011/0156 (COD)

CODEC 783
DENLEG 33
AGRI 235
SAN 122
OC 201

ADDENDUM TO THE "I/A" ITEM NOTE

from:	General Secretariat of the Council
to:	COREPER/COUNCIL
No. Cion prop.:	12099/11 DENLEG 98 AGRI 480 SAN 137 CODEC 1108
Subject:	Proposal for 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 **(first reading)** – Adoption a) of the Council's position b) of the statement of the Council's reasons – Statements **COMMON GUIDELINES** **Deadline for consultation: 19.4.2013**

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."

Statement by the United Kingdom

The United Kingdom supports the aim to simplify the regulatory framework for foods for vulnerable groups and considers that the proposed text largely achieves this objective. However, the UK does not support the use of delegated acts to amend the Union list of substances and therefore is unable to support the proposal. Decisions on the authorisation of individual substances should be achieved by means of implementing acts using the examination procedure in Regulation (EU) 182/2011. The use of a delegated act in this particular circumstance must not be considered as a precedent for other areas of food policy.

_____