# 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, 19 May 2016

Chairman: 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 stating 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 of the Regulation, including total diet replacement for weight control (hereinafter TDR).

The Commission recalled the previous discussions held in the Expert Group on the subject of TDR on 20 April 2015 and 22 June 2015. At that time Member States favoured to follow the compositional requirements of EFSA's Scientific Opinion on the essential composition of total diet replacement for weight control[2] (hereinafter EFSA's Scientific Opinion). On this basis the Commission put forward its work to finalise the adoption of the concerned delegated act. In the course of the last months few Member States raised concern on the technical feasibility of manufacturing TDR in line with EFSA's Scientific Opinion. Following this, the Commission considered it appropriate to carry out additional consultation with Member States. The Working Document submitted to Member States' expert for the purpose of the Expert Group meeting, reflects the outcome of this last consultation.

The Commission also noted that the text could be subject to further changes following discussions. The Commission invited Member States' experts to express their views on the aspects covered by the Working Document.

### Compositional requirements

While introducing the first point on the composition requirements of TDR, the Commission reported to Member States on the consultations which have been carried out with relevant industry. It explained in detail the concerns of the industry on the technical feasibility of manufacturing TDR in line with EFSA's Scientific Opinion, in particular regarding the levels recommended for protein, linoleic acid, α-linoleic acid, choline and the upper level of magnesium and the different options presented by them to the Commission in the last months, ranging from lowering the levels for the abovementioned substances, to putting forward a

[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

research programme in order to analyse the aspects of the technical feasibility of manufacturing.

The Commission informed Member States that it has been assessing the concerns of industry by different means in the course of the last year. As a result, to address concerns on the technical feasibility to manufacture TDR in line with EFSA's Scientific Opinion, a transition period of five years has been identified as an appropriate solution.

During the discussions on that issue, a wide majority of Member States, stating the importance and priority of EFSA's recommendations, confirmed their view that EFSA's Scientific Opinion in terms of the future compositional requirements of TDR should be followed. One Member State stated explicitly that changes can be only supported if they are substantiated by scientific reasoning. Few of them requested the addition of dietary fibre on mandatory basis contrary to EFSA's Scientific Opinion which does not foresee this. The majority of the Member States supported the solution of the Working Document allowing the addition of fibre on voluntary basis to TDR.

However, one Member State questioned EFSA's Scientific Opinion and presented its proposal regarding the values to be implemented in the future delegated act. It explained that according to its view if TDR is required to follow the composition recommended in EFSA's Scientific Opinion, TDR below 800kcal/day would disappear from the market.

Two other Member States expressed concerns with regard to the acceptability and increased price of TDR that would comply with EFSA's recommendations, but did not propose alternative values for the composition of those products.

**Name of the food**

The Commission presented this part of the Working Document and explained that during the last consultation Member States wished to introduce provisions on the name of the food. Discussion took place on the question whether the name of the food should be 'total diet replacement for weight control', as it is the case currently under Directive 96/8/EC[3] or in addition it should be allowed 'total diet replacement for weight loss', too to reflect the intended use of these products.

It was concluded in this respect that the majority of Member States is in favour of one name, which should be 'total diet replacement for weight control'. It was understood that according to the Working Document, a statement is already required on mandatory basis on TDR referring to the fact that these products are intended for healthy obese and overweight adults with the intention of weight loss. This provides the necessary information on the considered aspect.

[3]Commission Directive 96/8/EC on foods intended for use in energy restricted diets for weight reduction (OJ L 55, 6.3.1996, p.22)

**Statement on the intended targeted group**

The Commission presented this part of Working Document and explained that during the last consultation Member States wished to strengthen the mandatory statement on the label towards the intended target group of TDR with particular attention to obese pregnant or lactating women, adolescents or to individuals in medical conditions.

One Member State presented in the meeting that such statement should refer to the use under medical supervision, which may be applied with the assistance of other health care professional. In this way the differences in the health care systems of the Member States would be taken into account, while the groups mentioned above would be protected in the highest possible level.

Member States recognised the added value of the mentioned proposal. However, the importance of the clarity of the expressions used, while ensuring flexibility for Member States to adapt them to their own health care system, was also emphasised in this context.

**Nutrition and health claims**

The Commission presented this part of the Working Document and explained that during the last consultation the Member States were in favour of prohibiting the use of nutrition and health claims on TDR because of their specific nature and the vulnerable target group consuming them. However, taking into account that information on the presence of dietary fibre has been considered by Member States as useful, the Working Document proposes to permit the use of nutrition claim in this respect.

One Member State raised the question of introducing also a negative claim on the non-presence of dietary fibre in TDR. The majority of Member States did not favour such an option, since providing such information on voluntary basis might give the impression that the product does not contain an important substance – although according to EFSA' Scientific Opinion the addition of fibre on mandatory basis is not essential – and supplementation would be needed.

The Commission explained that information on the presence of fibre in the product could be also given through the nutrition declaration in the case such provision is introduced accordingly in the delegated act. Member States welcomed this approach.

**Statement 'very low calorie diet'/'low calorie diet'**

One Member State noted that indication 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. All other Member States that expressed views on that point, however were in favour of the introduction of such provisions on a voluntary basis.

## 2. Rules applicable for young child formulae after 20 July 2016

The Commission stated that according to the conclusions of the Report on young child formulae[4], such products if they were previously classified under Directive 2009/39/EC as foodstuffs intended for particular nutritional uses[5] after the repeal of this legislation will be governed solely by the horizontal rules of European food law.

In its introduction the Commission explained that in those Member States which consider young child formulae already now as fortified food in accordance with Regulation (EC) No 1925/2006[6], no changes are to be expected.
The Commission invited Member States for an exchange of views on the implementation of the applicable rules for young child formulae after 20 July 2016.

Some Member States stated that in certain cases the name of product might be considered as a health claim (e.g. growing up milk) and in this respect the provisions of Regulation (EC) No 1924/2006[7] should apply accordingly. In addition they mentioned that because of the delayed publication of the report food business operators will have little time to adapt to the new legal situation.

Member States also explained that when such foods will be considered as fortified foods in the future they will have to comply with Article 6(6) of Regulation (EC) No 1925/2006. This requires the addition of vitamins and minerals in a significant amount, as defined in Annex XIII of the Regulation (EU) No 1169/2011on food information to consumers[8]. However, the nutrient references values in this are for adults and not for young children.

The Commission explained that Article 6(6) of Regulation (EC) No 1925/2006 allows introducing derogations from the requirement of the significant amounts, and this is to be adopted in accordance with the procedure explained in the provision. In addition the Commission stated that existing national measures on young child formulae may remain in place if they are in line with the EU law.

[4] Report from the Commission to the European Parliament and the Council on young child formulae, COM(2016) 169 final, Brussels 31.3.2016
[5] OJ L 124, 20.5.2009, p.21
[6] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p.26)
[7] Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (OJ L 404, 20.12.2006, p.9)
[8] 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).

## 3. AOB

Following the question of one Member State the Commission confirmed what was discussed in the last meeting of the Expert Group on 22.02.2016. Food business operators are allowed to anticipate compliance with the relevant provisions of the new delegated Regulations, adopted under the framework of the FSG Regulation, before their date of entry into application.

Articles 20 and 21 of the FSG Regulation do not contain any explicit provision that would exclude the possibility of early compliance and that the objective and the spirit of those Articles are to ensure a smooth transition for food business operators adapting to the changes in the applicable rules. No diverging view was raised by Member States' experts.

One Member State provided the other Member States and the Commission with information on a recently published study on the effectiveness of partially hydrolysed protein in infant formula.