

SAFE Position Paper on:

The Adoption of a Delegated Regulation on Total Diet Replacement for Weight Control

About SAFE- Safe Food Advocacy Europe

SAFE's mission is to improve the representation of ordinary citizens in the EU debate concerning the future of EU food regulation.

SAFE is a non-profit European independent organization based in Brussels in charge to improve the representation of ordinary citizens in the EU debate concerning the future of EU food legislation. SAFE members are consumer associations, vegan and vegetarian associations based in different EU countries. *SAFE's main mission is to influence the future European Food Legislation in favor of the European consumers' interest.*

In a lifetime, an average 80-years-old consumer ingests 30 to 60 tons of food. We should not deny the dominant effect of nutrition on our health and well-being. Several reputable scientific studies underline how the large-scale industrialization of food and industrial agriculture are among the main causes of the increase of certain diseases, such as obesity, diabetes, cancer, Alzheimer, and many more.

EU food legislation is influenced by lobbyists. In Brussels there are more than 30.000 lobbyists, 70% of them work for industries and only 10% work for non-governmental organizations. The power of the agro food industries lobbying are causing a very uncertain and dangerous situation for EU consumers. There is a need for an independent organization in charge of improving consumer protection in the EU food safety system.

SAFE will strengthen the voice of the consumer interests in civil society and will contribute to reinforce participatory democracies in Europe.

More information is available on www.safefoodadvocacy.eu

SAFE Position

SAFE's key concerns on the adoption of a delegated Regulation on total diet replacement for weight control are summarized here below.

Art. 3 of the proposed legislation states that the following shall be additional mandatory particulars for total diet replacement for weight control:

➤ **A statement on the importance of maintaining an adequate daily fluid intake;**

Adequate fluid intake is an essential statement, however on the labelling the importance to practice sport and to change life style for a long-term maintenance of weight loss should be included. In the research described here below, during a period of eight weeks consumers have used diet meal replacements and have had very rapid weight loss. To be able to keep weight maintenance, it is fundamental to have a nutrition education and a healthy life style. As emphasized in the research, this is the only way for not re-gaining rapidly back all the lost weight. This is significant information that should be communicated to consumers.

The importance of education and a support programme for weight maintenance has been emphasized in the 2014 research of A.R. Leeds from the Diabetes and Endocrinology, Central Middlesex Hospital of London called “Formula food-reducing diets: a new evidence-based addition to the weight management tool box”. Here below you find a summary of the research:

“Formula diets, with an education and support programme, can deliver weight loss and weight maintenance of 10% of initial weight with sustained health benefit in osteoarthritis, obstructive sleep apnoea and psoriasis. Rapid initial weight loss was feared to be followed by rapid weight regain. However, provided initial weight loss is delivered in parallel with an intense education programme about nutrition, cooking, shopping and lifestyle for long-term maintenance; and where long-term support is provided, subsequent weight maintenance after VLCDs and LCDs has been shown to be possible.”¹

➤ **A statement that the product provides adequate amounts of all essential nutrients for the day;**

It is essential to add raw vegetables every day because they contain important phytonutrients for overweight and obese people to detoxify and to reduce the inflammation that all obese people have.

Brunella CARRATÙ and Elisabetta SANZINI (Centro Nazionale per la Qualità degli Alimenti e per i Rischi Alimentari), Istituto Superiore di Sanità of Rome state in the article titled “Active substances which are present in vegetal foods” that:

“Phytochemicals constitute a heterogeneous group of substances and evidence for their role in the protective effect on human health, when their dietary intake is significant, is emerging. These compounds have biological properties as antioxidant activity, modulation of detoxification enzymes, stimulation of the immune system, decrease of platelet aggregation and modulation of hormone metabolism. Glucosinolates and widely group of polyphenols, including the main

¹ Leeds A. R. (2014), p. 244

category of flavonoids, are examined. Since their weak estrogenic activity is of interest at present, isoflavones are discussed at length.”²

The study “Fruit and vegetable consumption and mortality” published in April 2013 by the American Journal of Epidemiology also confirms the importance of fruits and vegetables:

“In this study, the relation between fruit and vegetable consumption and mortality was investigated within the European Prospective Investigation Into Cancer and Nutrition. Survival analyses were performed, including 451,151 participants from 10 European countries, recruited between 1992 and 2000 and followed until 2010. Hazard ratios, rate advancement periods, and preventable proportions to respectively compare risk of death between quartiles of consumption, to estimate the period by which the risk of death was postponed among high consumers, and to estimate proportions of deaths that could be prevented if all participants would shift their consumption 1 quartile upward. Consumption of fruits and vegetables was inversely associated with all-cause mortality. Inverse associations were stronger for raw than for cooked vegetable consumption. These results support the evidence that fruit and vegetable consumption is associated with a lower risk of death.”³

- **A statement that the product should not be used for longer than eight weeks or repeated short periods of time without the advice of a health care professional;**

Period of eight weeks.

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Scientific Opinion on the essential composition of total diet replacements for weight control declared that:

“The Panel noted that there is no scientific evidence which supports the current provisions that labelling of low-calorie diets should inform consumers that low-calorie diets should not be used for more than three weeks without medical supervision. However, none of the studies which investigated adverse metabolic consequences of total diet replacements had a duration of more than three months. In particular, studies which investigated critical endpoints, such as the effect of total diet replacements for weight control on calcium loss and bone health, have not been conducted for periods longer than eight weeks. While the available evidence **does not give rise to any concern with respect to bone health in adults when total diet replacements for weight control are consumed for a single period of up to eight weeks,** there are no data on the impact of the **increased calcium losses on bone health** when these products are used over prolonged periods of time or repeatedly for short periods. In addition, the compositional advice given by the Panel is based on the assumption that total diet

² Carratù B., Sanzini E. (2005), p. 7

³ American Journal of Epidemiology (2013), p. 590; 598

replacements for weight control are used for a single short period of time and the nutrient content may not necessarily be appropriate when these products are consumed for prolonged or repeated short periods of time.”

The only aspect EFSA has analyzed in the Scientific Opinion is bone health in adults and there are no increased concerns for the use of the product for eight weeks however other elements are not considered. In addition, EFSA declares that the compositional advice is based on the assumption that total diet replacements are used for a single short period of time: is eight weeks a short period of time? As common sense and based on the weak EFSA Scientific Opinion the period should be reduced to three weeks.

Repeated short periods of time

Consumers will be very confused to comprehend the duration of ‘the short periods of time’ and the frequency of ‘repeated period of time’. It is necessary to have a clear definition of ‘repeated short periods of time’ on the text of the delegated Regulation. In the current text a consumer could interpret an eight-week period as a short period of time that can be repeated, while the EFSA’s Scientific Opinion states that “the compositional advice given by the Panel is based on the assumption that total diet replacements for weight control are used for a single short period of time”. This could be misleading for consumers.

➤ A statement that the product should not be used by individuals other than healthy overweight or obese adults without the advice of a health care professional;

- Other than Healthy overweight and obese adults

In the conclusion of the EFSA scientific opinion is written:

“The compositional advice given in the present opinion solely applies to total diet replacements for weight control which are to be used by otherwise healthy overweight or obese adults with the intention of weight loss. They are not intended for use in normal-weight adults, infants, children, adolescents, pregnant or lactating women and the elderly “

EFSA declared that total diet replacement products are not intended to use in normal weight adults and adolescents and this should be written on the labelling of the product. An adolescent could considered themselves as adults and a normal weight adults could consider themselves as an overweight person and as a consequence use total diet replacement products. This part of text is very misleading for the European consumer; the labeling should unambiguously exclude the use of the products for normal-weight adults, infants, children, adolescents, pregnant or lactating women and the elderly. The term elderly should also be further defined to avoid confusion.

- Advice of a health care professional: This statement means that an obese individual should use this product without previous advice of a health care professional. It is very rare than an obese individual is not affected by important pathologies, for this reason it is important to have a previous advice from a doctor before starting to use total diet replacement products for a period of eight weeks.

In the conclusion of EFSA's Scientific Opinion, it is declared that: "They may also not be appropriate for overweight or obese populations with *one or more medical conditions, such as, but not limited to diabetes, gout, thyroid diseases, kidney diseases, liver diseases, cardiovascular diseases and gallstones.*"

Most obese people could be affected by the medical condition described in EFSA's Scientific Opinion above and the sentence "but not limited to" is very generic and it could mean all type of ordinary medical conditions, which are common for obese people.

On the article of Lini Alappat and Atifb Awad titled "Obesity evidence and mechanism" published in 2015 on the "Nutrition Review" it is clearly written that:

*"The incidence of obesity is increasing worldwide and is hence considered a major public health concern. Obesity underlies the development of several metabolic complications including cardiovascular diseases, diabetes, and inflammation. Obesity is a major risk factor in the etiopathology of several health disorders including cardiovascular diseases, hypertension, hyperlipidemia, diabetes mellitus, and several types of cancers. Obesity and the aforementioned complications contribute to the development of metabolic syndrome."*⁴

Miae Doo and Yangha Kim (researcher in the Department of Nutritional Science and Food Management, Ewha University of Seoul in Korea) in the article "Obesity: interactions of genome and nutrients intake" of 2015 stated:

"Obesity is one of the major health concerns that pose a considerable burden to public health all over the world (1). It has been strongly associated with an increased risk of cardiovascular diseases, type 2 diabetes, metabolic syndrome, and some types of cancer. Some studies have shown that diets or foods with high appetite-controlling characters (such as vegetables, fruits, and whole grains) were inversely related to the prevalence of obesity. The cause of obesity is the complex impact of genetic and environmental factors. It is associated with increased risks of developing many chronic disease including cardiovascular disease, type 2 diabetes, arthritis, hypertension, and certain cancers such as esophagus, breast, endometrium, colorectal, gallbladder and possibly other types of cancers. As dietary nutrient intake is

⁴ Lini Alappat, Atif B Awad (2010), p. 729

an important environmental factor, many studies have shown that dietary intake plays a key role in the development of the obesity. Although many studies have observed the effects of quantity and quality of dietary nutrients on obesity, intervention studies are inconsistent.”⁵

Conclusion

Based on the above, SAFE would like to propose the following changes to the delegated Regulation on total diet replacement for weight control:

- To reduce the maximum period of intake to 3 weeks;
- To include a statement regarding the importance to practice sport and to change life style for a long-term maintenance of weight loss;
- To exclude on the labeling the use of the products for normal-weight adults, infants, children, adolescents, pregnant or lactating women and the elderly;
- To follow an advice of a health care professional before starting to take the total replacement products;
- To add some raw vegetables during the period of the intake of the total diet replacement products;
- To define “repeated short period of time” in the legislation text.

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