2024/169 5 March 2024

Specialised Nutrition Europe's position on the revision of Food Category 13

SNE calls for the maintenance of the current additive use for gluten-free foods, meal replacements for weight control and other foods for young children, and asks for FSG[1] status for young child formulae

SUMMARY

Discussions have resumed between the European Commission and Member States regarding the approach to be taken for the revision of Food Category (FC) 13 of Regulation (EC) 1333/2008.

Following the meeting of the Working Party of the Governmental Experts on Additives on 15 November 2023 and 23-24 January 2024, **Specialised Nutrition Europe (SNE) can understand the proposed approach to establish new food categories (as listed below) for gluten-free foods (GFF), meal replacements for weight control (MR) and other foods for young children, provided that the continuous authorizations of the currently permitted additives and the definition of young children are maintained.**

- FC 1.10 Milk-based drinks**, analogue drinks** and similar products intended for **young children**
- FC 18.1 Food bearing the health claim 'Meal replacement for weight control' as referred to in Regulation (EU) 2016/1413
- FC 18.2 Food marketed as 'gluten-free' or 'very low gluten' as referred to in Regulation (EU) No 828/2014

In addition, for young child formula (YCF), SNE would like to remind that the current approach is not in line with SNE's position to ask for compositional criteria for YCF in alignment with the new Codex Standard STAN 156-1987. Furthermore, this classification for YCF is not aligned with Codex General Standard on Food Additives (GSFA).

We strongly request that the specificities of the specialised nutrition categories continue to be recognised in terms of additives use. As neither the products themselves, nor the consumers to whom these products are intended have changed, the technological need for these additives remains unchanged.

For the last decades in the European Union, **a limited list of food additives has been** authorized for these foods intended for consumers with special dietary needs, with specific conditions of use ensuring that their use is safe: a loss of these additives **could hence lead to the disappearance of these products from the EU market.** The currently authorised additives for Gluten-Free Foods (GFF), Meal Replacements (MR) and other foods for young children are listed in the Annex of this document.

The authorization of these specific additives has been made in accordance with the provisions of Regulation (EU) 1333/2008:

- Their use is safe;
- Technological needs have been demonstrated;
- Benefits for the consumers have been clearly highlighted.

[1] Foods for specific groups

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu

A risk management decision taken without consideration of these above parameters would be contrary to the provisions of the Regulation (EU) 1333/2008, and more importantly, would be contrary to the general principles of the general EU food legislation (based on prior risk assessment).

Why it is important to maintain the authorisations of current additives:

The additives authorised for use in GFF, MR and other foods for young children are technologically needed[2]**.** With the repeal of Directive 2009/39/EC ("*PARNUTs Directive*"), GFF, MR and other foods for young children were transferred to the general EU food legislation. Yet, the **specificities of these three categories have been safeguarded.**

It is important to highlight that the currently authorised additives in GFF, MR and other foods for young children were safely assessed by EFSA and are used by consumers since decades without any safety or health concern. **As neither the products themselves, nor the consumers to whom these products are intended have changed, the technological need for these additives remains unchanged.**

Gluten-free foods (GFF)

Commission Implementing Regulation (EU) No 828/2014 maintains specific composition criteria and labelling requirements for the provision of information to consumers on the absence or reduced presence of gluten in food - similar to the ones of the "*PARNUTs*" framework.

SNE acknowledges the European Commission's proposal to create a new category for these products under FC 18.2 "Food marketed as 'gluten-free' or 'very low gluten' as referred to in Regulation (EU) No 828/2014", as long as the same conditions of use and the number of authorised additives are maintained.

Importantly, the currently used additives in gluten-free foods are the results of positive scientific evaluations, taking into account the technological need for these specific foods. In fact, gluten plays a technological role (mainly for texture), and its absence may require the use of some additives to maintain a product acceptable and attractive for the consumer, as we can find for products with gluten. The use depends *inter alia* on the product and on the composition. **These additives are safe, and their need has been demonstrated.** This is why they are currently authorised in gluten-free foods.

Coeliac patients need to follow a (lifelong) gluten-free diet. A diversity of acceptable products is nowadays available, ensuring that coeliac patients will be less tempted to derogate from their (lifelong) gluten-free diet.

As Recital 8 of Regulation (EU) No 828/2014 states, "in order to **enable individuals to find on the market a variety of foodstuffs appropriate for their needs and for their level of sensitivity, a choice of products should be possible with different low levels of gluten** within such a restricted range". A removal of additives in GFF would put at risk the diversity of products offered to the consumers and would go against Recital 8 of Regulation (EU) No 828/2014. As a consequence, coeliac patients would **derogate from the all-lifelong gluten-free diet** with negative consequences on their health and with a negative economic impact on national health care systems.

SNE members have a wide range of gluten-free products on the market, such as pasta, bread, biscuits, breakfast cereals, flours, snacks, etc. For this reason, it is also of great importance to maintain in FC 18.2 the following text that is currently included under FC 13.4 Foods suitable for people intolerant to gluten:

"Products in this category can also use additives that are allowed in the corresponding food counterparts

[2] Article 6.1 (b) of Regulation (EC) 1333/2008: "*there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means*".

categories".

Finally, the current general descriptor for FC 18 in Regulation (EU) 1333/2008 is *"Processed foods not covered by categories 1 to 17, excluding foods for infants and young children"*. However, this descriptor needs to be revised to **remove the reference to *"...excluding foods for infants and young children"*** as such statement would not allow for the use of the gluten-free statement in infant and young children foods.

Meal replacements (MR) for weight control

SNE acknowledges the European Commission's proposal to create a new category for these products under FC 18.1 "Food bearing the health claim 'Meal replacement for weight control' as referred to in Regulation (EU) 2016/1413", as long as the same conditions of use and the number of authorised additives are maintained.

MR are intended to support people living with obesity or overweight and who are willing to lose weight or maintain their weight after weight loss. MR are formulated to replace one or two of the main meals of the daily diet, providing the necessary nutrients with low caloric intake. MR are enriched in protein with a low carbohydrate and fat content which necessitates the use of additives for technological purposes to have an attractive product with a good texture and taste.

SNE calls for a continued use of sweeteners in these products, which are formulated to maintain a tasteful flavour and a low caloric profile simultaneously, in accordance with the European legislation[3]. MR have indeed proven to be an essential element of the diet of hundreds of thousands of Europeans. This efficacy has not only been tested by consumers but has also been acknowledged by EFSA for both weight reduction and weight maintenance[4]:

> "The *Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals in the context of energy restricted diets and reduction in body weight*".
>
> "*The Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals and the maintenance of body weight after weight loss."*

Sweeteners used in MR increase the palatability of foods and therefore consumers' acceptance. They have been safely used for decades in low calorie foods in order to provide the desired sweetness with practically no calories. Due to the set maximum energy content per person, a simple substitution of sweeteners with sugars for reaching the palatability would not be possible. Benefits of use of sweeteners are broadly documented in the scientific literature especially in the use of products intended to be used by overweight and obese consumers[5]. The use of sweeteners in meal replacements for weight control is therefore crucial to help reduce the overall energy intake in the diet and ensure dietary compliance[6].

As the food category is heterogenous, it offers many available choices for people living with obesity or overweight (e.g. chocolate- and cereal bars, shakes, soups), and helping individuals willing to control their weight by avoiding monotonous diets and enjoying a wide variety of options.

Given the obesity pandemic in Europe, helping obese and overweight people to take back control of their

[3] According to the Commission Regulation (EU) 2016/1413, the energy content shall not be less than 200 kcal and shall not exceed 250 kcal per meal
[4] Question EFSA-Q-2008-2154, EFSA-Q-2008-2155 EFSA Journal 2010 ; 8 (2) : 1466.
[5] Bellisle F. Intense Sweeteners, Appetite for the Sweet Taste, and Relationship to Weight Management. Curr Obes Rep 2015; 4(1): 106-110;
[6] Sorensen LB et al. Sucrose compared with artificial sweeteners: a clinical intervention study of effects on energy intake, appetite, and energy expenditure after 10 wk of supplementation in overweight subjects. Am J Clin Nutr 2014; 100(1):36-45

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu

weight and return to a balanced diet is a public health priority. MR are one of the few appropriate tools available to consumers, and unlike fad diets each year, MR guarantee substantial weight loss and play an important role for weight maintenance after weight loss without any deficiency in essential nutrients[7]. MR are well recognized in several current European and National Scientific Guidelines for the prevention and treatment of overweight an obesity[8].

The prohibition of currently authorised additives for MR would result in the disappearance of many slimming products from the market.

Other foods for young children

SNE acknowledges the European Commission's efforts to find a solution for other foods for young children, including young child formula. However, the proposal to create a new category for these products under FC 1.10 "milk-based drinks and similar products intended for children", is not acceptable as such.

Indeed, **'children' is not defined in the EU regulatory framework, and this could impact products that are currently not in the scope of young child formula**. In addition, having a dedicated list of additives for a category intended for children, knowing that the children population is included in the general population, would be a precedent.

Therefore, this proposal needs to refer to 'young children', as defined in article 2b of EU regulation 609/2013.

In addition, the same conditions of use, the number of authorised additives and the definition of "young children' need to be maintained.

Other foods for young children are specifically tailored for the 1-3 year age group. They are produced in accordance with the safety and quality standards that are required for all other foodstuffs for infants and young children, providing a valuable contribution to the nutrient intakes of young children.

SNE agrees with the current principle that the use of food additives in other foods for young children should be limited to the lowest levels necessary for the technological need. However, we would like to highlight that **the specific food additives currently authorized for other foods for young children are essential for preserving the nutritional quality, stability and/ or contributing to the manufacturing or storage of these products until the end of shelf life.**

SNE would also like to stress the importance of adding the following text under FC 1.10:

"These additives can also be used in other foods for young children in corresponding categories."

The reason for this addition is that other foods for young children is a broader category than milk-based products, also including **plant-based options and other foods for young children**, and the above-mentioned text is necessary to avoid interpretation issues related to the transfer of those products under FC.01 Dairy products and analogues.

As mentioned above, **this food category includes plant-based products**, which should be subject to further detailed changes in the Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives as follows:

[7] Astbury et al, (2019). A systematic review and meta-analysis of the effectiveness of meal replacements for weight loss. https://doi.org/10.1111/obr.12816

[8] German Guidelines on the Prevention and Treatment of Obesity which categorise meal replacements as tools for the prevention and treatment of obesity; Spanish Federation of Nutrition, Food and Dietetics Societies (FESNAD) and Spanish Society for the Study of Obesity (SEEDO): Evidence-based nutritional recommendations for the prevention and treatment of overweight and obesity in adults

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu

Guidance descriptors FC 1 and 1.10:

1.	Dairy products and analogues
	This category covers all types of dairy products that are derived from the milk of any milk-producing animal (e.g., cow, sheep, goat, buffalo, ass, horse), excluding products in category 2 "Fats and oils", category 3 "Edible ices", category 14 "Beverages" and category 16 "Desserts". This category also includes dairy analogues such as plant-based products (see 1.8 and 1.10). In the category 1.8, a "flavoured" product is a product with any kind of taste and/or flavour-giving element added (sugar, sweetener, flavouring, fruit preparation, spices, vegetables, etc.); this shall mean the contrary of "unflavoured". This category also contains corresponding lactose-free products.
1.10	**Milk-based drinks, analogue drinks and similar products intended for young children** ***"These additives can also be used in other foods for young children in corresponding categories."***
	[Current category: "Other foods for young children" *All authorisations of food additives would be copied from current category 13.1.4.]* In most cases, cow's or goat's milk is used as a source of protein, but the protein can be of non-animal origin (soy, rice, almonds etc.). They are marketed to young children.

In addition, for young child formula (YCF), SNE would like to remind that the current approach is not in line with SNE's position to ask for compositional criteria for YCF in alignment with the new Codex Standard STAN 156-1987. Furthermore, this classification for YCF is not aligned with Codex General Standard on Food Additives (GSFA).

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu

ANNEX
ADDITIVES CURRENTLY AUTHORISED PER CATEGORY

Foods suitable for people intolerant to gluten (13.4)

Additives (Group I)
Colours (Group II)
Polyols (Groupe IV)
Phosphoric acid-phosphates - di-, tri- and polyphosphates (E 338-452)
All additives in the gluten containing counterparts are authorised.

Meal replacements for weight control (13.3)

Additives (Group I)
Colours (Group II)
Colours with combined maximum (Group III)
Polyols (Group IV)
Quinoline yellow (E104)
Sunset yellow FCF / Orange yellow S (E110)
Ponceau 4R, Cochineal Red A (E124)
Lycopene (E 160 d)
Sorbic acid — sorbates; Benzoic acid — benzoates (E 200-213)
Phosphoric acid-phosphates - di-, tri- and polyphosphates (E 338-452)
Propane-1, 2-diol alginate (E 405)
Polysorbates (E 432-436)
Sucrose esters of fatty acids — sucroglycerides (E 473-474)
Polyglycerol esters of fatty acids (E 475)
Propane-1,2-diol esters of fatty acids (E 477)
Stearoyl-2-lactylates (E 481-482)
Sorbitan esters (E 491-495)
Acesulfame K (E 950)
Aspartame (E 951)
Cyclamic acid and its Na and Ca salts (E 952)
Saccharin and its Na, K and Ca salts (E 954)
Sucralose (E 955)
Neohesperidine DC (E 959)
Steviol glycosides (E 960)
Neotame (E 961)
Salt of aspartame-acesulfame (E 962)
Advantame (E 969)

Other foods for young children (13.1.4)

L-lactic acid (E270)

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu

Fatty acid esters of ascorbic acid (E 304)
Tocopherol-rich extract (E 306)
Alpha-tocopherol (E307)
Gamma-tocopherol (E 308)
Delta-tocopherol (E 309)
Lecithins (E 322)
Citric acid (E 330)
Sodium citrates (E 331)
Potassium citrates (E 332)
Phosphoric acid (E 338)
Sodium phosphates (E 339)
Potassium phosphates (E 340)
Carrageenan (E 407)
Locust bean gum (E 410)
Guar gum (E 412)
Gum arabic (E414)
Xanthan gum (E 415)
Pectins (E 440)
Mono-and diglycerides of fatty acids (E 471)
Citric acid esters of mono- and diglycerides of fatty acids (E 472c)
Sucrose esters of fatty acids (E 473)
Sodium carbonates (E 500)
Potassium carbonates (E 501)
Ammonium carbonates (E 503)
Hydrochloric acid (E 507)
Sodium hydroxide (E 524)
Potassium hydroxide (E 525)
Oxidised starch (E 1404)
Monostarch phosphate (E 1410)
Distarch phosphate (E 1412)
Phosphated distarch phosphate (E 1413)
Acetylated distarch phosphate (E 1414)
Acetylated starch (E 1420)
Acetylated distarch adipate (E 1422)
Starch sodium octenyl succinate (E1450)

Avenue des Nerviens 9-31 1040 Brussels, Belgium
Tel: + 32 2 508 10 74
Fax: + 32 2 508 10 25
s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu