

Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the implementation of Article 11(1) of Regulation (EU) No 609/2013

18 June 2015

Summary Record

Participants:

DG SANTE, European Commission (Alexandra Nikolakopoulou, Tim Gumbel, Jacques Humieres, Francesco Carlucci, Dora Szentpaly)

AESGP - Association of the European Self-Medication Industry

EHPM - European Federation of Associations of Health Products Manufacturers

ELC - Federation of European Specialty Food Ingredients Industry

EUCOLAIT - European Association of Dairy Trade

SAFE - Safe Food Advocacy Europe

SNE - Specialised Nutrition Europe

VLCD Industry Group - Very Low Calorie Diet Industry Group

1. OPENING OF THE MEETING AND ADOPTION OF THE AGENDA

COM welcomed the participants by explaining that the objective of the meeting is to give the opportunity to interested parties to provide the Directorate General for Health and Food Safety (SANTE) with relevant comments on the content of the delegated act on total diet replacement for weight control and on the technical adaptations to the Annex of Commission Regulation (EU) No 432/2012¹ with respect to health claims on meal replacement for weight control.

Adoption of the delegated act is required by Article 11(1) 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 control² (hereinafter, the Regulation on Food for Specific Groups, FSG).

In addition recital 43 of the FSG Regulation foresees that statements on meal replacement products for weight control should be in the future regulated solely under Regulation (EC) No 1924/2006 on nutrition and health claims³, and should comply with the requirements set out therein. In this context the necessary technical adaptations to the conditions of use of claims authorised for such products is required.

The COM presented the agenda which was adopted without modification.

¹ OJ L 136, 25.5.2012, p.1

² OJ L 181, 29.6.2013, p. 35

³ OJ L 404, 30.12.2006, p. 9

2. DISCUSSION ON THE DRAFT DELEGATED REGULATION ON TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL

[on the basis of a Working Document describing the different provisions being considered for inclusion in the Delegated Regulation]

2.1. Introduction

COM presented the Working Document. It explained that the draft Delegated Regulation on total diet replacement for weight control aims at updating the existing rules laid down by Directive 96/8/EC⁴ for total diet replacement for weight control with an energy content between 800kcal/day and 1200kcal/day under the new framework of the FSG Regulation and at establishing rules for total diet replacement for weight control below 800kcal/day. These should be based on the most recent advice of the European Food Safety Authority on the essential composition of total diet replacement for weight control⁵ and previous discussions with Member States and stakeholders. Rules on labelling are mainly aimed at ensuring consistency with the new framework introduced by Regulation (EU) No 1169/2011 on the provision of food information to consumers⁶, with adaptations where necessary taking into account the products' characteristics.

COM also noted that the text could be subject to further changes following discussions.

2.2. Summary of the discussion

The discussion was structured so as to follow the order of the different Articles and Annexes being considered for inclusion in the Delegated Regulation.

2.2.1. Compositional requirements

COM explained that the proposed compositional requirements are following all the recommendations of EFSA's Scientific Opinion. COM 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.

SNE and VLCD Industry Group did not contest that after more than 20 years an update on the composition of total diet replacement for weight control is timely but expressed concerns regarding the proposed approach to entirely follow EFSA's opinion. In particular, the two associations explained 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. On this last point, it was noted that a bad taste for total diet replacement for weight control would

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 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.

⁶ OJ L 304, 22.11.2011, p. 18

make it more difficult for consumers to respect instructions of use for these products, and ultimately give them an incentive to turn to unregulated diets instead. It was also highlighted that there is a long history of safe use of products complying with the compositional requirements laid down in Directive 96/8/EC and that EFSA's recommendations are based on theoretical assumptions which do not reflect the reality.

The concerns expressed on the composition by SNE and the VLCD Industry Group were in particular related to the minimum amount of protein, choline, linoleic acid and α -linolenic acid, the absence of mandatory addition of dietary fibre and the maximum amount of magnesium.

ELC mentioned that EFSA's opinion being based on theoretical considerations and according to the federation it this does not take into account how total diet replacement for weight control are consumed in practice. For this reason the addition of fibre, DHA and EPA on a mandatory basis – taking into account the health benefit of these substances – should be required by the legislation.

SAFE noted that it should be ensured that also vegetarians can consume these products and consequently the source of protein should not only be of animal origin. COM replied that the proposal only regulates the quality of protein but does not specify the source of protein to be used. The requirements in the draft ensure that also protein of non-animal origin can be used, which allows that also vegetarians can consume total diet replacement for weight control.

While noting the concerns expressed by stakeholders regarding the proposed compositional requirements (especially those on the alleged impossibility to comply with some of these), COM explained that the legislation should first of all ensure the safety of total diet replacement for weight control, in particular taking into account their intended use and the difference from ordinary foods.

2.2.2. Specific requirements on food information

COM 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's 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.

Stakeholders agreed that the food information requirements should ensure that the intended use of total diet replacement for weight control is communicated the best possible way to consumers.

2.2.3. Specific requirements on the nutrition declaration

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 and on the other side are necessary to ensure consistency and clarify the relationship with Regulation (EU) 1169/2011

on food information to consumers. In addition it is also necessary to ensure consistency with provisions of the other delegated acts to be adopted under the FSG Regulation.

COM further explained that following discussions with Member States and stakeholders it seems appropriate to allow operators to indicate on a voluntary basis whether the product is a 'very low calorie diet' (provided that its energy content is below 800kcal/day) or a 'low calorie diet' (provided that its energy content is between 800kcal/day-1200kcal/day).

SNE expressed concerns regarding the proposal to request nutrition information on the energy and the amount of nutrients of the product per total daily ration. It was questioned if such information would not mislead consumers taking into account that in practise consumers tend to mix different varieties of total diet replacement for weight control products (e.g. in order to consume meals with different tastes during the day) and these products do not necessarily have the same composition.

COM took note of SNE's comment on the expression of nutrition information per total daily ration.

VLCD Industry Group welcomed the possibility to use the statements 'very low calorie diet' and 'low calorie diet' on a voluntary basis on total diet replacement for weight control.

2.2.4. Nutrition and health claims

COM 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.

SNE and VLCD Industry Group expressed their concerns on the COM's proposal. They highlighted that if the use of nutrition and health claims are prohibited it will not be possible to communicate to consumers about the weight loss properties of the products and about the presence of specific nutrients in the products.

The COM recalled that to communicate about the presence of specific nutrients in the product is granted via the nutrition declaration. Nevertheless it noted that the use of nutrition and health claims needs further reflection also in light of future discussions with Member States.

2.2.5. 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.

SNE and VLCD Industry Group expressed concerns regarding the financial consequences of such a notification requirement.

2.2.6. Entry into application

The Commission explained that the draft Delegated Regulation would give a four-year transition period to operators to adapt to the new rules.

SNE and VLCD Industry Group welcomed the long transitional period but noted that four years could not be sufficient to reformulate products in line with all the recommendations of EFSA.

3. DISCUSSION ON THE TECHNICAL ADAPTATIONS TO THE ANNEX OF COMMISSION REGULATION (EU) No 432/2012 WITH RESPECT TO HEALTH CLAIMS ON MEAL REPLACEMENT FOR WEIGHT CONTROL

COM explained that Directive 96/8/EC has laid down compositional and information requirements for products presented as a replacement for one or more meals of the daily diet, so called "meal replacement for weight control". At the same time two health claims are currently authorised for these products under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods and are included in the Annex of Commission Regulation (EU) no 432/2012.

In order to bear the claims, a food presented as meal replacement should comply with specifications laid down in Directive 96/8/EC in relation to meal replacement for weight control. In order to achieve the claimed effect, one or two meals should be substituted with meal replacements daily (depending on the claim).

The COM further explained that the FSG Regulation does not include in its scope meal replacement for weight control products. However the Regulation foresees in recital 43 that statements on the properties of such products should be in the future regulated solely under Regulation (EC) No 1924/2006.

Given that Directive 96/8/EC shall not apply anymore to meal replacement products after 20 July 2016, it is necessary that technical adaptations are made to the conditions of use of such claims in Annex to Regulation (EU) No 432/2012 in order to ensure that no legal gap exists for these products.

In this context, the COM presented the Working Document. According to this, the compositional requirements laid down for meal replacement products in Directive 96/8/EC should be transferred under the Annex of Regulation (EU) No 432/2012.

Stakeholders expressed support for the proposed approach but noted that some minor adjustments might be needed to ensure full consistency with other rules of food law and a smooth transition.