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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE EVALUATION

of the

**Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with
regard to nutrient profiles and health claims made on plants and their preparations and
of the general regulatory framework for their use in foods**

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Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods

The Nutrition and Health Claims Regulation ('Claims Regulation'), adopted in 2006, to protect consumers and to ensure an effective functioning of the internal market², frames the use of nutrition and health claims in the labelling, presentation and advertising of foods. It ensures that all claims on foods sold in the EU are clear, accurate and based on scientific evidence.

Nutrient Profiles

The Claims Regulation stipulates that the Commission shall establish nutrient profiles by 19 January 2009 for foods or certain categories of foods. In that context, nutrient profiles are thresholds of nutrients such as fat, sugars and salt above which nutrition and health claims are restricted or prohibited. The specific objective of the nutrient profiles is to avoid a situation where nutrition or health claims would mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices. Despite the initial progress, nutrient profiles have not been established at EU level given the high controversy of the topic and strong opposition by some Member States in 2009, when the Commission tried to establish them. On the other hand, consumer organisations have been regularly advocating for their setting.

This evaluation assesses the impact of the non-setting of nutrient profiles and whether, nutrient profiles are still fit for their purpose to ensure the objectives of the Claims Regulation.

The evaluation concludes that the specific objective pursued by nutrient profiles, i.e. to prevent a positive health message on foods high in fats, sugars and/or salt content, is still relevant today, as in the absence of nutrient profiles, consumers continue to be exposed to foods bearing claims, high in fats, sugars and/or salt. Nutrient profiles were expected to facilitate healthy food choices for consumers who would have been able to rely on claims without further investigation on nutritional information provided on the package.

A level playing field between food operators has not been achieved because some operators have reformulated their products, possibly in preparation for the establishment of nutrient profiles, while other operators have not, creating unfair competition. Food business operators that have not reformulated their products have avoided costs to re-label or to adapt the composition of foods bearing claims.

In 2016, the nutrition declaration³ became mandatory for all foods, in application of the Food Information to Consumers Regulation⁴. In parallel, the concept of nutrient profiling⁵ has increasingly been used as part of a number of nutrition policies across the EU, in particular for the development and

¹ This Executive summary of the Staff Working Document draws on the study and its findings prepared by the external contractor, it expresses the view of the Commission services and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

² i.e. free movement of goods, legal certainty, fair competition and innovation

³ Nutrition declaration is generally presented in a table format, at the back of pack and it relates to the energy value and the content of fat, saturated fat, carbohydrate, sugars, protein and salt.

⁴ Regulation (EU) No 1169/2011 on the provision of food information to consumers, (OJ L 304 22.11.2011, p. 18)

⁵ Nutrient profiling means the use of nutrient profiles in the context of nutrition policies.

implementation of front-of-pack nutrition labelling schemes aimed at assisting consumers to make healthier food choices. Neither the nutrition declaration nor any of the existing schemes have the same function as the nutrient profiles, i.e. to restrict or prohibit the use of claims on foods high in fats, sugars and/or salt.

Nutrient profiles are coherent with the wider EU policy as they are one of the tools aimed at improving nutrition, public health, and the prevention of diet-related non-communicable diseases. During the past years, Member States and industry have increasingly adopted food reformulation initiatives and used nutrient profiling in particular for the development of front-of-pack nutrition labelling schemes. Based on these developments, Member States and possibly the industry could prove more open to the concept of nutrient profiles compared to 2009.

Overall, the evaluation findings show that the specific objective pursued by the setting of nutrient profiles is still pertinent and necessary to meet the objective of the Claims Regulation, which is a high level of consumer protection. Therefore, the setting of nutrient profiles needs to be further considered.

Health claims on plants and their preparations and the regulatory framework on the use of plants and their preparations in foods

Plants and their preparations are widely available on the EU market as foods or as herbal medicines. Their classification as food or as medicine is the responsibility of Member States. Thus, a plant substance classified as a “food” in one Member State, can be classified as “medicine” in another Member State.

Herbal medicines have to be authorised before they are placed on the EU market, where safety, quality and efficacy of the product have to be demonstrated. If herbal medicines meet the criteria for “traditional use”, they can use a simplified registration route for Traditional Herbal Medicinal Products⁶, where “traditional use” data are accepted to substantiate safety and efficacy of the product.

By contrast, the use of plants as foods is governed by EU general rules and specific national rules. Nineteen Member States have adopted national legislation on plants used as foods, mainly through lists of authorised or banned plant substances. Only the use of health claims on plants as foods is specifically harmonised at EU level by the Claims Regulation.

The Claims Regulation stipulates that health claims made on foods, including on plants, should only be authorised after a scientific assessment of the highest possible standard by the European Food Safety Authority (EFSA) where human intervention studies are an essential element. In 2009, no health claim on plant substances used in foods received a favourable assessment by EFSA, mainly due to the absence of human intervention studies, which led to a suspension of the authorisation procedure in 2010. In 2012, the Commission established an ‘on-hold’ list of 2,078 health claims relating to plant substances, which may still be used on the EU market under the responsibility of the business operators provided that they comply with the general principles and conditions of the Claims Regulation and the relevant national provisions, pending a final decision.

The evaluation findings show that in the current situation consumers continue to be exposed to unsubstantiated health claims from the on-hold list and may believe that the beneficial effects communicated with the on-hold claims have been scientifically assessed and risk managed, whilst this is not the case.

Food business operators have benefited from the current situation, as they have been able to continue using health claims on plant substances without having to undertake clinical trials to support the application for health claims. The pharmaceutical industry claims to face higher production and

⁶ Traditional herbal medicinal products (THMPs) are herbal medicinal products. Herbal medicinal products are defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two.

regulatory costs⁷ than food business operators producing food supplements that contain the same plant substances and can bear similar health claims, without being subject to the same requirements.

The Claims Regulation is coherent with other EU legislation applicable to plants used in foods, and with international initiatives in that field. However, there is a discrepancy in the recognition of “traditional use” data for claims made on foods and Traditional Herbal Medicinal Products.

On the general framework on plants used in foods, the evaluation concludes that the safety of foods containing plants is adequately addressed by the EU general rules on food safety, the existing national rules⁸ and, where necessary, the use of the Article 8 procedure of the Fortified Foods Regulation⁹, which assesses the safety of certain plant substances in foods which represent a potential risk to consumers. The fact that nineteen Member States have adopted national rules to address the issue of safety and that there is an increasing demand from Member States to use the Article 8 procedure suggest that plant substances used in food may give rise to adverse health effects and would merit a closer and more systematic scrutiny.

Furthermore, the evaluation shows that it is not coherent to have harmonised rules on health claims while the use of plants in foods is governed by national rules. The absence of a harmonised EU regulation on the use of plants in foods has mainly negative impacts for food business operators, particularly on product innovation and on the possibility to market the same product simultaneously in multiple Member States.

Although the classification¹⁰ (“food” versus “medicine”) would remain under the remit of Member States, EU harmonisation on plants used in foods through a positive or a negative list of plants would improve the situation with regard to safety and the smooth functioning of the internal market.

Overall, the evaluation findings show that, in the current situation, the objectives of the Claims Regulation are not fully attained. It could be appropriate to explore the notion of 'traditional use' in the efficacy assessment of health claims on plants used in foods together with the effects of the co-existence, on the EU market, of Traditional Herbal Medicinal Products on the same plant substances. In the light of the shortcomings highlighted above about the smooth functioning of the internal market and the possible openness to the notion of '*traditional use*' to substantiate health claims on plants, there are merits for further studying the potential EU harmonisation of the field of plants, including the safety aspect.

⁷ Registration/renewal fees, authorisation fees, pharmacovigilance, good manufacturing practice, and other requirements.

⁸ National lists of permitted or prohibited plants used in foods, notified to the Commission and justified on grounds of public health protection.

⁹ 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. 26–38

¹⁰ To note that the existing rules on classification, as such, have not been subject of this evaluation, as they do not fall under the scope of the food legislation.