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, 22 June 2015

Chairman: Ms Alexandra Nikolakopoulou / Mr Jacques Humieres

1. Exchange of views on the draft delegated Regulation on total diet replacement for weight control

The Commission welcomed the experts by recalling the context of the meeting: Article 11 of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[1] (hereinafter 'FSG Regulation') requires the Commission to adopt delegated acts on the specific compositional and information requirements for the categories of food falling within the scope the Regulation, including total diet replacement for weight control.

The Commission recalled the previous discussion held in the framework of the Expert Group on specific points related to total diet replacement for weight control on 20 April 2015 and asked Member States' experts to provide detailed feedback on all the aspects covered by the Working Document (which describes the provisions that are considered for inclusion in the draft delegated Regulation on total diet replacement for weight control).

The Commission noted that the text of the draft delegated Regulation could be subject to further changes following discussions and that the same text was presented to the stakeholders in a meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on 18 June 2015.

The Commission also explained that the text ensures as much consistency as possible with the other delegated acts to be adopted in line with Article 11 of the FSG Regulation and on which discussions are more advanced.

Following this, the Commission presented the content of the Working Document and opened the floor for discussion on the different topics.

Compositional requirements

The Commission explained that the proposed compositional requirements are following all the recommendations of EFSA's Scientific Opinion on the essential composition of total diet replacement for weight control[2]. The Commission acknowledged that this would require product reformulation, but recalled that EFSA's advice is the most recent thorough scientific assessment of this type of products.

[1] OJ L 181, 29.6.2013, p. 35

[2] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the essential composition of total diet replacement for weight control. EFSA Journal 2015;13(1):3957

Member States supported in general the approach presented by the Commission regarding the compositional requirements. Some of them requested the addition of dietary fibre on a mandatory basis contrary to EFSA's Scientific Opinion. Others noted that maintaining fibre addition on voluntary basis could be problematic if the possibility to make claims on these products was not granted.

The Commission also reported to the Member States the concerns expressed by industry in the course of the Working Group Meeting of the Advisory Group on the Food Chain and Animal and Plant Health[3] which discussed the same Working Document on 18 June. Industry questioned the technical feasibility to manufacture total diet replacement for weight control with minimum amounts recommended by EFSA's Scientific Opinion on protein, linoleic acid, α-linolenic acid, choline and the upper level of magnesium. Industry noted that from a technological point of view, manufacturing these products with the amounts proposed by EFSA's Scientific Opinion would be extremely difficult (if not impossible in certain cases), highly expensive and would have a negative impact on taste.

One Member State noted in this respect that their relevant national industry association did not share the same concerns expressed in the Working Group Meeting of the Advisory Group on the Food Chain and Animal and Plant Health by the industry about the possibility to follow EFSA's recommendations. Another Member State underlined the need to obtain independent advice on the issue of technical feasibility given that different positions seem to be reported within the industry.

The Commission concluded that it will further carry out internal reflections in order to examine the question of technical feasibility of manufacturing total diet replacement for weight control in line with the recommendations of EFSA's Scientific Opinion and on its implications.

Specific requirements on food information and on the nutrition declaration

The Commission presented the part of the Working Document related to specific requirements on food information for total diet replacement for weight control, in particular proposals on mandatory labelling requirements to specify conditions of use of the product (e.g. statements on people that should avoid using the product without the advice of a health care professional or on the recommended period of consumption in the absence of such advice). It explained that the proposed labelling requirements are based on EFSA Scientific Opinion and should be considered in light of the proposed compositional requirements. Consequently, if the risk manager decided to derogate from EFSA's recommendations with respect to the product's composition, this would need to be reflected also in changes to the labelling requirements.

Member States did not object to the Commission's approach. Some noted that the recommended period of consumption in the absence of advice of health care professionals could be reduced to increase consumers' protection. Others suggested specifying in the label that the product should not be consumed by pregnant/lactating women in the absence of medical advice.

[3] http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/dgs-consultations_working-groups_20150618_summary_en.pdf

COM explained that the proposed specific requirements on the nutrition declaration on the one side aim at maintaining the provisions of Directive 96/8/EC[4] and on the other side are necessary to ensure consistency and clarify the relationship with Regulation (EU) 1169/2011 on food information to consumers[5]. In addition it is also necessary to ensure consistency with provisions of the other delegated acts to be adopted under the FSG Regulation.

Some Member States noted that indication of whether the product is a 'low calorie diet' (if its energy content is between 800kcal/day and 1200kcal/day) or a 'very low calorie diet' (if its energy content is below 800kcal/day) should be requested on a mandatory basis rather than left as a choice for the operator. The majority of the Member States were however in favour of the introduction of such provisions on a voluntary basis.

Nutrition and health claims

The Commission introduced its proposal to prohibit the use of nutrition and health claims on total diet replacement for weight control. It explained that because of the specific nature of total diet replacement for weight control and the vulnerable target group consuming them, it needs to be seriously considered if marketing methods as claims are appropriate in this context.

The Commission also explained that this approach was generally criticised by stakeholders who noted that the use of nutrition and health claims is essential to be able to communicate to consumers about the weight loss properties of the products and on specific nutrients present in the products.

The majority of the Member States supported the Commission's proposal although some Member States acknowledged that some derogations could be further considered (e.g. claims on fibre, if kept voluntary).

Notification

COM presented its proposal which would require notification to national competent authorities of the placing on the market of total diet replacement for weight control unless a Member State exempts the operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.

The majority of Member States supported notification systems.

[4] Commission Directive 96/8/EC of 26 February 1996 on food intended for use in energy restricted diets for weight reduction (OJ L 55, 6.3.1996, p.22).

[5] 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).

The Commission concluded discussions on this agenda point and encouraged Member States to submit further comments in writing that could contribute to the Commission's reflection.

2. Exchange of views on the administrative procedure to apply Article 3 of Regulation (EU) No 609/2013 on food for special medical purposes

The Commission explained that Article 3 of the FSG Regulation allows the Commission, in order to ensure the uniform implementation of the Regulation, to adopt implementing decisions on whether a given food falls within the scope of Regulation and, if so, to which specific food category covered by the Regulation. In preparation of the future application of this Article (as of 20 July 2016), the Commission provided a presentation on some points for reflection related to the practical application of Article 3. This was necessary because no details are provided in the Regulation on the procedural steps to follow when adopting a decision pursuant to that Article.

The Commission's presentation focused on the scope of a possible decision, on the role of EFSA in providing scientific advice to the Commission and on the role of stakeholders to prepare dossiers for EFSA's assessment (if relevant).

Member States provided some preliminary comments (e.g. that EFSA's involvement should only be sought for complex borderline cases on which Member States disagree, that the protection of data confidentiality should be ensured) but asked for more time to reflect on the issue.

The Commission invited Member States to submit comments in writing by the end of July 2015.

3. AOB

Following the request of Finland, an exchange of views took place on the minimum and maximum amounts for vitamin D proposed in the draft delegated Regulation on infant formula and follow-on formula and their relation with national vitamin D supplementation policies in the Member States. On the basis of the available information and the following discussion the Commission concluded that it is unlikely that the national supplementation policy on vitamin D of Member States would be affected.