#### **EUROPEAN COMMISSION**



Brussels, 12.05.2021 C(2021) 3343 final

Dear Chair,

The Commission would like to thank the Sénat for its Opinion on the implementation of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

The Commission welcomes the Sénat's interest in this Regulation and takes due note of the points addressed by the Sénat's Committee on European Affairs, notably the issue of the non-implementation of nutrient profiles and of health claims on botanicals. The Commission is pleased to have this opportunity to provide a number of clarifications regarding these issues raised and hopes that they will allay the concerns of the Sénat's Committee on European Affairs.

The Commission's Staff Working Document addressing these issues was published on 20 May 2020 with the Farm to Fork Strategy aiming at a fair, healthy and environmentally friendly food system. The Staff Working Document concluded that the purpose of the nutrient profiles is still pertinent and necessary to ensure a high level of consumer protection. On the issue of botanical health claims, the Staff Working Document concluded that it could be appropriate to explore the notion of "traditional use" in the efficacy assessment of health claims on botanicals used in foods together with the effects of the co-existence, on the European Union market, of traditional herbal medicinal products on the same botanical substances.

In its Farm to Fork Strategy, the Commission announced that, in order to facilitate the shift to healthier diets and stimulate food reformulation, it would adopt measures to empower consumers to make informed, healthy and sustainable food choices. In particular, the Commission will set, by the end of 2022, nutrient profiles restricting the promotion (via nutrition or health claims) of food high in fats, sugars and/or salt. The preparatory work for the setting of nutrient profiles has started. An inception impact

M. Jean-François RAPIN
Président de la commission
des affaires européennes du Sénat
Palais du Luxembourg
15, rue de Vaugirard
F-75291 PARIS

cc. M. Gérard LARCHER
Président du Sénat
Palais du Luxembourg
15, rue de Vaugirard
F-75291 PARIS

assessment<sup>1</sup> considering different options and describing the work that will be carried out was published in December 2020.

As a follow up to the Staff Working Document, the Commission is prioritising the initiatives under the Farm to Fork Strategy, in particular on food information to consumers and on the setting of nutrient profiles, for which very ambitious timelines have been set. Therefore, working on other issues at the same time, such as the issue of botanicals, will be considered in due time.

In response to the more technical questions in the Opinion, the Commission would like to refer to the attached annex.

The Commission hopes that these clarifications address the issues raised by the Sénat's Committee on European Affairs and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič Vice-President Stella Kyriakides Member of the Commission

<sup>&</sup>lt;sup>1</sup>https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Revision-of-food-information-to-consumers

#### **ANNEX**

The Commission has carefully considered each of the issues raised by the Sénat's Committee of European Affairs in its Opinion and would like to offer the following clarifications, grouped by topic.

### On nutrient profiles and botanical health claims

On nutrient profiles and botanical health claims, the Commission recalls the evaluation of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ("Claims Regulation") that it carried out, with specific focus on these two elements. In particular, the evaluation assessed whether the rules on nutrient profiles and on health claims on botanicals are still fit for their purpose to ensure the objectives of the Claims Regulation. The Commission finalised and published its Staff Working Document<sup>2</sup> on this evaluation, together with the Farm to Fork Strategy<sup>3</sup>, on 20 May 2020.

On nutrient profiles, the evaluation concluded that the specific objective pursued by the nutrient profiles, i.e. to prevent a positive health message on foods high in fats, sugars and/or salt, is still relevant today. The evaluation findings showed that, overall, the purpose of nutrient profiles is still pertinent and necessary to ensure a high level of consumer protection. Therefore, the setting of nutrient profiles needs to be further considered.

In its Farm to Fork Strategy, the Commission announced that, in order to facilitate the shift to healthier diets and stimulate food reformulation, it would set, by the end of 2022, nutrient profiles restricting the promotion (via nutrition or health claims) of foods high in fats, sugars and/or salt. The preparatory work for the setting of nutrient profiles has been launched. The inception impact assessment<sup>4</sup>, describing the work to be carried out and considering the different policy options, was published in December 2020. It was open for feedback by the public during six weeks, until 4 February 2021. During the course of 2021, all interested parties will be further consulted and, in particular, food business operators, consumers and Member States.

Nutrient profiles will be set up based on scientific knowledge about diet and nutrition, and their relation to health. In this context, the European Food Safety Authority has been mandated to provide its scientific advice. Nutrient profiles will restrict or prohibit the presence of a positive health message on food having an overall non-healthy profile.

On botanical health claims, the evaluation findings showed that, in the current situation, the objectives of the Claims Regulation are not fully attained. The Staff Working Document concluded that it could be appropriate to explore the notion of "traditional use" in the efficacy assessment of botanical health claims together with the effects of the

<sup>3</sup> COM(2020) 381 final

<sup>&</sup>lt;sup>2</sup> SWD(2020) 95 final

<sup>&</sup>lt;sup>4</sup>https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Revision-of-food-information-to-consumers

co-existence, on the European Union market, of traditional herbal medicinal products on the same botanical substances. However, the Commission is currently prioritising the initiatives under the Farm to Fork Strategy, in particular on nutrient profiles and on food information to consumers, for which very ambitious timelines have been set. In view of these priorities, the Commission has not been in a position to start work on the follow-up of the Staff Working Document related to health claims made on botanicals in food.

# On scientific assessments and pre-submission meetings carried out by the European Food Safety Authority

In the context of health and nutrition claims, the Commission would like to note that the European Food Safety Authority is responsible for carrying out the scientific assessments to confirm whether nutrition and health claims are scientifically substantiated.

Moreover, the European Food Safety Authority is committed to providing further guidance on the substantiation of health claims in specific areas. Since the beginning of the implementation of Regulation (EC) No 1924/2006, the European Food Safety Authority has adopted several general and additional specific guidance documents on different claimed effects in order to advise applicants of the required scientific evidence when submitting an application for the authorisation of a new health claim. Most guidance documents have been updated already to reflect cases and examples of past scientific assessments, as the European Food Safety Authority gains more experience in these assessments. The European Food Safety Authority is committed to bringing up to date all its related guidance documents.

As far as the request on pre-submission meetings is concerned, the Commission would like to draw the attention of the Sénat's Committee on European Affairs to the new Transparency Regulation<sup>5</sup>, which became applicable on 27 March 2021. As of that date, the new Article 32a of the General Food Law Regulation<sup>6</sup>, as amended by the Transparency Regulation, provides that the European Food Safety Authority may provide pre-submission advice at the request of a potential applicant. Such pre-submission advice should relate to the rules applicable to and the content required for an application and should not address the design of the studies to be submitted, as that remains the applicant's responsibility. The modalities of the provision of this pre-submission advice to potential applicants by the European Food Safety Authority are set out in the Practical Arrangements on the pre-submission phase and public consultations<sup>7</sup>, recently adopted by the European Food Safety Authority.

6.9.2019, p. 1).

<sup>&</sup>lt;sup>5</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231,

<sup>&</sup>lt;sup>6</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1).

https://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

# On the list of permitted nutrition claims and on the level playing field between food business operators

As far as the list of permitted nutrition claims is concerned, the Commission takes note of the considerations of the Sénat's Committee on European Affairs that this list should take account of innovations and scientific knowledge in the field of food and would therefore be updated regularly. Since the last update, the Commission has not been made aware of a need to add new nutrition claims to the list of permitted nutrition claims.

On the level playing field between food business operators, particularly on the point regarding the nutrition claim "no added sugars", the Commission is currently reflecting on how to best ensure a harmonised and consistent application of this claim across the European Union market.

### On the education policy in the field of food

Last, on the education policy in the field of food, the Commission considers that it is well-known that dietary habits developed in childhood can persist into adulthood, with negative or positive health effects. The Commission wants to create an environment where making the healthy choice for children, as well as adults, is the easy choice. The establishment of nutrient profiles for health claims will help to restrict the promotion of foods high in nutrients where excessive intakes in the overall diet are not recommended, such as fat, sugars and salt. Additionally, the Commission will review the European Union school scheme to focus even more on healthy and sustainable food and to strengthen its educational messages on the importance of healthy nutrition, sustainable food production and consumption, and reducing food waste. Furthermore, to protect children from aggressive marketing of food products high in fat, sugars and salt, the Commission will continue to encourage and support Member States to strengthen their national regulatory and non-regulatory measures.