



fighting heart disease
and stroke

european heart network

Nutrient profiles and nutrition and health claims – a European Heart Network paper

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Introduction

The aim of this paper is to describe the role of nutrient profiles in the context of the European Union (EU) regulation (EC) No 1924/2006 on nutrition and health claims made on foods (Claims regulation).

Whereas the primary objective of the Claims regulation is to ensure the effective functioning of the internal market in relation to claims whilst providing a high level of consumer protection, it also, if more implicitly, requires a high level of health protection.

In the EU, the major health burden is chronic diseases. These diseases, which include cardiovascular diseases, cancer, neuropsychiatric conditions, diabetes, and chronic respiratory disease, account for an estimated 86% of all deaths in Europe and 77% of the overall disease burden. Amongst these, cardiovascular diseases (CVD) are by far the largest cause of death in Europe, accounting for almost half of all deaths.

A poor diet is a major modifiable risk factor for CVD as well as many other chronic diseases. Nutrition and health claims on foods that respect nutrient profiles can help address the burden of CVD.

About the European Heart Network

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and other like-minded non-governmental organisations throughout Europe. EHN has members in 25 countries in Europe. EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, capacity-building and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

Summary

In the EU, the major health burden is chronic diseases. These diseases, which include cardiovascular diseases, cancer, neuropsychiatric conditions, diabetes, and chronic respiratory disease, account for an estimated 86% of all deaths in Europe and 77% of the overall disease burden.¹ Amongst these, cardiovascular diseases (CVD) are by far the largest cause of death in Europe accounting for almost half of all deaths. A poor diet is a major modifiable risk factor for CVD as well as several other chronic diseases.

In 2006, the European Union (EU) adopted a regulation on nutrition and health claims made on foods and non-alcoholic beverages (Claims regulation). True to EU rules a main objective of the Claims regulation is to ensure the effective functioning of the internal market in relation to claims, whilst providing a high level of consumer protection. Though not explicitly stated in Article 1 of the regulation, a further objective is a high level of health protection. This flows from the intent of the regulation combined with Article 168 of the Treaty of the Functioning of the European Union.

It should be noted that putting a claim on a product is a choice made by manufacturers. The Claims regulation does not mandate claims, it merely stipulates the conditions that have to be met if a claim is made.

A pillar of the Claims regulation is the condition that foods bearing claims must comply with nutrient profiles. This condition is set out in the regulation's Article 4. The reasons for this condition are found in the recitals, particularly recital 11, which states:

The application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet.

The World Health Organization (WHO) defines nutrient profiling as the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health² and has recognised nutrient profiling as a useful tool for a variety of applications.³ Applications include conditions for bearing health and nutrition claims. Numerous food companies have developed their own nutrition criteria or nutrient profiles.⁴

Not only is nutrient profiling a recognised science; across the world, many nutrient profile models have been developed⁵ and significant progress in the validation of nutrient profiling,

¹ <http://www.euro.who.int/en/health-topics/noncommunicable-diseases>

² World Health Organization, Guiding Principles and Framework Manual for the development or adaptation of nutrient profile models (First Edition). Geneva: WHO, in press

³ Vienna Declaration on Nutrition and Noncommunicable Diseases in the Context of Health 2020. Copenhagen: WHO Regional Office for Europe; 2013 (http://www.euro.who.int/_data/assets/pdf_file/0003/234381/Vienna-Declaration-on-Nutrition-and-Noncommunicable-Diseases-in-the-Context-of-Health-2020-Eng.pdf?ua=1)

⁴ <http://www.ehnheart.org/publications/publications/publication/705-ehn-research-on-nutrient-profile-model.html>

⁵ Scarborough, P., Payne, C., Agu, C. G., Kaur, A., Mizdrak, A., Rayner, M., Boyland, E. (2013). How important is the choice of the nutrient profile model used to regulate broadcast advertising of foods to children: A comparison using a targeted data set. European Journal of Clinical Nutrition, 67(8), 815-820. doi:10.1038/ejcn.2013.112

as a concept, has been made.⁶ In Europe, recent developments demonstrate that creating a pan-European model is eminently feasible.

The Claims regulation has been applied since 1 July 2007. However, though obliged by the regulation's Article 4, the European Commission has as of today – six years after the deadline in Article 4 – failed to establish nutrient profiles.

As a result hereof, nutrition and health claims can be put on any food and non-alcoholic product and, indeed, can be found on potentially millions of such products across the EU.⁷ The reason why claims are so prevalent is that food manufacturers believe that they are important ways of marketing their products to consumers. However, the presence of claims may lead consumers to overestimate the healthiness of products bearing such claims – and consequently to overconsume them.⁸

Overconsumption of foods that do not have healthy nutrient profiles is a problem in an EU where death from heart disease and stroke (and other cardiovascular conditions) accounts for 40% of all deaths.⁹ Particularly so because modifiable risk factors (such as smoking, physical activity and poor diet) contribute significantly to the risk of cardiovascular disease. To minimise premature mortality from heart disease and stroke and to sustain the fall in death rates from these and other cardiovascular conditions, policies that help improve dietary patterns and avoid high intakes of nutrients known to be detrimental to cardiovascular health, are needed.

No single food and nutrition policy measure can achieve further reductions in cardiovascular diseases; a package of policy interventions is needed.¹⁰ Part of the package is ensuring that foods and non-alcoholic beverages which make health and nutrition claims meet nutrient profiles.

EHN recommends that:

- the European Commission proceeds immediately with establishing nutrient profiles in accordance with Article 4 in the Claims regulation
- the European Commission bases its nutrient profile model on work already done in Europe; the model should allow only the healthiest products to bear claims.

⁶ Masset, G., Scarborough, P., Rayner, M., Mishra, G., & Brunner, E. J. (2015). Can nutrient profiling help to identify foods which diet variety should be encouraged? Results from the Whitehall II cohort. *British Journal of Nutrition*, 113(11), 1800–1809. doi:10.1017/S000711451500094X1

⁷ Kaur A, Scarborough P, Matthews A *et al.* (2015) How many foods in the UK carry health and nutrition claims, and are they healthier than those that do not? *Public Health Nutr*; doi:10.1017/S1368980015002104

⁸ Roe B, Levy A & Derby B. The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data. *J Public Policy Mark* (2009) 18, 89–115

⁹ Nichols M, Townsend, N, Scarborough P, Luengo-Fernandez R, Real J, Gray A, Rayner M (2012); *European Cardiovascular Disease Statistics 2012*. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis - <http://www.ehnheart.org/cvd-statistics.html>

¹⁰<http://www.ehnheart.org/publications/publications/publication/521-diet-physical-activity-and-cardiovascular-disease-prevention.html>

Nutrient profiles

Nutrient profiling is the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health.¹¹

Nutrient profiling allows differentiating between foods that are more likely to be part of a healthy diet from those that are less likely. The latter include notably foods that contribute to excess consumption of energy, saturated fats, trans fats, added sugar or salt. Whilst nutrient profiling categorises foods, not diets, they can be used through policy to improve the overall nutritional quality of diets.¹² The method helps place individual foods in a spectrum from healthy (or most healthful) to unhealthy (or least healthful).¹³

The World Health Organization (WHO) has recognised nutrient profiling as a useful tool for a variety of applications.¹⁴ Applications include conditions for bearing health and nutrition claims but also restricting marketing of foods to children.¹⁵

Numerous food companies have developed their own nutrition criteria or nutrient profiles to distinguish their 'healthier options'.¹⁶

Across the world, many nutrient profile models have been developed¹⁷ and significant progress in the validation of nutrient profiling as a concept has been made.¹⁸ In Europe, WHO published its nutrient profile model in February 2015.¹⁹ This model has been designed for eliminating the marketing of certain foods and drinks (HFSS foods) to children. Food and drinks companies have also developed a model for the same purpose: the EU Pledge.²⁰ Even if the nutrient profiling model for the Claims regulation may be different from those for marketing restrictions, these developments demonstrate that creating a pan-European model is eminently feasible.

EU Claims regulation

In 2006, the EU adopted a regulation on nutrition and health claims.²¹ It harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. The intention of the regulation

¹¹ World Health Organization, Guiding Principles and Framework Manual for the development or adaptation of nutrient profile models (First Edition). Geneva: WHO, in press

¹² http://www.euro.who.int/_data/assets/pdf_file/0005/270716/Nutrient-Profile-Model_Version-for-Web.pdf?ua=1

¹³ Public Health Nutrition: 17(12), 2637–2640 doi:10.1017/S1368980014002080/

<http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9391820&fileId=S1368980014002080>

¹⁴ Vienna Declaration on Nutrition and Noncommunicable Diseases in the Context of Health 2020. Copenhagen: WHO Regional Office for Europe; 2013 - http://www.euro.who.int/_data/assets/pdf_file/0003/234381/Vienna-Declaration-on-Nutrition-and-Noncommunicable-Diseases-in-the-Context-of-Health-2020-Eng.pdf?ua=1

¹⁵ http://www.euro.who.int/_data/assets/pdf_file/0005/270716/Nutrient-Profile-Model_Version-for-Web.pdf?ua=1

¹⁶ <http://www.ehnheart.org/publications/publications/publication/705-ehn-research-on-nutrient-profile-model.html>

¹⁷ Scarborough, P., Payne, C., Agu, C. G., Kaur, A., Mizdrak, A., Rayner, M., Boyland, E. (2013). How important is the choice of the nutrient profile model used to regulate broadcast advertising of foods to children: A comparison using a targeted data set. *European Journal of Clinical Nutrition*, 67(8), 815-820. doi:10.1038/ejcn.2013.112

¹⁸ Masset, G., Scarborough, P., Rayner, M., Mishra, G., & Brunner, E. J. (2015). Can nutrient profiling help to identify foods which diet variety should be encouraged? Results from the Whitehall II cohort. *British Journal of Nutrition*, 113(11), 1800-1809. doi:10.1017/S000711451500094X1

¹⁹ http://www.euro.who.int/_data/assets/pdf_file/0005/270716/Nutrient-Profile-Model_Version-for-Web.pdf?ua=1

²⁰ <http://www.eu-pledge.eu/content/eu-pledge-nutrition-criteria>

²¹ <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1924>

is to protect public health. Even if this is not expressed explicitly in Article 1 of the regulation, it comes through in its recitals and is also required by Article 168 of the Treaty of the Functioning of the European Union.

Unlike labelling of certain nutrients²², claims are not mandatory. Putting a claim on a product is a choice made by manufacturers, not an obligation.

When manufacturers do choose to put claims on their food products, the products must comply with conditions required by the Claims regulation. One of these conditions, set out in the regulation's Article 4, is that the product must comply with specific nutrient profiles. This condition applies equally to nutrition and health claims.

Article 4 is a pillar of the regulation. In a context of a high and increasing prevalence of obesity and chronic diseases, the regulator recognised that there was a need to '*...avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet...*'²³ as well as to ensure that '*A nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or if it encourages or condones excessive consumption of any food or disparages good dietary practice*'.²⁴

In accordance with Article 4 of the Claims regulation, the European Commission should have established these nutrient profiles by 19 January 2009. More than six years after the deadline, the European Commission has yet to establish them.

Impact of claims

Prevalence and impact on behaviour

The Claims regulation has been applied since 1 July 2007. Under this regulation nutrition claims that comply with the conditions set out in the annex to the regulation are allowed.²⁵ Insofar as health claims are concerned, the European Food Safety Agency (EFSA) is responsible for verifying the scientific substantiation of the submitted claims.²⁶

Examples of nutrition claims: 'low in fat'; 'high in fibre'; 'high in vitamins or minerals'

Examples of health claims: '...contribute to the normal function of the heart'; '...contribute to the maintenance of normal blood cholesterol levels'

²² REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers

²³ Recital 11 of the claims regulation

²⁴ Recital 18 of the claims regulation

²⁵ http://ec.europa.eu/food/safety/labelling_nutrition/claims/nutrition_claims/index_en.htm

²⁶ <http://www.efsa.europa.eu/en/topics/topic/nutrition>

One result of the lack of EU nutrient profiles, setting minimum nutritional criteria for foods to bear claims, is that nutrition claims and approved health claims can be put on any product. Such claims may be found on potentially millions of foods across the EU.²⁷

Though we do not know exactly how many products bear *health* claims in the EU, a European study, covering five EU Member States, found that on average one in ten (11%) food products bear health claims.²⁸

With respect to *nutrition* claims, the European study referred to above found that in the same five EU Member States, on average one in five food products (21%) bears a nutrition claim.²⁹

The high prevalence of claims, particularly nutrition claims – which include claims for vitamins and minerals – indicates that food companies believe that these claims are important ways of marketing their products to consumers. However, the presence of claims may lead consumers to overestimate the healthiness of products bearing such claims – and consequently overconsume those foods.³⁰ Currently, some research shows that foods that make health and nutrition claims are only marginally healthier than foods that do not make claims.³¹

On the other hand, health and nutrition claims could potentially help consumers make healthier food purchases provided that the products that bear these claims are genuinely healthier or more healthful than those which do not bear claims. This potential would be enhanced by the setting of mandatory nutrient profiles.

Impact on health

Over the past 30 years, death rates from cardiovascular diseases (CVD), in particular coronary heart disease (CHD) and stroke, have fallen by more than 50% in several European countries.³² At least half of the fall can be attributed to risk factor improvements.³³ The greatest benefits appear to have come from reductions in mean cholesterol concentrations, smoking prevalence and blood pressure levels.³⁴ The remainder of the fall can be attributed to improvements in medical and surgical treatments.

Nevertheless, CVD – the main forms of which are CHD and stroke – remains the main cause of death in the EU accounting for more than 1.9 million deaths each year – 40% of all

²⁷ Kaur A, Scarborough P, Matthews A *et al.* (2015) How many foods in the UK carry health and nutrition claims, and are they healthier than those that do not? *Public Health Nutr*; doi:10.1017/S1368980015002104.

²⁸ Personal communication; research submitted for publication

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³⁰ Roe B, Levy A & Derby B. The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data. *J Public Policy Mark* (2009) 18, 89–115

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³² Nichols M, Townsend, N, Scarborough P, Luengo-Fernandez R, Real J, Gray A, Rayner M (2012); *European Cardiovascular Disease Statistics 2012*. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis - <http://www.ehnheart.org/cvd-statistics.html>

³³ EuroHeart II; Work Package 6: CHD mortality projections to 2020, comparing different policy scenarios - <http://www.ehnheart.org/projects/euroheart-ii/euroheart-ii-publications/publication/787-chd-mortality-projections-to-2020-comparing-different-policy-scenarios.html>

³⁴ <http://www.euro.who.int/en/health-topics/noncommunicable-diseases/cardiovascular-diseases/data-and-statistics>

deaths.³⁵ CVD is also a major cause of disability and a significant economic burden across the EU, estimated to cost the EU economy almost 196 billion euros every year.³⁶

Additionally, inequalities in mortality from CVD are estimated to account for almost half of the excess mortality in lower socio-economic groups in most European countries.³⁷

Any reduction in CVD will result in major health gains as well as reductions in health inequalities and a substantial proportion of heart disease and stroke is avoidable. WHO estimates that 80% of premature deaths from these causes could be avoided by controlling the main risk factors, which include unhealthy diets (alongside tobacco use and physical inactivity).³⁸

To reduce premature mortality from heart disease and stroke, policies that help improve dietary patterns and avoid high intakes of nutrients known to be detrimental to cardiovascular health are needed. Respecting nutrient profiles as a condition for food products to bear a claim is one such policy that contributes to achieving dietary goals, which in turn help prevent avoidable premature deaths.

Likewise, limiting claims to products that respect a strict nutrient profile model, based on best available science, may also help to avoid negative dietary changes in the European population, observed in some EU countries, which in turn lead to an increased prevalence of critical risk factors for CVD, such as high blood cholesterol.³⁹

Other considerations

As stated earlier in this paper, nutrient profile models are being developed across the world for a variety of applications, all with the aim of protecting public health. At the same time, a record-breaking number of trade concerns, including specific nutrition labelling schemes – such as the voluntary ‘colour coded’ front of pack nutrition labelling recommended in the UK and the Food Health Regulations in Chile – has been raised before the World Trade Organization’s (WTO) Committee on Technical Barriers to Trade.⁴⁰

EU nutrient profiles for claims could set a high standard for the world. This could in turn help settle disputes, future and ongoing, in the context of the WTO and potentially more widely.

³⁵ Nichols M, Townsend, N, Scarborough P, Luengo-Fernandez R, Real J, Gray A, Rayner M (2012); *European Cardiovascular Disease Statistics 2012*. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis - <http://www.ehnheart.org/cvd-statistics.html>

³⁶ Idem

³⁷ Prof. Dr Johan P. Mackenbach, ‘*Health Inequalities: Europe in Profile*’ 2006
http://ec.europa.eu/health/ph_determinants/socio_economics/documents/ev_060302_rd06_en.pdf

³⁸ <http://www.euro.who.int/en/health-topics/noncommunicable-diseases/cardiovascular-diseases>

³⁹ EuroHeart II; Work Package 6: CHD mortality projections to 2020, comparing different policy scenarios - <http://www.ehnheart.org/projects/euroheart-ii/euroheart-ii-publications/publication/787-chd-mortality-projections-to-2020-comparing-different-policy-scenarios.html>

⁴⁰ http://www.wto.org/english/news_e/news14_e/tbt_04nov14_e.htm

Conclusions

Whilst cardiovascular diseases remain the main cause of death in the EU, accounting for more than 1.9 million deaths each year⁴¹, the significant fall in death rates over the past 30 years is a notable success. Reductions in mean cholesterol concentrations, smoking prevalence and blood pressure levels explain a significant part of this fall.⁴²

To sustain this positive trend and avoid dietary changes that could halt and reverse it, and to help realise the potential of avoiding 80% of premature deaths from heart disease and stroke, policy measures targeting populations throughout the EU are necessary. The reductions in mean cholesterol and blood pressure levels, referred to in the paragraph above, came primarily from dietary changes, not use of medicines (e.g. cholesterol lowering and antihypertensive drugs).⁴³

No single food and nutrition policy measure can achieve further reductions in cardiovascular diseases; a package of policy interventions is needed.⁴⁴ Part of the package is ensuring that foods and non-alcoholic beverages which make health and nutrition claims meet nutrient profiles.

WHO defines nutrient profiling as the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health⁴⁵ and has recognised nutrient profiling as a useful tool for a variety of applications – including conditions for bearing health and nutrition claims.⁴⁶ In Europe, recent developments demonstrate that creating a pan-European model is eminently feasible.

Under Article 4 of the Claims regulation, the European Commission is under an obligation to establish nutrient profiles. These should have been established by 19 January 2009. They have not.

EHN recommends that:

- the European Commission proceeds immediately with establishing nutrient profiles in accordance with Article 4 in the Claims regulation
- the European Commission bases its nutrient profile model on work already done in Europe; the model should allow only the healthiest products to bear claims.

⁴¹ Nichols M, Townsend, N, Scarborough P, Luengo-Fernandez R, Real J, Gray A, Rayner M (2012); *European Cardiovascular Disease Statistics 2012*. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis - <http://www.ehnheart.org/cvd-statistics.html>

⁴² EuroHeart II; Work Package 6: CHD mortality projections to 2020, comparing different policy scenarios - <http://www.ehnheart.org/projects/euroheart-ii/euroheart-ii-publications/publication/787-chd-mortality-projections-to-2020-comparing-different-policy-scenarios.html>

⁴³ idem

⁴⁴ <http://www.ehnheart.org/publications/publications/publication/521-diet-physical-activity-and-cardiovascular-disease-prevention.html>

⁴⁵ World Health Organisation, Guiding Principles and Framework Manual for the development or adaptation of nutrient profile models (First Edition). Geneva: WHO, in press

⁴⁶ Vienna Declaration on Nutrition and Noncommunicable Diseases in the Context of Health 2020. Copenhagen: WHO Regional Office for Europe; 2013 (http://www.euro.who.int/_data/assets/pdf_file/0003/234381/Vienna-Declaration-on-Nutrition-and-Noncommunicable-Diseases-in-the-Context-of-Health-2020-Eng.pdf?ua=1)