EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control

Summary report

Brussels, 14 July 2014

Chairman: Mr Basil Mathioudakis

1. Exchange of views on certain elements of the future delegated act on infant and follow-on formulae

The Commission opened the meeting by summarizing the conclusions of EFSA in its opinion on the essential composition of infant and follow-on formulae that was adopted on 26 June 2014. The Commission sought the views of experts on the approach to follow in the forthcoming delegated act on infant and follow-on formulae with respect to the ***ingredients that should be included on a mandatory basis*** to the products, and the ***optional ingredients*** that could be added on a voluntary basis. Experts agreed that the advice of EFSA should be followed with respect to the ingredients that should be present on a mandatory basis.

As regards the presence of optional ingredients, experts had diverging views. Some delegations favoured a centralised prior authorisation procedure for optional ingredients, established at EU level on the basis of EFSA's advice. These delegations underlined that this procedure would ensure the same high level of consumer protection in the EU and would avoid the risk of having different judgments from national authorities on the suitability of products.

Other delegations were in favour of allowing operators to add optional ingredients as it is the case today (under the operators' responsibility, provided that the ingredients are safe and suitable, and under the control of Member States). These delegations were in favour, at the same time, of revising the approach to the use of nutrition claims on taurine, fructo-oligosaccharides/galacto-oligosaccharides and nucleotides in infant formulae. These ingredients can currently be added to formulae and operators can make nutrition claims about their presence in infant formulae. Since, as concluded by EFSA, the scientific evidence has not sufficiently proven their beneficial effect yet, these delegations would support prohibiting the use of these claims. In their view, this approach would ensure flexibility for product development while guaranteeing adequate consumer protection.

The Commission noted the different positions. It asked experts to further consult at national level, taking into account all the different technical and political facets of the matter, including the impact of a centralised authorisation procedure on administrative burden and red tape and the consequent implications for innovation and competitiveness of EU industry.

The Commission then introduced the issue of ***protein hydrolysates as protein sources for infant and follow-on formulae***. The Commission recalled EFSA's conclusions whereby specific information on the protein sources used and the technological processes applied to hydrolyse the protein is essential to assess the safety and suitability of these formulae. The Commission asked experts to get more information on the different products present in their market and to further reflect on whether they would support more specific requirements on the manufacturing of these formulae in the delegated act.

Experts supported a revision of the conditions of use for the health claim on 'hypoallergenic' properties of infant formulae manufactured from protein hydrolysates. Delegations agreed that, as underlined by EFSA in its opinion, the efficacy of these products should be assessed on a case-by-case basis through clinical studies carried out on the specific formulae. Experts would support an assessment of EFSA and an authorisation at EU level and agreed that any modification of the existing rules should take into account the different products currently on the market using the claim and the need to minimise market disruptions.

The Commission then moved on to the issue of ***maximum amounts for micronutrients*** in infant and follow-on formulae. Experts agreed that maximum amounts should be set in the legislation, even if these amounts were not proposed by EFSA in its opinion. Experts also agreed that further consideration could be given to revising some of these maximum amounts in order to take into account EFSA's views on the matter.

Discussions then moved on to the ***nutrition claims "lactose only" and "lactose-free"***, currently allowed under certain conditions for infant formulae. Delegations agreed with the Commission that these should not be considered as nutrition claims anymore but as statements for which conditions are set in the legislation. This will ensure consistency with recital 42 of the FSG Regulation whereby statements on the absence or reduced presence of lactose should be regulated under Regulation (EU) No 1169/2011 on the provision of food information to consumers. Delegations then exchanged views on the conditions for the use of these statements, and in particular of the statement "lactose-free". There was overall support for allowing all infant formulae (and not only those based on soy protein) to bear the "lactose-free" statement if the product contains less than 10 mg/100 kcal of lactose. In this context, certain delegations drew the attention of the Expert Group to the fact that the statement "lactose-free" is increasingly used as a marketing tool to promote products for the general population (rather than lactose intolerant consumers).

The Expert Group then discussed the ***nutrition claim on omega-3 content***, currently allowed under certain conditions for infant formulae. Delegations underlined that if the rules are changed in the delegated act to make the addition of DHA required for all formulae, on the basis of EFSA's advice, the wording of this claim should be modified to make sure that consumers are informed that the characteristic being claimed belongs to the entire category of infant formulae rather than to the specific product. Some delegations also added that the possibility to use this claim should only be granted for a certain amount of time, until consumers get used to the mandatory presence of DHA in infant formulae, and the possibility to use it should be reviewed in the future.

2. Exchange of views on the guidance on food for special medical purposes

The Commission presented its preliminary views on the forthcoming guidance document on the classification of food for special medical purposes. The Commission explained that the document could be structured in three parts: a first part of the document could

contain general principles related to the legislation on food for special medical purposes (in particular the definition). The second part could contain examples of products on which there is consensus among Member States with respect to their status as food for special medical purposes. The third part could contain elements describing how the Commission intends to apply Article 3 of the FSG Regulation after 20 July 2016 in case of products notified as food for special medical purposes (in order to ensure uniform implementation of the rules, Article 3 of the FSG Regulation empowers the Commission to decide by means of implementing acts (a) whether a given food falls within the scope of the Regulation and/or (b) to which specific category of food covered by the Regulation a given food belongs).

Experts agreed with the structure proposed by the Commission and underlined that they would be further reflecting on additional elements that could be included in the document. Experts also agreed that EFSA's scientific advice will be an important element to prepare Article 3 decisions regarding products notified as food for special medical purposes.