



UCL Université catholique de Louvain
Faculté de droit et de criminologie

EU and US Regulations on Nutrition and Health claims on Food Labeling: Comparison and Relevance

Mémoire réalisé par :

Ysaline Mouthuy

Promoteur :

Paul Nihoul

Plagiat et erreur méthodologique grave

Le plagiat, fût-il de texte non soumis à droit d'auteur, entraîne l'application de la section 7 des articles 87 à 90 du règlement général des études et des examens.

Le plagiat consiste à utiliser des idées, un texte ou une œuvre, même partiellement, sans en mentionner précisément le nom de l'auteur et la source au moment et à l'endroit exact de chaque utilisation*.

En outre, la reproduction littérale de passages d'une œuvre sans les placer entre guillemets, quand bien même l'auteur et la source de cette œuvre seraient mentionnés, constitue une erreur méthodologique grave pouvant entraîner l'échec.

* A ce sujet, voy. notamment <http://www.uclouvain.be/plagiat>.

Table of Content

INTRODUCTION	1
Part I. Factual Study.....	3
Part II. Regulation of Nutrition and Health Claims on Food Labeling	5
1. Introduction.....	5
2. EU Regulation	5
A. Introduction.....	5
a. Context	5
i. Competence of the European Union.....	5
ii. Authority in charge of food labeling.....	6
b. Background.....	6
c. Overview of the Regulation 1924/2006	8
B. Authorized Claims under the Current Regulation	8
a. General conditions for making a claim.....	8
i. General principles.....	8
ii. Scientific substantiation for claims	9
iii. Nutrient profiles	9
iv. Nutrition labeling.....	10
b. Nutrition Claims.....	11
i. Definition	11
ii. Authorized claims	11
iii. Comparative claims	12
c. Health claims	13
i. Definition	13
ii. Authorized claims.....	13
1. General function claims.....	14
2. New function claims	15
3. Claims on disease-risk reduction and child development or health	16
C. Enforcement and Non-compliance	17
3. American Regulation	18
A. Introduction.....	18
a. Context	18
i. Competence of the federal government.....	18

ii.	Authority in charge of food labeling.....	19
b.	Background.....	19
c.	Overview of the Regulation and Amendments	20
B.	Authorized Claims under the Current Regulation	21
a.	Nutrient Content Claims.....	21
i.	Definition.....	21
ii.	Authorized claims	21
b.	Health Claims.....	22
i.	Definition.....	22
ii.	Authorized claims	23
iii.	Qualified health claims	24
c.	Structure/Function Claims.....	25
i.	Definition.....	25
ii.	Authorized claims	25
d.	Dietary Statement	26
C.	Enforcement and Non-compliance	26
4.	Overview of the International Context	28
A.	WTO Obligations and International Trade	28
B.	Codex Alimentarius	29
5.	Comparison of the Regulations	30
A.	Introduction.....	30
B.	Categories of Claims and Conditions.....	30
a.	Categories of Claims	30
b.	Claims Concerning Nutrition	31
c.	Health Claims.....	33
C.	Enforcement and Non-Compliance	34
a.	Competent Authority	34
b.	Class Actions	35
c.	Actions of the Competitors	36
D.	Nutrition Information.....	36
E.	Conclusion	37
Part III.	Scientific research over the consumer's attitudes towards nutrition and health claims.....	39
1.	Introduction.....	39
2.	Review of the studies	39

A.	Consumer Interest in Food Labeling	39
B.	Perception of the Claim Depending on the Consumer-Related Variables	40
C.	Perceptions of the claims depending on the product and claim variables	42
a.	Carrier Product	43
b.	Format of the Claim.....	43
c.	Types of Health Claims, Alleged Benefits, and Country	44
D.	Consumer’s Perception of the Credibility of the Claim	47
E.	Consumer’s Understanding of the Scientific Evidence of Health Claims	48
F.	Consumer’s Perception of the Product	48
G.	Influence of Nutrition and Health Claims on the Consumers Purchase Choice of Food Products.....	50
H.	Conclusion	52
Part IV.	Relevance of the regulations	53
1.	Introduction.....	53
2.	The Authorization of Food Claims	53
3.	Differences of Receptiveness Between the Countries	54
4.	Nutrition Information.....	54
5.	The “Average Consumer” in the EU Regulation	54
6.	Different Kinds of Claims in Regulations	55
7.	Bias	56
8.	Class Actions	56
9.	Scientific Evidence Level.....	57
10.	Influence of Nutrition and Health Claims on Diet	57
CONCLUSION		60
BIBLIOGRAPHY		62

I would like to thank the people without whom the present paper would not have been.

First, I thank my advisor, Professor Paul Nihoul for his supervision and precious advice. Thanks to Ellen for helping me to find relevant articles.

I also thank my family and friends who supported me not only in the context of this paper, but also during these five years of law school.

I thank in particular my brother Pierre-Alexis and my friends Maria and Clay for their remote assistance.

Finally, I would like to thank my principal source of support who endured me during the writing of this study, and who was my principal reader and commentator. His critics, comments, and encouragements were necessary. Simon, thanks for always being there for me.

INTRODUCTION

As consumers, we are increasingly concerned by what we eat. We pay attention to our food in order to control our weight, our cholesterol, or our general health. Some of us look for food with vitamins, others for food with fibers or with few calories. In response to this growing interest, the food industry reacted by alleging the beneficial effects of their products on the label: *'Source of Calcium'*, *'Light'*, *'Facilitates the digestion'*, *'Protein builds strong bones and teeth'*, etc. Sometimes, food is even claimed to reduce the risk of a disease and, in such cases, the distinction between food and drugs may become unclear.

Are we sufficiently protected against these potentially misleading claims? This paper will focus on the current regulations concerning nutrition and health related claims. The goal is to examine the relevance of the current regulations. For this purpose, it is pertinent to compare two relatively different contexts: the EU and the US frameworks, and to examine the attitudes of the consumers.

To what extent are we confronted with nutrition and health claims? Which kind of claims can we find in our supermarkets? Are they frequently found? Are the claims related to nutrition more popular than those related to health? The first part of this paper will briefly discuss the level of penetration of those claims in our supermarkets.

The second part will focus on the EU and US laws. How and to which extent are regulated the claims that we meet in the supermarket aisles? Does a law exist for food claims in particular or do claims fall under the interdiction of misleading advertising? Are they all authorized, and if yes, under which conditions can they be made? Both the EU and US frameworks will be examined in turn. For each, the background of the regulation, the categories of claims, their conditions for making claims, and the enforcement procedures will be analyzed. Moreover, after an overview of the international approach to regulate claims, the European and American legislations will be compared. Some key differences will be underlined, criticized and will raise the necessity of taking into account the attitudes of the consumers towards nutrition and health related claims.

The third part of this paper will summarize scientific studies analyzing typical consumer behavior when presented with food claims. Research in this field is abundant and ongoing, yet still incomplete. The studies present the idea that consumers' understanding of the claim and

the perception of the product depend on multiple variables. This review will bring some answers to the underlined issues of the current regulations.

The consumers' perceptions of the claims do not always correspond with the purpose of the current regulations. Claims are potentially misleading for consumers and this lack of congruence heightens the danger. This study will conclude by criticizing apparent deficiencies of the current regulations from the point of view of the consumers' understanding of the claims.

Part I. Factual Study

It is interesting to examine to which extent nutrition and health surround us in our everyday life. A ride in a Belgian supermarket quickly demonstrates that nutrition and health are well present on food products. Three kinds of products are analyzed, because of their particular predisposition to wear nutrition and health claims: cereals, margarines, and yogurts.

On the cereals supermarket shelf, about 85 different boxes of cereals can be found. By analyzing the front of the packages, one can easily observe that references to beneficial nutrients are numerous. Out of the 85 cereals boxes, more than one fifth underline the presence of some nutrients by mentioning its name on the front packages. The nutrients cited include calcium, protein, iron, vitamins, antioxydant or selenium. Claims characterizing the level of a nutrient appear on around one seventh of the cereals boxes. They concern a wide range of nutrients (*'Good source of Calcium', 'Rich in 4 vitamins and iron'*), but in most cases, they concern fibers (*'X% of nutritional daily value', 'Rich in fibers', or 'Source of fibers'*). About ten products highlight a reduced level of fat (*'(only) X% of fat' or 'Low (saturated) fat'*); and two others a reduced level of a nutrient (*'Poor in sugar' and 'Poor in salt'*). The claim *'Natural'* or *'100% natural'* appears on 4 boxes, and *'Organic'* on one.

References to health are unusual on the cereals boxes in Belgium. Oatmeal apart, only one front-of-package mentions a body function benefit: *'Source of Vitamines D. For solid bones'*. Three oatmeal products also claim *'Oatmeal contributes to regulate cholesterol'*¹.

Claims relative to health are more frequent in the US. For instance, on the different General Mills cereals packages, the following claims can be found: *'Three grams of soluble fiber daily from whole grain oat food, like Cheerios cereals, in a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. Cheerios provides 1 gram per serving', 'A low fat part of your heart healthy diet (...)', 'Studies show more whole grain can help manage weight', 'May reduce the risk of heart disease (Diet low in saturated fat and cholesterol may reduce the risk of heart disease. Chocolate Cheerios cereal is fat (1.5 g), saturated fat free and naturally cholesterol free)'*. Moreover, the brand Kellogg's, also strongly present in the Belgian supermarket, uses health claims in America (e.g. *'Now provides fiber, a great way to keep kids healthy'*), as well as Quaker (*'Diet rich in whole grain foods and other plant foods*

¹ The following statement is added to this claim: « Une portion de flocons d'avoine contient 46% des 3 grammes de fibres bêta-glucanes nécessaires au quotidien afin de réduire le taux de cholestérol ».

and low in saturated fat and cholesterol may help reduce the risk of heart disease'). All these mentions do not only claim a health benefit, but also concern the reduction of a risk-disease. Such long disease-risk reduction claims are not present on the cereals packages in Belgium.

Margarines, a fat product per se, also carry certain allegations. On about twenty different margarines, six are labeled as '*Light*' and five underline the reduction of cholesterol. Less than ten products underline the presence or level of a nutrient with mentions as '*30% more omega 3*', '*2 types of omega 3*', '*Minerals, vitamins, omega 3*', '*Source of omega 3*', '*A guarantee level of vitamin A et E*', '*Extra calcium + 7 vitamins*'. Comparative claims are also present ('*70% less saturated fat than butter*'). A claim relates to the body function: '*Contains essential fat, important for the development of children*'.

Yogurts are another example of products likely to carry nutrition and health claims. Products without any claims are rare. The most popular claims appearing on yogurts are: '*0% of fat*', '*Light*', '*Contains bifidus*', '*Reduce the cholesterol*', '*contributes to a good intestinal health*', '*Natural*'. These claims and comparative claims are also present on the yogurt's labels in the American supermarkets. For instance, Activia products contain a claim that is not present on the Activia yogurts in Belgium: '*Helps naturally regulate your digestive system*'. Other products also mention '*Our probiotic cultures enhance digestive & immune health*'.

To give a more general idea of the presence of nutrition and health related claims, let's look at an audit performed in 2010 on the penetration of nutrition information on food labels across EU supermarkets². According to this audit, the European average of the penetration of front-of-pack claims is 25% for nutrition claims and 2% for health claims. These numbers are higher in the US where the average penetration of nutrient content claims and health claims is respectively 34% and 4%³.

From this factual study, several questions can be raised. Are these claims authorized? Does a legal framework exist that classifies and defines them? How are the claims controlled? As claims are more numerous in the US, is there a difference between the regulations in the US and the EU?

² S. STORCKSDIECK GENANNT BONSMANN, L.F. CELEMIN, A. LARRANAGA et al., "Penetration of nutrition information on food labels across the EU-27 plus Turkey", *Eur. J. Clin. Nutr.* 64, 2010, pp. 1379–1385.

³ L. LEGAULT, M.B. BRANDT, N. MCCABE, C. ADLER, A.M. BROWN, S. BRECHER, "2000-2001 food label and package survey: an update on prevalence of nutrition labeling and claims on processed, packaged foods", *J. Am. Diet Assoc.* 104(6), 2004, pp. 952-958.

Part II. Regulation of Nutrition and Health Claims on Food Labeling

1. Introduction

Consumers are exposed to nutrition and health claims when looking for food in the supermarket. They may be interested in alleged claims as '*Low cholesterol*' or '*reduce the risk of heart disease*'. In order to appear credible to the consumers and to protect them against misleading information, nutrition and health have to be controlled by authorities.

There is no internationally binding law regulating food claims. This matter is regulated by the individual states. To examine the relevance of a regulation concerning nutrition and health claims, two legal frameworks of two different entities will be compared. Regulation at the European Union level and regulation at the federal level in the United States will be analyzed. They both have implemented a precise regulation authorizing certain nutrition and health claims. Nonetheless, both legal frameworks differ from each other.

This chapter discusses the current regulations and compares them. The goal is to understand and to develop a critique of the way nutrition and health claims are currently regulated.

2. EU Regulation

A. Introduction

a. Context

i. Competence of the European Union

The European Union has jurisdiction over matters that are explicitly conferred by the Member States. It can only act within the competence granted in the Treaties of the European Union. According to the article 153 of the Treaty establishing the European Community, the EU is competent concerning consumer protection⁴. "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their

⁴ Consolidated version of the treaty establishing the European Community of 24 December 2006, *O.J.E.U.*, 29 December 2006, C. 321.

interests”⁵. Informing consumers is the primary goal of food labeling, even if health and fair trade considerations are also present⁶.

The legislation concerning food labeling adopted by the EU is binding for the Member States. As food labeling constitutes a shared competence, the Member States can adopt their own legislation to the extent that the EU has not exercised its competence. In the matter of nutrition and health claims, the EU adopted a detailed regulation that is binding for the Member States. National regulations must comply with the EU law, which does not leave much room⁷. However, Member States can always implement additional conditions on non-compulsory labeling.

ii. Authority in charge of food labeling

An EU authority is necessary to control the respect of the EU food law. The European Food Safety Authority (EFSA) is an independent European agency funded by the EU budget and created “to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply”⁸. Its role is to assess and communicate all risks associated with the food chain. It renders scientific assessment at the request of the European Commission and the European Parliament or on its own initiative. Its principal role concerning food claims is to give scientific advice about them. The EFSA also influences the process of adoption or revision of European legislation⁹.

b. Background

The EU legislation concerning nutrition and health claims is recent. Before the 21st century, no legislation at the EU level regulated this particular matter. There existed a general prohibition of misleading labeling. A Directive of 1979 already stated that labeling must not mislead the purchaser, particularly as to the characteristics of the foodstuff¹⁰, and another

⁵ Consolidated version of the treaty establishing the European Community, art. 153.

⁶ Directive 1979/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, *O.J.*, 1979, L. 33/1, Preamble.

⁷ J.-C. BUREAU, E. VALCESCHINI, “European Food-Labeling Policy: Successes and Limitations”, *Journal of Food Distribution Research* 34, November 2003, p. 71.

⁸ Europa website, http://europa.eu/agencies/regulatory_agencies_bodies/policy_agencies/efsa/index_en.htm

⁹ EFSA website, <http://www.efsa.europa.eu/en/aboutefsa/efsawhat.htm>

¹⁰ Directive 1979/112/EEC, art. 2(1).

directive of 1984 banned misleading advertising¹¹. Nonetheless, there were no particular legislations concerning the claims on food labels.

Due to this absence of harmonization and due to the increased number of claims present on the labels, some Member States started to adopt their own legislation¹². This led to discrepancies among the Member States in the terms, conditions and circumstances in which such claims could be made¹³. The EU had to react in order to keep a high level of consumer protection and to guarantee the free movement of foodstuff in the internal market¹⁴.

At the very end of the 20th century, the EU started to think about a regulation of the food claims. In a paper on food safety, the Commission discussed in 2000 the need to have legislative proposal in order to regulate the claims:

“The Labelling Directive prohibits the attribution to any foodstuff of the property of preventing, treating or curing a human disease or reference to such properties. The Commission continues to consider that labelling and advertising of a foodstuff should not contain such health claims. It is indeed true that a good balanced diet is a prerequisite for good health, but claims that the intake of food can prevent, treat or cure one disease or another could in fact lead consumers to unbalanced dietary choices. The Commission will however consider whether specific provisions should be introduced in EU law to govern “functional claims” [...] and “nutritional claims” [...]. Furthermore, the Commission will consider the need of bringing the requirements of the Nutrition Labelling Directive into line with consumer needs and expectations”¹⁵.

The following year, the matter was debated by the European Commission on a paper discussing the nutrition and functional claims¹⁶. Its study did not concern health claims. Its goal was to gather comments and “to include as broad a spectrum of stakeholders [industry groups, consumer groups and other groups] as possible in drawing up the proposed legislation”¹⁷. It recognized the increasing interest of consumers for healthy products and the proliferation of the claims appearing on the labels. It underlined the lack of specific

¹¹ Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising, *O.J.*, 19 September 1984, L. 250. This directive was replaced in 2006 by the Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, *O.J.U.E.*, 27 December 2006, L. 376.

¹² D. HOLLAND, H. POPE, *EU Food Law and Policy*, The Hague, Kluwer Law International, 2004, p. 72; O’ROURKE, *European Food Law*, 3rd Ed., London, Sweet and Maxwell, 2005, p. 136.

¹³ D. HOLLAND, H. POPE, *op. cit.*, p. 72.

¹⁴ O’ROURKE, *op. cit.*, p. 136.

¹⁵ White Paper on Food Safety of the Commission of the European Communities, COM (1999) 719 final, 12 January 2000, p. 32, available at http://europa.eu/legislation_summaries/other/132041_en.htm

¹⁶ Discussion Paper on nutrition claims and functional claims of the European Commission, prepared by the Directorate General Health and Consumer Protection (SANCO D4), available at http://ec.europa.eu/food/food/labellingnutrition/claims/claims_discussion_paper.pdf

¹⁷ European Commission website, http://ec.europa.eu/food/food/labellingnutrition/claims/background_en.htm

legislation in this field, and the insufficiency of the basic provision that claims should not mislead the consumer. The comments were numerous and stakeholders communicated their deception that health claims were not yet addressed¹⁸.

In 2003, the first commission proposal was addressed the issue of the nutritional claims, as well as the health claims. In 2005, the proposal was unanimously endorsed by the EU health ministers, and adopted in 2006 by the European Parliament.

c. Overview of the Regulation 1924/2006

Regulation 1924/2006 was adopted by the EU decision-makers in December 2006, and applied from 1 July 2007¹⁹. This regulation harmonizes the provisions laid down by regulations in the Member States which are related to nutrition and health claims. The EU, which promotes the free movement of food throughout the EU market, intervened in reaction to the threat to the uninhibited movement of foodstuff. It also wanted to promote innovations in the area of health food. The main aim of the Regulation was to ensure a high level of consumer protection and, in order to do so, to draw up an exhaustive list of permitted claims that manufacturers could use as of January 2010.

The Regulation 1924/2006 applies to all nutrition and health claims including commercial communications and trademarks which may be construed as nutrition or health claims.

This Regulation establishes the different conditions under which claims can be made on food labels. General conditions exist for all the claims. The EU policy-makers also established two principal categories of claims: nutrition claims and health claims, for which specific conditions apply.

B. Authorized Claims under the Current Regulation

a. General conditions for making a claim

i. General principles

General principles apply to all the claims aimed under the Regulation 1924/2006, that is, nutrition claims as well as health claims. A claim cannot be false, ambiguous, misleading, rise to doubt about the safety of other foods, or encourage or condone excess consumption of a

¹⁸ D. HOLLAND, H. POPE, *op. cit.*, p. 70.

¹⁹ Regulation (EC) n° 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, *O.J.E.U.*, 18 January 2007, L. 12.

food²⁰. This was already enshrined in the general legislation of the EU. Moreover, the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim²¹. Some claims are completely prohibited. For instance, when a beverage contains more than 1.2% by volume of alcohol, any health claim is prohibited²².

ii. Scientific substantiation for claims

All food claims must be based on generally accepted scientific evidence²³. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with this Regulation²⁴.

iii. Nutrient profiles

To bear a claim, the product must comply with a nutrient profile²⁵. Nutrient profiles concern conditions on the levels of nutrient for which excessive intakes in the overall diet are not recommended. This condition exists “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 a balanced diet”²⁶.

The European Commission must establish these nutrient profiles and therefore choose a nutrient profiling tool. The system was expected to set limits for the amounts of sugar, salt, and fat in specific categories of foods, where, if exceeded, would not allow the food product to bear any claims²⁷. The primary goal was to finalize nutrient profiling for 2009, but it failed due to internal and external oppositions. The issue appeared to be so delicate that a vote was proposed in 2010 to delete this provision in the Regulation. This proposition was nonetheless not accepted. Thus, as of today, the European Commission did not adopt the nutrient profiles yet. It indicated that it will make an impact assessment. The issue could certainly constitute an

²⁰ Regulation (EC) n° 1924/2006, art. 3.

²¹ Regulation (EC) n° 1924/2006, art. 5.

²² Regulation (EC) n° 1924/2006, art. 4.

²³ Regulation (EC) n° 1924/2006, art. 6.

²⁴ Regulation (EC) n° 1924/2006, art. 6.

²⁵ Regulation (EC) n° 1924/2006, art. 4.

²⁶ Regulation (EC) n° 1924/2006, preamble (10).

²⁷ Nutritional Outlook website, “EU Nutrient Profiles: Back on the Table?”, 9 October 2012, available <http://www.nutritionaloutlook.com/article/eu-nutrient-profiles-back-table-3-10531>

important discussion point in 2013²⁸. However, answering to a question, the Commission said not to be in position to propose a detailed planning for the setting of nutrient profiles²⁹.

iv. Nutrition labeling

A claim can only be made on a label if this label also includes a nutrition declaration³⁰. Under the current EU law, the nutrition information is optional and only becomes compulsory when a nutrition claim is made on the label, in a presentation or in advertising. In any case, the nutrition information must be presented in tabular form (except if lack of space), with the number aligned and containing the energy value and the amount of protein, carbohydrate, sugars, fat, saturated fat, fibre and sodium³¹. The information must be printed in legible and indelible characters³².

According to the new regulation n°1169/2011, the nutrition information will become mandatory from 13 December 2016, whether a claim is present or not on the food label³³. However, as of 13 December 2014, labels with a voluntary nutrition declaration shall comply with the requirements of the Regulation 1169/2011³⁴. In addition to a nutrition table on the back-of-pack, the energy value or the energy value together with the amounts of fat, saturates, sugars, and salt, shall appear on the front-of-pack, expressed per 100 g or per 100 ml.³⁵

²⁸ Nutraceuticals World website, “Nutrient Profiles Back on the EU Agenda”, 16 April 2012, available at http://www.nutraceuticalsworld.com/contents/view_breaking-news/2012-04-16/nutrient-profiles-back-on-the-eu-agenda/; NUTRAingredient website, “Nutrient profiling back on EU agenda says policy expert”, 16 April 2012, available at <http://www.nutraingredients.com/Regulation/Nutrient-profiling-back-on-EU-agenda-says-policy-expert>

²⁹ European Parliament website, <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2013-000448&language=EN>

³⁰ Regulation (EC) n° 1924/2006, art. 7.

³¹ Council Directive n° 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs, *O.J.E.C.*, 6 October 1990, L. 276, art. 2, 4, and 7.1.

³² Directive n° 90/496/EEC, art. 7.1.

³³ Regulation (EU) n°1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) n°1924/2006 and (EC) n°1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) n°608/2004, *O.J.E.U.*, 22 November 2011, L. 304.

³⁴ Regulation (EU) n°1169/2011, art. 54.2.

³⁵ Regulation (EU) n°1169/2011, art. 30.3 and 34.3.

b. Nutrition Claims

i. Definition

The EU policy-makers distinguished nutrition claims from health claims and defined this category separately. A nutrition claim is defined as any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to (a) the energy (calorific value) it provides, provides at a reduced or increased rate, or does not provide; and/or (b) the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain³⁶. A simple mention of a substance or nutrient or a quantitative statement as it can be found on numerous cereal packages does thus not constitute a nutrition health.

ii. Authorized claims

The regulation sets up a list of authorized claims:

- *low energy, energy-reduced, energy-free,*
- *low fat, fat-free, low saturated fat, saturated fat-free,*
- *low sugars, sugars-free, with no added sugars,*
- *low sodium/salt, very low sodium/salt, sodium/salt-free,*
- *source of fibre, high fibre,*
- *source of protein, high protein,*
- *source of [name of vitamin/s] and/or [name of mineral/s],*
- *high [name of vitamin/s] and/or [name of mineral/s],*
- *contains [name of the nutrient or other substance],*
- *increased [name of the nutrient], reduced [name of the nutrient],*
- *light/lite,*
- *naturally/natural*³⁷.
- *Source of omega-3 fatty acids, High omega-3 fatty acids fat, High monounsaturated fat, High polyunsaturated fat, and High unsaturated fat*³⁸.

The listed claims, or the claims likely to have the same meaning for the consumer, can only be made in compliance with the conditions established in the Annex of the Regulation.

³⁶ Regulation (EC) n° 1924/2006, art. 2.2(4).

³⁷ Regulation (EC) n° 1924/2006, Annex.

³⁸ The list was completed in 2010: Commission Regulation (EU) n°116/2010 of 9 February 2010 amending Regulation (EC) n°1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims, *O.J.E.U.*, 10 February 2010, L. 37/16.

Requirements exist for each one. For instance, ‘*Low energy*’ can be made when the food product contains less than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/ 100 ml for liquids³⁹. A claim that a food is ‘*low in fat*’ may only be made when the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk)⁴⁰.

The list of nutrition claims is again currently in revision. The claim ‘*Without added sodium/salt*’ could be added. Also, the conditions concerning some actual claims could be reviewed⁴¹.

A food manufacturer that wants to place a nutrient claim on the label of its product can only make use of one of the listed claims. All other nutrition claims are not allowed. For instance, a claim such as ‘*X% fat-free*’ is no longer accepted. The manufacturer must also know the amount of the nutrient in the food, and check if this amount complies with the particular requirements concerning the claim⁴².

iii. Comparative claims

Comparative claims are authorized when they compare the composition of the food in question with a range of foods of the same category, which do not have a composition that allows them to bear a claim⁴³. The difference in the quantity of a nutrient and/or the energy value must be stated and the comparison shall relate to the same quantity of food⁴⁴. Claims as ‘*30% more Omega 3*’ present for instance on the margarine in our supermarkets are thus allowed.

³⁹ Regulation (EC) n° 1924/2006, Annex.

⁴⁰ *Id.*

⁴¹ Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, “Allégations nutritionnelles et de santé : les dernières avancées réglementaires”, document available at http://www.economie.gouv.fr/files/Nutri-doc_version%20revue.pdf

⁴² B. AISBITT, *Nutrition and Health Claims: the Facts on your Food*, Synthesis report n°5, EuroFIR, British Nutrition Foundation, 2007, p. 8, available at http://www.eurofir.net/sites/default/files/EuroFIR%20synthesis%20reports/Synthesis%20Report%205_Nutrition%20and%20health%20claims_the%20facts%20on%20your%20food.pdf

⁴³ Regulation (EC) n° 1924/2006, art. 9.

⁴⁴ *Id.*

c. Health claims

i. Definition

Health claims are the second category set up by the EU policy-makers. A health claim is defined as a claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health⁴⁵.

ii. Authorized claims

Health claims are prohibited unless they comply with the general requirements of the Regulation 1924/2006. Food manufacturers are allowed to make such claims when the label displays a statement indicating the importance of a varied and balanced diet and a healthy lifestyle, the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect⁴⁶. It must also mention, where appropriate, a statement addressed to persons who should avoid using the food, and an appropriate warning for products that are likely to present a health risk if consumed excessively.⁴⁷ Health claims are not allowed when they suggest that health could be affected by not consuming the food, or make reference to the rate or amount of weight loss or to recommendations of health professionals⁴⁸. A claim as '*lose 3 kg in 3 weeks*' is thus prohibited.

These are the minimal conditions for health claims. Within this category, the EU Commission establishes a distinction between general function claims, new function claims and disease-risk reduction claims. Various additional conditions are required for each category.

The authorization procedures are also different according to the different claims. The authorization to make a health claim must be granted at the EU level. The EFSA has an important role in this process. Whenever the EFSA must provide a scientific opinion, it will verify that the health claim is substantiated by scientific evidence and that the wording of the health claim complies with the criteria laid down in this Regulation⁴⁹.

⁴⁵ Regulation (EC) n° 1924/2006, art. 2.2(5).

⁴⁶ Regulation (EC) n° 1924/2006, art. 10.2.

⁴⁷ *Id.*

⁴⁸ Regulation (EC) n° 1924/2006, art. 12.

⁴⁹ Regulation (EC) n° 1924/2006, art. 16.

1. General function claims

“General function” claims refer to the role of a nutrient or substance in growth, development and body functions, to psychological and behavioral functions, or to slimming and weight control, satiety or reduction of available energy from the diet⁵⁰.

According to the Regulation 1924/2006, the European Commission had to draw up a list of authorized functions claims. For this purpose, food manufacturers submitted their claims with a relevant scientific justification to the competent authority in their Member State. The EU countries provided then for over 44,000 claims. These 44,000 claims were consolidated in approximately 4,600 claims, which were sent to the EFSA for consultation⁵¹.

The EFSA checked the validity of allegations and gave a scientific opinion for each one. For instance, concerning health claims related to the reduction of gastro-intestinal discomfort, the Panel on Dietetic Products, Nutrition and Allergies concluded, on the basis of the data presented, “that a cause and effect relationship has not been established between the consumption of the food constituents which are the claims”⁵². The EFSA transferred its scientific opinions to the European Commission. The Commission adopted a list of 222 authorized general function health claims and published it in the Commission Regulation of May 2012⁵³. The EFSA and the Commission made thus a strict selection. The other claims were rejected because they were not based on sufficient scientific evidence. “Surprisingly, some claims that were widely used in the past and approved by several national health agencies have been rejected, such as claims regarding prebiotics and probiotics products”⁵⁴. Claims having the same meaning for the consumer (because of the same relationship between the food and the health) are permitted claims and are subject to the same requirements⁵⁵.

Claims appearing in this list can only be made if the carrier food product does not exceed the limits set by the nutrient profile and the requirements set up for the particular claim. Some requirements refer to the conditions used for nutrition claims. Let’s take the example of the claim ‘*Source of Vitamin D. For solid bones*’ present on some cereals. This claim would

⁵⁰ Regulation (EC) n° 1924/2006, art. 13.1.

⁵¹ European Commission website, http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm

⁵² EFSA website, <http://www.efsa.europa.eu/en/efsajournal/pub/2858.htm>

⁵³ Commission Regulation (EU) n°432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health, *O.J.E.U.*, 25 May 2012, L. 136. This list has been adopted lately. The original deadline was by 31 January 2010.

⁵⁴ Lexology website, C. GAUTHIER, “Food health claims: challenges for ASEAN manufacturers”, 12 November 2012, available at <http://www.lexology.com/library/detail.aspx?g=76fa4d5d-1ae4-46bf-a04c-3fca7657b08c>

⁵⁵ Regulation (EC) n° 432/2012, preamble.

correspond to *'Vitamin D contributes to the maintenance of normal bones'*, which is present in the list. This claim is authorized for food which is at least a source of vitamin D as referred to in the claim *'Source of [name of the vitamin] and/or [name of the mineral]'* as listed in the Annex to Regulation 1924/2006⁵⁶. Others, less numerous, are submitted to specific conditions. For example, one of the listed claims is *'Beta-glucans contribute to the maintenance of normal blood cholesterol levels'*. This claim may be used only for food which contains at least 1 g of beta-glucans from oats, oat bran, barley, barley bran. "In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of these beta-glucans" ⁵⁷. The allegation present on our oatmeal *'Oatmeal contributes to regulate cholesterol'* is then authorized, and the back-of-pack mentions that 3 g are necessary to obtain the beneficial effect.

This new list was a breakthrough in the protection of consumers and upset the world of the food industry. The regulation has applied from 14 December 2012, six months after its entry into force. The food business operators got 6 months to adapt their labels. After this period of transition, the 222 claims (or very similar claims) are the only permitted functions health claims and the food business operators' non-scientifically based claims had to be removed from the market.

Concerning the claims that are not listed, the EFSA will continue to assess health claims under the individual authorization process⁵⁸.

2. New function claims

"New function" claims refer to newly developed scientific evidence and/or which include a request for the protection of proprietary data⁵⁹. It concerns newly developed substances that can have a beneficial effect (e.g. a combination of lycopene, vitamin E, lutein and selenium helps to prepare and activate tanning)⁶⁰.

Those claims require the submission of a scientific dossier to the EFSA and are authorized on a case-by-case basis. The food manufacturer submits its application to the

⁵⁶ Commission Regulation (EU) n°432/2012, Annex.

⁵⁷ *Id.*, European Commission website, "EU register on nutrition and health claims", <http://ec.europa.eu/nuhclaims/resources/docs/euregister.pdf>

⁵⁸ Regulation (EC) n° 1924/2006, art. 13.4.

⁵⁹ Regulation (EC) n° 1924/2006, art. 13.5; EFSA website, <http://www.efsa.europa.eu/en/topics/topic/article13-5.htm>

⁶⁰ *Id.*

competent authority of the Member State. It compiles a dossier containing the evidence of the relationship between the product and the health benefit. The application also includes the applicant's details, the characteristics of the food in respect of which the health claim is to be made, a copy of the studies (including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation), and, where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification⁶¹. These data are protected during five years⁶².

The application is sent to the EFSA. The EFSA has 5 months to evaluate the scientific evidence of the claim. It does not accept or refuse the claim. This is the role of the Commission to which the EFSA issues its opinion. The Commission has to take a decision within 2 months⁶³. So far, 27 scientific opinions have been adopted and 13 have been withdrawn by the Commission. For instance the EFSA rendered a favorable advice in December 2012 about the claim related to the *Vitis vinifera* L. seeds extract that '*helps to drain the body in case of water accumulation*'⁶⁴.

3. Claims on disease-risk reduction and child development or health

Claims on disease-risk reduction and child development or health have to be permitted by the EFSA as well⁶⁵. Consider the following examples of such claims: '*Eating 3g of long chain omega 3 fatty acids a week may help to reduce the risk of heart disease*' or '*Calcium is important for developing strong bones in childhood*'⁶⁶. Such claims appear to very rare in supermarkets.

The applicant submits its dossier to the competent authority in its Member State, which transmits it to the EFSA⁶⁷. The EFSA gives its opinion about the claim within five months and the Commission accepts it or not⁶⁸. In this case, the Commission has two months to take

⁶¹ Regulation (EC) n° 1924/2006, art. 15.3.

⁶² Regulation (EC) n° 1924/2006, art. 20.1.

⁶³ Regulation (EC) n° 1924/2006, art. 18.

⁶⁴ EFSA website, <http://www.efsa.europa.eu/en/efsajournal/pub/2998.htm>

⁶⁵ Regulation (EC) n° 1924/2006, art. 14.

⁶⁶ B. AISBITT, *Nutrition and Health Claims: the Facts on your Food*, op. cit., p. 11.

⁶⁷ Regulation (EC) n° 1924/2006, art. 15.

⁶⁸ Regulation (EC) n° 1924/2006, art. 16 and 17.

its decision. As this procedure is public, the stakeholders and the public may also send comments to the Commission⁶⁹.

So far, the Panel has refused 103 claims and adopted 75 scientific opinions⁷⁰. For example, in December 2011, the EFSA accepted a claim that states “*Barley beta-glucans have been shown to lower/reduce blood cholesterol. High cholesterol is risk factor in the development of coronary heart disease*”⁷¹. There is an additional requirement for these claims: they have to bear a statement that indicates that the disease has multiple risk factors and that altering one of these factors may or may not have a beneficial effect⁷².

C. Enforcement and Non-compliance

The EFSA intervenes only to check the scientific substantiation of submitted claims. There is no European authority that controls whether the food claims respect the conditions for making such claims. Member States are responsible for verifying the compliance of the food manufacturers with the EU legislation.

The EU regulation is clear. There are lists of authorized claims with requirements, and some other claims can be submitted for approval. The authorization process occurs before the claim appears on the label. Food manufacturers know exactly which claims they can make. In general, the amount of false, misleading or non-authorized claims is thus limited. As a result, there is little case law.

However, infringements exist, and lawsuits are conceivable. If condemned, food producers are exposed to the sanctions established in the Member State. Criminal sanctions are possible for misleading publicity, but most of the time, the withdrawal of the claim will be enforced and/or a large fine will be due. The associated reputation damage can be even more harmful. Lawsuits can be initiated by associations of consumers or by competitors.

For instance, in France, the association Consommation, logement, et cadre de vie (CLCV) launched a lawsuit against Candia. This brand displayed on its cartons the claim ‘*Silhouette active vous aide naturellement à manger moins*’, despite the negative opinion of the French authority. In November 2012, Candia was condemned by the tribunal of Paris to withdraw all

⁶⁹ Regulation (EC) n° 1924/2006, art. 16.6.

⁷⁰ EFSA website, <http://www.efsa.europa.eu/en/topics/topic/article14.htm>

⁷¹ Scientific Opinion on the substantiation of a health claim related to barley beta-glucans and lowering of blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) n° 1924/2006, December 2011, <http://www.efsa.europa.eu/en/efsajournal/pub/2471.htm>

⁷² Regulation (EC) n° 1924/2006, art. 14.2.

health allegations on the packaging of its products, with the threat of a 2000 € daily penalty payment of delay⁷³.

Another legal example is the lawsuit against Andros launched by its competitor Yoplait, because it used the claim ‘*Recette moins sucrée*’ on the labels of its products. It is a comparative nutritional claim and then the label should have mentioned the sugar content and the reduction. Andros had to pay damages for deceptive practice and unfair concurrency⁷⁴.

In the two cases above, the Regulation 1924/2006 has been invoked, in addition to the national regulation. The Regulation is relatively new, which can also explain the lack of jurisprudence.

3. American Regulation

A. Introduction

a. Context

i. Competence of the federal government

The federal government dominates the regulation of food safety in the US. It has a constitutional power to regulate the commerce between the states and thus to impose rules concerning food labeling⁷⁵. Food law is also regulated at the state and local level. The States have to comply with the federal law, but they can decide to impose additional standards in their own state. Some states, such as California, have adopted strong consumer protection statutes. Most of the times, changes in the federal regulation are directly inspired by previous state regulations.

⁷³ TI Paris, 13 Nov. 2012 ; Consommation, logement et cadre de vie website, “Publicité trompeuse : Candia condamnée”, 21 November 2012, available at <http://www.clcv.org/nos-actions-en-justice/publicite-trompeuse-candia-condamne.html>; Nomos website, “Candia condamnée pour les publicités sur son produit ‘Silhouette Active’”, available at

http://www.nomosparis.com/index.php?option=com_content&view=article&id=554:candia

⁷⁴ Nomos website, “Andros condamnée pour son allégation ‘recette moins sucrée’ », available at http://www.nomosparis.com/index.php?option=com_content&view=article&id=553:andros-condamnee-pour-son-allegation-l-recette-moins-sucree-r&catid=45&Itemid=169

⁷⁵ 21 U.S.C. §331 ; Am. Jur. 2d, Commerce §11 ; D. M. ALLEN, “Validity, under Commerce Clause (Art I, § 8, Cl 3), of state statutes regulating labeling of food”, 79 *A.L.R. Fed.*, 1986, p. 246; North Dakota State University website, <https://www.ndsu.edu/pubweb/~saxowsky/aglawtextbk/chapters/foodlaw/USagencies.html>

ii. Authority in charge of food labeling

The Food and Drug Administration (FDA) is a federal governmental agency within the Department of Health and Human Services. It is in charge of the protection of public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices and cosmetics, and by ensuring that food is safe and sanitary⁷⁶. The FDA is competent in the matter of food labeling and nutrition and health related claims. It enforces the law and establishes guidance for industries.

Another federal regulatory authority, the Federal Trade Commission (FTC), is competent to control the nutrition and health claims. Created in 1914, the role of the FTC is “[t]o prevent business practices that are anticompetitive or deceptive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process; and to accomplish this without unduly burdening legitimate business activity”⁷⁷. While the FDA has the authority to regulate food labels, the FTC has jurisdiction over general advertising. There is an obvious overlap of their authorities when it comes to control nutrition and health claims. As a consequence, the FTC and the FDA established the “Working Agreement Between the Federal Trade Commission and the Food and Drug Administration” of June 1954. This Agreement foresees among other things that “[w]ith exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics”⁷⁸.

b. Background

The US regulation concerning food claims dates from the beginning of the 20th century. Together with Japan, the US was the first country in the world to adopt policies regulating food health claims. In 1906, the old Food and Drug Act already foresaw that “If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or

⁷⁶ American National Standards Institute website,
http://www.standardsportal.org/usa_en/USG/fda.aspx#Regulatory

⁷⁷ Food Trade Commission website, <http://www.ftc.gov/ftc/about.shtm>

⁷⁸ FDA website,
<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm>

misleading in any particular”⁷⁹. The Federal Food, Drug and Cosmetic Act (FDCA) of 1938 also dealt with food labeling, preventing unfair and deceptive trade practices⁸⁰. Among other things, food shall be deemed misbranded if any other information required was not prominently placed thereon with such conspicuousness and is not likely to be understood by the ordinary consumer⁸¹. Misbranded food is also prohibited under the Code of Federal Regulations⁸².

However, this regulation was not sufficient. During the 1980s, the amount of false claims increased. ‘*Light*’ appeared on particularly fat cheesecakes and high fiber cereals were presented as the miracle against cancer (for instance the All-Bran of Kellogg). As the FDA was unable to control such claims, the Congress had to react⁸³.

c. Overview of the Regulation and Amendments

The first regulation specifically concerning nutrition and health claims appeared in 1990 in the Nutrition Labeling and Education Act (NLEA). This law, amending the FDCA, directed the FDA to set premarket approval standards for health and nutrition for food products⁸⁴. The Act required all nutrient content claims and health claims to comply with the FDA regulation. In 1994, the Dietary Supplement and Health Education Act provided for the use of structure/function claims. These regulations were a success and the companies adapted the composition of their products to be allowed to make claims as ‘*Light*’ or ‘*Low Fat*’. “As a result, more than 1500 new products that met FDA requirements for such claims were introduced in 1994”⁸⁵.

At that time, the companies could only use a health or nutrient content claim if the FDA published a regulation authorizing such a claim⁸⁶. That changed in 1997 when the FDCA was further amended. The Food and Drug Administration Modernization Act of 1997 allowed

⁷⁹ R.W. AUSTIN, “The federal food legislation of 1938 and the food industry”, *Law and Contemporary problems*, 1939, p. 138, available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1942&context=lcp>

⁸⁰ 21 U.S.C. §343.

⁸¹ 21 U.S.C. §343 (f).

⁸² 21 C.F.R. §101.18.

⁸³ B.A. SILVERGLADE, “The Nutrition Labeling and education Act-Progress to Date and Challenges for the Future”, *Journal of Public Policy & Marketing* 15(1), American Marketing Association, Spring 1996, p. 148.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ FDA website, “Health Claim Notification for the Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease”, available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073631.htm>

health claims based on an authoritative statement of a scientific body of the US government or the National Academy of Sciences.

Three categories of food claims exist under the American legislation: nutrient content claim, health claims and structure/function claims. The requirements are different for each type of claims.

B. Authorized Claims under the Current Regulation

a. Nutrient Content Claims

i. Definition

A nutrient content claim is a claim characterizing the level of a nutrient in a food (e.g. 'free' or 'high'). Terms as 'more', 'reduced' can also be used when claims describe the content of a nutrient compared to the level of another food⁸⁷. A quantitative statement (e.g. '200mg sodium') does not constitute a nutrient content claim.

ii. Authorized claims

Nutrient content claims are allowed by the Nutrition Labeling and Education Act of 1990. To be made, they must first be authorized by the FDA. The FDA set up the following list of core terms that can be used:

- *Free of [fat, saturated fat, cholesterol, sodium, salt, sugars and calories],*
- *Very Low in sodium*
- *Low in [fat, saturated fat, cholesterol, sodium and calories],*
- *Lean and Extra Lean defined for meat, poultry, seafood, game meat and meal type products (definition includes criteria for fat, saturated fat and cholesterol),*
- *High and Good source of [a beneficial nutrient with a daily value (DV)],*
- *Reduced and Less in [fat, saturated fat, cholesterol, sodium, sugar and calories],*
- *More of [a beneficial nutrient with a DV],*
- *Light [for fat or calories or in sodium]*⁸⁸.

Only these claims, or their synonyms, can be used⁸⁹. The claims can only be made if the characterization of the level made in the claim uses terms which are defined in regulations⁹⁰.

⁸⁷ J.C. ROWLANDS, J.E. HOADLEY, "FDA perspectives on health claims for food labels", *Toxicology* 221, Elsevier, 2006, p. 36.

⁸⁸ 21 C.F.R. §101.54, §101.62(e); FDA website, <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>; <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide>;

For each kind of term, the FDA fixed the conditions that have to be fulfilled. The product in question must respect the requirements established for the desired claim. For instance, food that contains 10 percent more of the recommended daily intake (RDI) for vitamins or minerals per 100 g of food than an appropriate reference food, can present on its label the mentions ‘More’ or ‘Enriched’ describing these nutrients⁹¹.

Nutrient claims are authorized only when they characterize a nutrient contained in the nutrition labeling⁹². Sometimes, a disclosure statement is required when a nutrient content claim is made and when another nutrient in that food exceeds certain prescribed levels⁹³. Moreover, the claims have to respect some requirements regarding their size or their type⁹⁴. The type size of the claim may be no more than twice as prominent as the statement of identity (name of the food)⁹⁵.

No nutrient content claim may be made on food intended specifically for use by infants and children less than 2 years of age, except for claims regarding % RDI of vitamins and minerals⁹⁶.

b. Health Claims

i. Definition

Health claims are defined as “any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition”⁹⁷. Health claims imply both a substance and a disease or health-related condition, associated with the substance. They can also be implied depending on the context in which they are presented⁹⁸.

⁸⁹ 21 C.F.R. §101.13(b).

⁹⁰ 21 C.F.R. §101.13(b).

⁹¹ 21 C.F.R. §101.54(e).

⁹² J.C. ROWLANDS, J.E. HOADLEY, “FDA perspectives on health claims for food labels”, *op. cit.*, p. 36.

⁹³ 21 C.F.R. §101.13(h)(1)-(3).

⁹⁴ A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity (21 C.F.R. §101.13(f)).

⁹⁵ 21 C.F.R. §101.13(f).

⁹⁶ 21 C.F.R. §101.13(b)(3).

⁹⁷ 21 C.F.R. §101.14(a)(1).

⁹⁸ *Id.*

ii. Authorized claims

Before 1997, companies needed the FDA to publish a regulation authorizing the health claim before using it. Since the Food and Drug Administration Modernization Act of 1997, food manufacturers can submit to the FDA a notification of the desired health claim based on authoritative statement from an appropriate scientific body of the US government or the National Academy of Sciences⁹⁹.

The FDA reviews the scientific evidence of the claims by using the Significant Scientific Agreement Standard. This means that the agency only approves health claims that are supported by a significant scientific agreement among experts qualified by scientific training and experience¹⁰⁰. The process of approval can take a long time since it involves the participation of scientists, consumers and other interested parties¹⁰¹.

This process takes place before the manufacturers can put the claim on any label. Manufacturers must indeed submit a notification of their claim at least 120 days before the introduction of the labeled food into the market¹⁰².

Currently, twelve kinds of claims have been approved that make a link between a nutrient and a disease. The Code of Federal Regulations provides one or a few models for each one. For instance, the following health claims are authorized: “*Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors*”¹⁰³, “*Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis*”¹⁰⁴, “*Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers*”¹⁰⁵, “*While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease*”¹⁰⁶. The long claims we could find on the Cheerios cereals in the US are thus

⁹⁹ B. AISBITT, *Nutrition and Health Claims: the Facts on your Food*, op. cit., p. 36.

¹⁰⁰ 21 C.F.R. §101.14(d)(1); J.C. ROWLANDS, J.E. HOADLEY, “FDA perspectives on health claims for food labels”, op. cit., p. 36.

¹⁰¹ B. SILVERGLADE, I.R. HELLER, *Food Labeling Chaos. The case for reform*, Center for Science in the Public Interest, 2010, part VI.1.

¹⁰² FDA website,

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm056975.htm>

¹⁰³ 21 C.F.R. §101.76(e).

¹⁰⁴ 21 C.F.R. §101.72(e) and (f).

¹⁰⁵ 21 C.F.R. §101.73(e)(1).

¹⁰⁶ 21 C.F.R. §101.75(e)(1).

authorized. In order for a health claim to be made, the nutrient appearing in the claim must not exceed a fixed level¹⁰⁷.

iii. *Qualified health claims*

The significant scientific agreement test applying for health claims was contested. In 1998, a dietary supplement marketer asked the authorization for four health claims that the FDA refused to give¹⁰⁸. A lawsuit started. In 1999, in *Pearson v. Shalala*¹⁰⁹, the US Court of Appeals for the District of Columbia Circuit held that the FDA's refusal to authorize four health claims made with reasonable disclaimers constituted a violation of the First Amendment (protection of the commercial free speech)¹¹⁰.

The FDA reacted to this sentence. In 2003, it adopted the guide "Consumer Health Information for Better Nutrition Initiative". This FDA guide allows "qualified health claims", health claims for which the evidence is not sufficient to meet the significant scientific agreement standard. Qualified health claims must be accompanied by a disclaimer that the evidence is uncertain, for instance as follows: *'Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease'*¹¹¹. The language of the claims is different because the qualified health claim must be worded "in such a way that consumers are not misled about the nature of the supporting science"¹¹².

Qualified health claims also need approval of the FDA. Manufacturers must submit a petition. "Qualified health claims are still based on the totality of publicly available evidence

¹⁰⁷ 21 C.F.R. §101.14(d).

¹⁰⁸ The claims were the following : 1) Consumption of antioxidant vitamins to a possible reduction of risk of certain cancers; 2) Consumption of fiber to a possible reduction of risk of colorectal cancer; 3) consumption of omega-3 fatty acids to a possible reduction of risk of coronary heart disease; and 4) a higher level of folic acid than is found in foods in common form to a possible reduction of risk of neural tube defect. D.B. MCCOLL, C.P. BUMP, "Qualified Health Claims: Creatures of Case Law", *F.D.L.I.*, November/December 2005, p. 33, available at http://www.hpm.com/pdf/MCCOLL_BUMP.pdf

¹⁰⁹ *Pearson v. Shalala*, 164 F.3d 650 (D.C Cir. 1999); J.C. ROWLANDS, J.E. HOADLEY, "FDA perspectives on health claims for food labels", *op. cit.*, p. 39.

¹¹⁰ J.W. EMORD, "Pearson v. Shalala: The Beginning of the End for FDA Speech Suppression", *Journal of Public Policy & Marketing* 19(1), Spring 2000, p. 139, available at <http://www.jstor.org/stable/30000494>

¹¹¹ FDA, Guidance for Industry: A Food Labeling Guide, 12. Appendix D, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064923.htm>

¹¹² *Id.*

but the scientific support does not have to be as strong as that for significant scientific agreement”¹¹³.

The FDA uses a ranking system to categorize health claims¹¹⁴. A letters grading system determines the level of scientific evidence of the claim. *A* appears when there exist a high significant scientific agreement about the health claim. Qualified claims are graded by a *B* when there is good scientific evidence but not conclusive, by a *C* when the evidence is limited and not conclusive, and by *D* when there is little conclusion¹¹⁵. The FDA provides for appropriate qualifying language for each one¹¹⁶.

c. Structure/Function Claims

i. Definition

Structure/function claims allege the role of a particular substance on the normal structure or function in humans. ‘*Calcium builds strong bones*’ is such a claim. They may also characterize the means by which a nutrient acts to maintain such structure or function (e.g. ‘*Antioxidants maintain cell integrity*’) or describe general well-being from consumption of a nutrient¹¹⁷.

ii. Authorized claims

Structure/functions claims are not subject to review or approval of the FDA¹¹⁸. They just have to be notified no later than 30 days after the product goes to the market. These claims, authorized since 1938, are increasingly used since a few years, because they do not have to comply with the strict requirements of health claims¹¹⁹.

Function/structure claims might not be subject to FDA review, but they still must be truthful and cannot be misleading. Manufacturers must have some substantiation about their claims (e.g. clinical studies). The Dietary Supplement Health and Education Act of 1994 has established different requirements. Such claims may be related to a disease, if the statement

¹¹³ *Id.*

¹¹⁴ FDA website, <http://www.fda.gov/ohrms/dockets/dailys/03/Aug03/080103/03n-0069-rpt0001-04-Attachment-b-vol4.pdf>

¹¹⁵ FDA website, <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>

¹¹⁶ FDA website, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm053832.htm>

¹¹⁷ FDA website, <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>

¹¹⁸ J.C. ROWLANDS, J.E. HOADLEY, “FDA perspectives on health claims for food labels”, *op. cit.*, p. 36.

¹¹⁹ B. SILVERGLADE, I.R. HELLER, *Food Labeling Chaos. The case for reform*, *op. cit.*, part VI.1.

also reveals the extent of the disease in the US¹²⁰. If the claim is made about a dietary supplement, a disclaimer is required that the FDA did not evaluate the claim and that the dietary supplement is not intended to “diagnose, treat, cure or prevent any disease”¹²¹.

If a claim appears to be false or misleading, the FDA can intervene. However, it will only be after the claim has been launched in the marketplace. Currently, the FDA relies on the case-by-case enforcement actions.

d. Dietary Statement

Nutrient content claims, health claims and function claims must be distinguished from the dietary statement. A dietary statement is made when neither a specific substance nor a related disease is mentioned. For instance, the statements ‘*Diets rich in fruits and vegetables may reduce the risk of some types of cancer*’ or ‘*Carrots are good for your health*’ do not mention a specific substance and are as such not health claims. Dietary guidance may be used without pre-review by the FDA. However, the FDA can always estimate that it is not truthful and misleading¹²².

C. Enforcement and Non-compliance

In a case of non-compliance with the law, different actions can be taken by the FDA, the Federal Trade Commission (FTC), the consumers and competitors.

When food companies do not comply with the regulations, the FDA can issue warning letters. As a second step, the FDA has the power to impose fines and other civil penalties, like product seizure. Court injunctions are also possible. Very often, if the claim is criticized by the FDA, food manufacturers voluntarily withdraw the controversial claim. This is what happened in 2009 when the FDA sent a warning letter to General Mills because the statement on its Cheerios label indicated ‘*clinically proven to help lower cholesterol*’, making the product a drug under federal law¹²³. Another example was the Kellogg’s Cocoa Krispies case. Since 2009, Kellogg indicated on the package ‘*Now helps support your child’s immunity*’,

¹²⁰ FDA website, <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>

¹²¹ FDA, “Claims that can be made for Conventional Foods and Dietary Supplements”, September 2003, available at <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>

¹²² 21 C.F.R. §101.14; FDA website,

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm> and <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>

¹²³ FDA website, <http://www.fda.gov/iceci/enforcementactions/warningletters/ucm162943.htm>; The Wall Street Journal website, “Cheerios’ Health Claims Break Rules, FDA says”, 13 May 2009, available at <http://online.wsj.com/article/SB124216077825612187.html>

provoking a lot of criticism. This was a health claim that required FDA approval. Furthermore, there was no evidence that the Krispies would improve children's immune status. In response, Kellogg's announced to delete the claim.

In this field, the US FTC has an important role. The FTC is a federal agency that polices false, misleading and unsubstantial claims. For instance, the FTC issued a complaint against Kellogg Company for a false claim that indicated '*Clinically shown to improve kids' attentiveness by nearly...20%*' on the Kellogg's Frosted Mini-Wheats cereal¹²⁴. Another case was about the Activia products of Dannon. The labels displayed that Activia '*Helps strengthen your body's defenses immunity*'. The FTC ruled that Dannon did not have adequate scientific evidence to support its claims. In 2009, Dannon agreed for a settlement with the FTC, and paid \$21 million to the states to settle the charges¹²⁵.

Independently, or in addition to the actions of the regulatory authorities, consumers also have the right to react in case of infringements. Most of the time, the lawsuits occur in the form of class actions. Class actions are governed by Federal Rules of Civil Procedure Rule 23 and 28 U.S.C.A. §1332(d). This Rule is an "opt out" process, which means that the decision shall take effect with respect to all members of the class (even those who did not formally intervene in the proceedings), except of those who express their desire to be excluded. Nutritional allegation related class actions multiplied over the last years, and the phenomenon "has even risen dramatically over the past few years"¹²⁶. The causes of actions invoked by the consumers are multiple: unlawful, unfair, or fraudulent practices, namely misleading and deceptive advertising and methods of competition, or breach of an implied warranty of merchantability¹²⁷. Consumers' groups (as the Center for Science in the Public interest) are involved in some of the class actions.¹²⁸

¹²⁴ In the Matter of Kellogg Company, a corporation, FTC, WL 2402679, Docket n° C-4262, July 2009; FTC website, <http://www.ftc.gov/os/caselist/0823145/100602kelloggorder.pdf>

¹²⁵ Agreement containing consent order, FTC, n° 082 3158, available at <http://www.ftc.gov/os/caselist/0823158/101215dannonagree.pdf>; DICKERSON B.E., "Recent developments in food and drug law: Leading lawyers on dealing with increased enforcement, keeping up-to-date with FDA requirements, and developing compliance practices", *Aspatore*, 2011, p. 3.

¹²⁶ M. J. O'FLAHERTY, "Class Action Consumer Litigation : A Rising Enforcement Risk for Aggressive Food Labeling Claims", 2 October 2012, available at <http://agfdablog.com/2012/10/02/class-action-consumer-litigation-a-rising-enforcement-risk-for-aggressive-food-labeling-claims/> ; A.B. ENDRES, N.R. JOHNSON, M.N. TARR, "United States food law update: health care reform, preemption, labeling claims and unpaid interns: the latest battles in food law", *Journal of Food Law & Policy*, Fall 2010, p. 322.

¹²⁷ M. J. O'FLAHERTY, "Class Action Consumer Litigation : A Rising Enforcement Risk for Aggressive Food Labeling Claims", *op. cit.*

¹²⁸ *Id.*

For example, a class action still in progress against Kellogg Company started in 2010 in the California federal district court. The action concerned the claims present on the Kellogg's Nutri-Grain bars: *'Excellent Source of Calcium'*, *'More of the Whole Grains Your Body Needs'*. Plaintiffs claimed that the packaging deceptively mislead consumers because the Nutri-Grain bars contain trans-fats that increase the risk of heart disease and cancer. Kellogg Company dismissed the class action¹²⁹. Similarly, a class action has been inspired by California mums against Nutella which alleged that it *'contributes to a tasty yet balanced breakfast'*¹³⁰. Nutella agreed to a 3 million settlement in 2012¹³¹.

Over the last years, yogurt companies have increasingly alleged health benefits of probiotic ingredients in their products. In parallel with the action of the FTC, a class action has also been launched against the claim on Activia and condemned Dannon¹³². In 2009, a class action was started against Yoplait in Florida¹³³. Yoplait Yo-Plus yogurt labels contained the statements: *'Helps Naturally Regulate DIGESTIVE HEALTH with Optibalance'*, *'Try it 10 Days and See How Different You Feel!'* and *'Yo-Plus special formulation helps keep your digestive system on the right track'*. A settlement was reached after more than 3 years. In February 2013, General Mills (Yoplait) agreed to pay \$8,5 million to settle the suits launched in Florida, California, Ohio and New Jersey.

4. Overview of the International Context

A. WTO Obligations and International Trade

The US was the first to adopt a regulatory framework concerning nutrition and health claims, followed by the European Union. Today, the approaches of the EU and the US are converging. This is due to the common increasing concerns of consumers but also to the trade between the two entities and the international regulation.

¹²⁹ Foodnavigator website, "Nutri-Grain legal challenge has 'no merit' says Kellogg", 4 February 2010, available at <http://www.foodnavigator-usa.com/Business/Nutri-Grain-legal-challenge-has-no-merit-says-Kellogg>

¹³⁰ In re Ferrero Litigation, 278 F.R.D. 552 (S.D. California 2011).

¹³¹ The Globe and Mail website, "Nutella backs off 'balanced breakfast' claims after hit with \$3 million lawsuit", 27 April 2012, available at <http://www.theglobeandmail.com/news/world/nutella-backs-off-balanced-breakfast-claims-after-hit-with-3-million-lawsuit/article4103025/>; ABCnews website, "Nutella: Consumer Class Action Settlement", 29 April 2012, available at <http://abcnews.go.com/blogs/business/2012/04/nutella-consumer-class-action-settlement/>

¹³² *Wiener et al. v. Dannon Company*, 255 F.R.D. 658 (C.D. California 2009).

¹³³ *Fitzpatrick v. General Mills*, 263 F.R.D. 687 (S.D. Florida 2010).

WTO agreements (e.g. the Agreement on Technical Barriers to Trade) prohibit measures that constitute an obstacle to global free trade. The risk of constituting such an obstacle is limited for nutrition and health claims. However, to facilitate trade between two countries and to avoid discrimination of products, it might be preferable to have similar regulations. Indeed, in a context where food circulates freely all over the world, differences in labeling can be an obstacle. Huge multinational corporations such as Kellogg, General Mills or Dannon distribute their food in many continents. When distributing their food inside a country, they have to respect the legislation prevailing in this country, and, among other things, the labeling regulations. A global international harmonization could certainly be useful.

B. Codex Alimentarius

In 1963, the Food and Agriculture Organization and the WTO created the Codex Alimentarius Commission to develop food standard and guidelines. The purpose was to protect consumers, to ensure fair trade practices in the food trade, and to coordinate all the standards of international organizations. The Codex Alimentarius is thus a collection of guidelines, a code of practices relating to food, food production and food safety. One of the general standards concerns food labeling.

Codex Alimentarius guidelines exist for claims in general, but also for nutrition and health claims. Nutrition claims were regulated first; the health claims were added in 2004. These standards are based on two principles. First, a claim cannot be “described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect”¹³⁴. Second, the firm marketing the food should be able to justify the claims made¹³⁵. The guidelines prohibit some claims and authorize others under certain conditions¹³⁶. They also give a definition of nutrition and health claims.

A nutrition claim means any representation which states, suggests or implies that a food has a particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals¹³⁷.

¹³⁴ General Guidelines on Claims, Codex Guidelines 1/1979, art. 1, available at <http://www.codexalimentarius.org/standards/list-of-standards/>

¹³⁵ *Id.*, art. 1.

¹³⁶ *Id.*, art. 4 and 5.

¹³⁷ Codex Guidelines for use of nutrition and health claims, 23/1997 revised and amended, art. 2.1.

Authorized nutrient content claims, describing the level of a nutrient contained in the food, are listed and submitted to conditions¹³⁸.

Health claims are defined as any representation that states, suggest, or implies a relationship between a food and health. It includes nutrient function claims, other functions claims and reduction of disease claims¹³⁹.

Even if these international guidelines are not mandatory for the different states, most national governments take them into account. In order to avoid WTO disputes, it is important for the different countries over the world to adopt legislation similar to the international standard of the Codex Alimentarius. The WTO regularly makes reference to the Codex Alimentarius and the Resolution 39/248 of the United Nations encourages the States to transpose these standards in their domestic laws, where possible.

5. Comparison of the Regulations

A. Introduction

Both the EU and the US regulate nutrition and health claims. Their respective approaches present some discrepancies. In this part, the differences in the two regimes will be underlined. The comparison of regulations will open the door to some questions on the relevance of both regulations, and underline the need to examine the consumers' understanding of the nutrition and health claims.

B. Categories of Claims and Conditions

a. Categories of Claims

The categories of claims have not been established in the same way in the EU and in the US. The conditions under which a claim can be made vary depending on the category of claims. The consequence is that food manufacturers willing to make the same claim must respect different requirements depending on the place where they want to sell the product. One can also wonder if this difference in nutrition and health claim is relevant from the point of view of the consumers.

¹³⁸ *Id.*, art. 5.

¹³⁹ *Id.*, art. 2.2.

b. Claims Concerning Nutrition

While the EU deals with nutrition claims, the US speaks about nutrient content claims. Both categories are similar; they suggest that the food has benefits by characterizing the level of a particular nutrient. They can also in both cases be comparative.

EU and US regulators have established a list of nutrition claims. Having a list of authorized claims with clear conditions limits the flexibility of the food manufacturer and protects the consumers against misleading claims. The list avoids the abuse of such claims and the consumers can trust the claim and evaluate the product according to its needs. Here are the two lists compared:

	EU REGULATION	AMERICAN REGULATION
<i>FREE</i>	<i>Energy-free, Fat-free, Saturated Fat-free, Sugars-free, Sodium/salt-free, With no added sugars</i>	<i>Free of [fat, saturated fat, cholesterol, sodium, salt, sugars and calories]</i>
<i>LOW</i>	<i>Very low sodium/salt</i> <i>Low energy, Low fat, Low saturated fat, Low sugars, Low sodium/salt</i>	<i>Very Low in sodium</i> <i>Low in [fat, saturated fat, cholesterol, sodium and calories]</i>
<i>SOURCE</i>	<i>Source of fibre, Source of protein, Source of [name of vitamin/s] and/or [name of mineral/s]</i> <i>Contains [name of the nutrient or other substance], Source of omega-3 fatty acids</i>	<i>Good source of [a beneficial nutrient with a DV]</i>
<i>HIGH</i>	<i>High fibre, High protein, High [name of vitamin/s] and/or [name of mineral/s], High omega-3 fatty acids fat, High monounsaturated fat, High polyunsaturated fat, High unsaturated fat</i>	<i>High [a beneficial nutrient with a DV],</i>
<i>REDUCED</i>	<i>Energy-reduced, Reduced [name of the nutrient],</i> <i>Light/Lite</i>	<i>Reduced and Less in [fat, saturated fat, cholesterol, sodium, sugar and calories],</i> <i>Light [for fat or calories or in sodium]</i>
<i>INCREASED</i>	<i>Increased [name of the nutrient],</i>	<i>More of [a beneficial nutrient with a DV]</i>
<i>OTHER</i>	<i>Naturally/Natural</i>	<i>Lean and Extra Lean defined for meat, poultry, seafood, game meat and meal type products</i>

The two lists are broadly the same but present some differences. '*Free cholesterol*' is for instance a claim that is not authorized in the EU, contrary to the US¹⁴⁰. Synonyms of the core terms in the American list can be used. Also, the European Regulation states that other claims than those mentioned can be used if the claim is likely to have the same meaning for the consumers. But what kind of wording could have the same meaning for the consumers? One can wonder if it is not broader than what the regulators thought.

Conditions for making a nutrition claim are different depending on the regulation and a claim made in the EU has thus a different meaning than the identical claim made in the US. For instance, a product with '*Source of protein*' in the EU could not always bear the '*Source of protein*' claim in the US, and vice-versa. This claim can be made in the EU if at least 12% of the energy value of the food is provided by protein¹⁴¹. However, this claim is allowed in the US when proteins constitute 20% or more of the daily value per RACC¹⁴². This constitutes a problem for food manufacturers that want to sell their food in both the EU and the US.

A very popular claim currently does not appear in the American list, but it is present in the EU list: the mention '*Natural*'. While this mention is present everywhere in our supermarkets, its exact meaning is very difficult to define. In the EU '*Natural*' can be used as a prefix to the nutritional claim when a food meets the conditions laid down for the use of this nutritional claim¹⁴³. This mention is absent from the American list. It is not considered as a nutrient content claim and the FDA has no rules concerning this claim. There is no definition available. However, the claim '*Natural*' is authorized by the FDA. The FDA continues to judge these claims case-by-case¹⁴⁴. "[T]he agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances"¹⁴⁵. The absence of regulation poses problems. This allegation confuses the consumers and many class actions in California are filed under California's unfair competition law and the consumer Legal Remedies Act¹⁴⁶. Consumers reasonably expect that the food marker '*All natural*' for instance does not contain genetically modified ingredients or artificial ingredients. This is why class actions have been launched against the '*All natural*' labeled products as the Tostitos and

¹⁴⁰ 21 C.F.R. §101.62(d).

¹⁴¹ Regulation (EC) n° 1924/2006, Annex.

¹⁴² 21 C.F.R. §101.54(b).

¹⁴³ Regulation (EC) n° 1924/2006, Annex.

¹⁴⁴ IFT13 website, "Is there a definition for natural food?", June 2008, available at <http://www.am-fe.ift.org/cms/?pid=1000744>

¹⁴⁵ FDA website, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm>

¹⁴⁶ J. ECKHARDT, "No Slow Down to Class Action Lawsuits in California Regarding Food Labeling and Marketing", October 2011, available at <http://www.foodliabilitylaw.com/joseph-eckhardt.html>

SunChips Snacks of Frito-Lay's¹⁴⁷, products that are made with genetically modified ingredients¹⁴⁸. The FDA should then maybe regulate this claim to make it clear for the consumers, as well as the food manufacturers.

Another difference concerns the claim '*Healthy*'. It is considered as a health claim by the EU regulation. However, the FDA envisages this claim as an implied nutrient content claim. It can be used when the food is useful in creating a diet that is consistent with dietary recommendations if the food meets the conditions for total fat, saturated fat, cholesterol, and other nutrients¹⁴⁹.

c. Health Claims

The EU and the US have a different definition of health claims. While a health claim sets a relationship between a nutrient and the health in the EU, it establishes a link between a substance and a disease/related condition in the US.

The US make a distinction between function claims (and dietary statements) and health claims, while general functions claims are considered as health claims in the EU.

The significant consequence of this difference is that function/structure claims (and dietary statements) are not submitted to FDA authorization as the health claims, according to the American regulation. This distinction can be criticized because the difference between a function/structure claim and a health claim is often subtle. "For example, companies cannot state without prior FDA approval that a nutrient in a food 'may help reduce the risk of heart disease', but they can state without FDA approval that the nutrient 'helps maintain a healthy heart'"¹⁵⁰. Do the consumers make a difference between these claims? If not, the FDA should treat both claims with the same standards. The EU does not meet this problem to the same extent since the authorized function claims are listed, and the other health claims (new function claims and claims related to a disease) are submitted to the control of the EFSA.

¹⁴⁷ The lawsuit is in process, and has been centralized in New York (In re: Frito-Lay North America, Inc. All Natural Litigation, WL 6554657, 2012).

¹⁴⁸ Natural Society website, "Lawsuit Slams "All Natural" Snack Makers for Containing Harmful GMO Ingredients", 31 January 2012, available at <http://naturalsociety.com/lawsuit-slams-all-natural-snack-makers-for-containing-harmful-gmo-ingredients/>; American Bar Association website, "Confusion in Court over "All Natural"", 30 April 2012, available at <http://apps.americanbar.org/litigation/committees/classactions/articles/spring2012-0412-all-natural-labels-mean-marketing.html>

¹⁴⁹ 21 C.F.R. §101.65(d)(2).

¹⁵⁰ B. SILVERGLADE, I.R. HELLER, *Food Labeling Chaos. The case for reform*, *op. cit.*, part VI.1.

This difference also creates a trade problem when the US wants to export to the EU. The majority of function/structure claims are considered as unsubstantiated in the EU¹⁵¹. “Scores of products sold in the US feature claims EU regulators believe are not supported by science”¹⁵². The scientific assessment of the EFSA is the highest possible substantiation standard and health claims in the EU have to be proven in healthy persons via clinical trials.

Which category choice should be preferred? The point of view of the consumers will be studied later on. From an international trade perspective, the EU system is closer to the Guidelines of the codex Alimentarius than the American system. The guidelines have established the same categories of claims. However, “the EU regulation goes into far more detail on what can constitute a legitimate claim, and in particular, the type of procedure involved in substantiating claims made”¹⁵³. To facilitate trade with other countries, it is always preferable to follow the international standards. For this reason, the EU system of categories can be considered as preferable.

C. Enforcement and Non-Compliance

a. Competent Authority

In the US, monitoring takes place at the federal level. The FDA and the FTC can sue food companies in case of infringement. In the EU, the Member States are responsible for controlling whether food manufacturers comply with the regulation. Actions can be taken by the authorities competent for this matter. For instance, in Belgium, the authorities that can intervene in case of infraction are the Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA) and the SPF Economie¹⁵⁴. For a question of efficiency, it seems better that this monitoring remains at the State Members level.

¹⁵¹ Nutraingredients website, “US structure/function claims under scrutiny as EFSA ups the ante”, September 2011, available at <http://www.nutraingredients-usa.com/Regulation/US-structure-function-claims-under-scrutiny-as-EFSA-ups-the-ante>

¹⁵² J.M. HOSKIN, “Contrasts and similarities: structure-function claims in the US and EU. Pros and cons for regulators, industry, and customers”, Regional Symposium 2012, document available at http://www.cfs.gov.hk/english/rc/sci_events/files/Symposium_2012/Symposium_2012_Free_Paper_3.pdf

¹⁵³ C. MCMAOLAIN, *EU Food Law-Protection Consumers and Health in a Common Market*, Portland, Hart Publishing, 2007, pp. 226-227.

¹⁵⁴ Two other instances are also competent : the Direction générale du Contrôle et de la Médiation du SPF Economie, and the Agence Fédérale des Médicaments et des Produits de Santé ; SPF website, <http://www.health.belgium.be/eportal/foodsafety/advertising/index.htm?fodnlang=fr>

b. Class Actions

A huge difference lies in the actions available to the consumers. The US authorizes that a large group of people collectively bring a claim to court.

A class action has the advantage, or disadvantage, to be easily within reach of the consumers. If a class action is launched against a food company, it is mentioned on different sites. For instance, the website “Top Class Action” allows starting a Class Action or filling a claim form easily¹⁵⁵. On such sites, the consumers that bought the controversial product within the period during which the claim was made are encouraged to fill out a claim form. No proof that they bought the product is required. It suffices to download the form and indicate name, address and the number of products purchased in the period in question. Furthermore, a paragraph “Certification” has to be signed. For instance, the certification paragraph can mention “I certify that I purchase the number of jars of Nutella indicated on the Claim Form above during the period January 1, 2008 to February 3, 2012”¹⁵⁶. Sometimes, it is clearly indicated how much you can gain. For the Cocoa Krispies of Kellogg, “You can get \$5 per box you bought, up to 3 boxes per household”¹⁵⁷. This procedure renders filing a claim really easy for consumers, some would argue even too easy.

This class action phenomenon also influences the European Union. Numerous Member States have introduced collective redress systems after 2000 (Denmark, Finland, Netherlands, Sweden, etc). In 2009, Italy for instance adopted a class action law which allows class actions of consumers against a private corporation, in particular in case of unfair or anticompetitive commercial practices¹⁵⁸. This class action is different from the US class action because it only binds those that opt in to the claim (opt-in law). In many other Member States, the question is regularly rising. A similar reform is envisaged in France, UK and Germany. For instance, in France, with the change of majority in 2012, the question of introducing class actions into French law is debated again¹⁵⁹.

¹⁵⁵ <http://www.topclassactions.com>

¹⁵⁶ <https://nutellaactionsettlement.com>

¹⁵⁷ <http://consumerist.com/2011/06/27/get-15-in-rice-krispies-cereal-class-action>

¹⁵⁸ Art. 140bis of the Italian Consumer Code; PRINCIPE G., “Italian class actions. An update”, March 2012, document available at

<http://globalclassactions.stanford.edu/sites/default/files/documents/Italian%20Class%20Actions%20Principe.pdf>

¹⁵⁹ European Parliament, “Overview of existing collective redress schemes in EU Member States”, July 2011, document available at

<http://www.europarl.europa.eu/document/activities/cont/201107/20110715ATT24242/20110715ATT24242EN.pdf>

Anyway, the principle remains that class actions are not authorized in the European Union. In case of infringement, the association of consumers will represent the collective interests of the consumers of the Member States (e.g. Association Test-Achat in Belgium).

Should the Member States introduce the class action process into their law? A class action can be particularly efficient in case of misleading claims on a product's label. It would be easier for consumers to assert their rights. Most often, consumers do not endure a damage that is sufficiently significant to launch a lawsuit individually. A class action system could also dissuade food manufacturers to make false claims. However, one can argue that this system is not necessary in the EU. The Member States have in general a legislation that is more protective of consumers than the legislation in the US. This reduces the risk of infringement. Alternative consumer protection procedures function efficiently. Moreover, the grounds of the class actions can be contested. The fact that consumers can recover the amount of the product supposes they bought the product only because it presented a claim and because they trusted the claim. In reality, do the consumers trust the claims, and are they influenced by them when purchasing? This will be examined later on when reviewing the scientific studies.

c. Actions of the Competitors

Beside the action of the authorities, consumers and associations, competitors can also have an interest in the withdrawal of a claim. Indeed, misleading labeling can cause damages to competitors since the labeled product would be more attractive to the consumers. In the EU, as in the US, a competitor can always invoke the regulation when another food manufacturer indicates non authorized or misleading nutrition and health claims on its products. The regulations protect thus the food manufacturers themselves.

D. Nutrition Information

Currently in the EU, the nutrition information is only mandatory when a nutrition or health claim is made. It will become mandatory in any case at the end of 2016. This change can only be encouraged since it promotes the right to know to which extent nutrients are present in our food.

In the US, nutrition information is mandatory on food labels, whether making a claim or not. The nutrition information is uniformed since 1973. Voluntary at that time, it became mandatory in 1990, likely because the federal government turned very concerned by

increasing obesity in the country. The nutrition labeling is a part of a larger fight against obesity and diet-related diseases. In 2009-2010, more than one third of adults and almost 17% of youth were obese in the US¹⁶⁰. The US pushed the EU to adopt a nutritional labeling. According to the European Commission, between 10% and 30% of EU adults are obese¹⁶¹. One can wonder if nutrition information can contribute to reducing the amount of overweight people.

E. Conclusion

Both regulations are protective of consumers. Because all nutrition and health claims have to be authorized before being made, the EU system is even more protective of the consumer rights. This is not the case in the US, where function/structure claims can be made without prior control. The consequence is that manufacturers continue to make misleading claims. This, in combination with the consumers' increasing awareness and interest, has caused numerous important lawsuits over the last years.

The advantages of a strict regulation are evident from the point of view of the consumer protection. It also protects the competitors of food manufacturers deciding to make nutrition or health claims. But what about the food manufacturers that make such claims? The EU regulation has been criticized "for potentially putting small operators to great expense in order to be able to produce the data necessary to substantiate claims that they may wish to make about their food products"¹⁶². The costs of the scientific substantiation process in the EU have been estimated to range between €4.51 to €7.65 million¹⁶³. On average, making a demand for a claim costs approximately €980 to €1,663 (for a general function claim), and €6,750 for a health claim¹⁶⁴. This cost is substantive for small manufacturers. However, nutrition and health claims regulations also present benefits for food manufacturers. A system of prior authorization provides for legal certainty to food manufacturers themselves. The problem of costs does not manifest itself when there is a list of authorized claims with the requirements. Food manufacturers know exactly which claim they can display on their products.

¹⁶⁰ Centers for Disease Control and Prevention website, <http://www.cdc.gov/nchs/data/databriefs/db82.htm>

¹⁶¹ European Commission, Strategy for Europe on nutrition, overweight and obesity related health issues – Implementation Progress Report 2010, Brussels, 2010.

¹⁶² C. MCMAOLAIN, *EU Food Law-Protection Consumers and Health in a Common Market*, op. cit., p. 230.

¹⁶³ G. BROOKES, "Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU Food Supplement Sector and Market. European Health Claim Alliance", GBC Ltd., UK, 2010.

¹⁶⁴ *Id.*, p. 8.

With these regulations, if well implemented and enforced, consumers can trust the nutrition and health claims present on food labeling. The consumer should, however, remain critical towards the allegations. Even the chips and ice-cream are labeled as '*Light*', these products still contain many calories. The nutritional information should be taken into account.

Similarly, consumers also have to keep in mind that claims are not mandatory and that food manufacturers decide if they place a claim or not. Some products do not mention nutrition or health claims, even if they could. It is then possible that a product that mention '*Low fat*' contains more fat than a similar product that does not mention anything. The consumer should then not limit himself to look at the front of package, and should always investigate the nutrition labeling.

Different questions have been raised in this part that necessitate the examination of the consumers' attitudes towards nutrition and health claims.

Part III. Scientific research over the consumer's attitudes towards nutrition and health claims

1. Introduction

The principal goal of the examined regulations is to offer the consumer reliable, comprehensive and clear information about food. The consumer is the main stakeholder in the regulations. Bringing the law into line with consumers' needs and expectations is essential. But are the nutrition and health claims regulations in accordance with the perception of the consumers? How do the consumers in reality understand and react to nutrition and health claims? Do they understand the differences between the different categories of claims? Do they trust them? Which factors intervene in the understanding process? Regulators, because they also want to promote public health by authorizing health claims, as well as food manufacturers, have to know which types of claim are better understood by the consumers.

Different scientific research has been conducted all over the world in order to study consumers' attitudes towards nutrition and health claims. The matter is very complex and the existing research is not sufficient. Consumers do not constitute a homogeneous group and multiple factors (linked to the individual consumer or to the product and claim) influence the way the consumers look at food labeling and perceive the information featured by nutrition and health claims. This will affect the understanding of the claim, the perception of the product and purchasing attitudes.

The scientific research conducted in this field is reviewed below. This part will only concern an overview of the results of the studies. This will allow us to criticize afterwards the regulation and some already underlined differences between the European and American regulations according to their relevance for the consumers.

2. Review of the studies

A. Consumer Interest in Food Labeling

Before examining the understanding of the claim, it is important to know whether consumers look at the label of a product and read it before buying it. A majority of consumers looks at food labeling. In the US, only 5% of the respondents admit that they do not look at

any information¹⁶⁵. However, this varies according to the socio-demographic characteristics of the consumers (cf. below).

Many consumers limit their information gathering to the front-label¹⁶⁶. Nutrition information, which appears often on the back of the packaging, is perceived as too complicated by many consumers and is thus neglected¹⁶⁷. People who do not look at the label invoke a lack of time, familiarity with the product, the format of the label or the small text¹⁶⁸. Yet, nutrition information helps people who read it to eat healthier, and to lose weight¹⁶⁹.

It has longtime been sustained that nutrition and health claims do not have an impact on whether consumers investigate nutrition information or not¹⁷⁰. However, an in-store study showed that consumers tend to abbreviate their search behavior when a nutrition health claim is present, ignoring the nutrition fact information¹⁷¹.

B. Perception of the Claim Depending on the Consumer-Related Variables

Socio-demographic characteristics such as gender, age, marital status and education influence the consumer's perception of food claims¹⁷².

Women, especially with a high socio-economic status, pay more attention to a healthy diet¹⁷³. They are more familiar with the health effects of some nutrients such as fibers and antioxidants¹⁷⁴. This might be attributed to the feeling they have to be responsible for the

¹⁶⁵ Food Standards Agency, Review and Analysis of Current Literature on Consumer Understanding of Nutrition and Health Claims Made on Food, 2007, London, p. 13, citing the 2004 research of Institute of Grocery Distribution, available at <http://www.food.gov.uk.proxy.bib.ucl.ac.be:888/multimedia/pdfs/healthclaims.pdf>

¹⁶⁶ A.S. LEVY, S.B. FEIN, Consumers' ability to perform tasks using nutrition labels, *Journal of Nutrition Education* 30(4), 1998, pp. 210–217.

¹⁶⁷ P.G. WILLIAMS, Consumer understanding and use of health claims for foods, *Nutrition Reviews* 63(7), 2005, p. 258.

¹⁶⁸ Food Standards Agency, Review and Analysis of Current Literature on Consumer Understanding of Nutrition and Health Claims Made on Food, 2007, London, p. 12.

¹⁶⁹ It has been shown that women who look at the nutrition information weigh nearly 9 pounds less than those who do not: M.L. LOUREIRO, S.T. YEN, R.M. NAYGA, The effects of nutritional labels on obesity, *Agricultural economics* 43(3), 2012, pp. 333–342.

¹⁷⁰ G.T. FORD, M. HASTAK, A. MITRA, D. J. RINGOLD, Can consumers interpret nutrition information in the presence of health claim? A Laboratory investigation, *Journal of publicity &Marketing* 15, 1996, pp. 16–27.

¹⁷¹ B. ROE, A.S. LEVY, and B.M. DERBY, The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data, *Journal of Public Policy & Marketing* 18 (1), 1999, pp. 89–105.

¹⁷² G. NOCELLA, O. KENNEDY, Food health claims – What consumers understand, *Food Policy* 37(5), October 2012, p. 573; G. ARES, A. GÁMBARO, Influence of gender, age and motives underlying food choice on perceived healthiness and willingness to try functional foods, *Appetite* 49(1), 2007, pp. 148–158.

¹⁷³ J. BOGUE, T. COLEMAN, D. SORENSON, Determinants of consumers' dietary behaviour for health-enhancing foods, *British Food Journal* 107, 2005, pp. 4–16.

¹⁷⁴ G. ARES, A. GIMÉNEZ, A. GÁMBARO, Consumer perceived healthiness and willingness to try functional milk desserts. Influence of ingredient, ingredient name and health claim, *Food Quality and Preference* 20, 2009, pp. 50–56.

well-being of the family¹⁷⁵. Women perceive more benefits specific to products with general health claims, while men perceive more benefits specific to products with specific health claims¹⁷⁶. The different perception between women and men depends also on the particular combinations between the carrier product, the alleged benefits and the nutrients¹⁷⁷. Moreover, due to the fact that the risks of disease increase with the age, middle-aged and elderly consumers are more attracted by reduction of disease risk claims¹⁷⁸. The level of education of the consumers is another factor¹⁷⁹. Well educated consumers know more about the relationship diet-disease and better understand such claims¹⁸⁰.

The number of people concerned by and interested in what they eat increases, because there is a growing awareness that an appropriate diet can contribute to reduce the risk of certain diseases¹⁸¹. Nonetheless, the knowledge of nutritional information still greatly varies amongst consumers¹⁸². The level of nutrition knowledge influences the ability to interpret the meaning of nutrient and relationships¹⁸³, the understanding of the claim and the intention to purchase the product¹⁸⁴. Studies are not unanimous on the extent of the impact of the nutrition knowledge on the perception of the claims by the consumer¹⁸⁵. Ares et al. related that strong knowledge encourages people to try food that offers certain benefits (e.g. more fibres)¹⁸⁶ and Lalor et al. demonstrated that higher levels of nutrition knowledge have the consequence of reducing the trust in health claims¹⁸⁷. Deeper studies should be conducted in this area that take

¹⁷⁵ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 573.

¹⁷⁶ M. DEAN, R. SHEPHERD, A. ARVOLA et al., Consumer perceptions of healthy cereal products and production methods, *J. Cereal. Sci.* 46, 2007, pp. 188–196.

¹⁷⁷ W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, Consumer appeal of nutrition and health claims in three existing product concepts, *Appetite* 52, 2009, p. 686.

¹⁷⁸ G. NOCELLA, O. KENNEDY, *op.cit.*, 2012, p. 573; ARES G., GIMÉNEZ A., GÁMBARO A., *op. cit.*, 2009, p. 51.

¹⁷⁹ H.C.M. VAN TRIJP, I.A. VAN DER LANS, Consumer perceptions of nutrition and health claims, *Appetite* 48(3), May 2007, p. 319.

¹⁸⁰ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 573.

¹⁸¹ *Id.*

¹⁸² R. BRENNAN, B. CZARNECKA, S. DAHL, L. EAGLE, O. MOUROTI, Regulation of nutrition and health claims in advertising, *Journal of Advertising Research* 1, 2008, pp. 57–70.

¹⁸³ Food Standards Agency, Review and Analysis of Current Literature on Consumer Understanding of Nutrition and Health Claims Made on Food, 2007, London, <http://www.food.gov.uk/multimedia/pdfs/healthclaims.pdf>

¹⁸⁴ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574; M. DEAN, P. LAMPILA, R. SHEPHERD, A. ARVOLA, A. SABA, M. VASSALLO, E. CLAUPEIN, M. WINKELMANN, L. LAHTEENMAKI, Perceived relevance and foods with health-related claims, *Food Quality and Preference* 24, 2012, p. 132.

¹⁸⁵ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, Symposium 2: Nutrition and health claims: Help or hindrance: European consumers and health claims: Attitudes, understanding and purchasing behavior, *Proceedings of the Nutrition Society* 71(2), 2012, p. 233.

¹⁸⁶ G. ARES, A. GIMENEZ, A. GAMBARO, Influence of nutritional knowledge on perceived healthiness and willingness to try functional foods, *Appetite* 51, 2008, pp. 663–668. This has also been reported by W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, Consumer appeal of nutrition and health claims in three existing product concepts, *Appetite* 52, 2009, pp. 684–692.

¹⁸⁷ F. LALOR, J. KENNEDY, P. WALL, The impact, among third-level students, of nutrition knowledge on behavior towards products with health claims. *Proc. Nutr. Soc.* 68, 2009, E131.

into account the multiple other variables. In any case, nutritional education should be reinforced and the role of educators, consumer's groups, food manufacturers (through their publicity), and regulatory agencies is essential¹⁸⁸.

Besides the socio-demographic criteria and the nutritional knowledge, personal beliefs in the positive relationship between the diet and health influences the consumer behavior are another important factor¹⁸⁹. A claim that constitutes a particular relevance for a consumer having a special motivation has more consumer appeal¹⁹⁰. Indeed, the personal need to pay attention to health has an important impact on how the consumer considers the product bearing the claim¹⁹¹. Positive disposition also occurs when a relative or friend is affected by the related condition, but to a lesser extent¹⁹².

The familiarity that the consumer has with the product influences consumers' attitudes. Respondents in a study that have already used the carrier product before find health claims more attractive and convincing, and express their intention to use them more in the future¹⁹³. The previous experience with the functional ingredient and the health claims in question also plays a role in the consumer's acceptance of the product¹⁹⁴.

C. Perceptions of the claims depending on the product and claim variables

The second kind of variables is related to the product and the way information is communicated. The carrier product, the format and terminology of the claim and the allaged benefits are the most important criteria.

¹⁸⁸ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574.

¹⁸⁹ W. VERBEKE, J. SCHOLDERER, L. LÄHTENMÄKI, Consumer appeal of nutrition and health claims in three existing product concepts, *Appetite* 52, 2009, p. 686.

¹⁹⁰ E. VAN KLEEF, H.C. VAN TRIJP, P. LUNING, Functional foods: Health claim-food product compatibility and the impact of health claim framing on consumer evaluation, *Appetite* 44, 2005, p. 304; W. VERBEKE, J. SCHOLDERER, L. LÄHTENMÄKI, *op. cit.*, 2009, p. 686; M. DEAN, R. SHEPHERD, A. ARVOLA et al., *op. cit.*, 2007, p. 195; P.D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, Consumer understanding of nutrition and health claims: source of evidence, *British Journal of Nutrition* 98, 2007, p. 476.

¹⁹¹ M. DEAN, R. SHEPHERD, A. ARVOLA et al., *op. cit.*, 2007, p. 190.

¹⁹² F. LALOR, C. MADDEN, K. MCKENZIE et al., Health claims on foodstuffs: A focus group study of consumer attitudes, *J. Funct. Foods* 3, 2011, pp. 56–59; M. DEAN, P. LAMPILA, R. SHEPHERD, A. ARVOLA, A. SABA, M. VASSALLO, E. CLAUPEIN, M. WINKELMANN, L. LAHTENMAKI, *op. cit.*, 2012, pp. 129–135.

¹⁹³ W. VERBEKE, J. SCHOLDERER, L. LÄHTENMÄKI, *op. cit.*, 2009, p. 689; J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 233.

¹⁹⁴ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 233.

a. Carrier Product

It is well established that the perception of the claims largely depends on the base product, the category of product carrying the claim (e.g. yoghurt)¹⁹⁵. The carrier product has the largest impact on consumers' perception of healthiness and willingness to try the product¹⁹⁶. If the base product or ingredient is healthy, the claim will be more credible and better perceived¹⁹⁷. Hence, certain categories of food are more appropriate to carry health claims and certain combinations of food product-claims are preferred depending on the country¹⁹⁸.

b. Format of the Claim

Preformatted claims authorized by the authorities, especially the disease-risk reduction claims, are sometimes long and precise in order to avoid being misleading. Does this length influence the consumers' understanding? The results of the study led by Wansink *et al.* showed that short claims on front label generate more attribute-specific thoughts and stronger favorable beliefs towards the product than longer claims¹⁹⁹. Short claims are thus more understandable by the consumers and help to communicate beneficial aspects of the product²⁰⁰. This research confirms other studies claiming that short claims on the front label generate a more believable and positive image in the consumer's mind²⁰¹. This preference for short claims is not homogeneous. The research of Grunert *et al.* conducted in North European countries showed that there exists another group of consumers that prefers more detailed information on health claims²⁰².

¹⁹⁵ T. BECH-LARSEN, K.G. GRUNERT, The perceived healthiness of functional foods: A conjoint study of Danish, Finnish and American consumers' perception of functional foods, *Appetite* 40, 2003, pp. 9-14

¹⁹⁶ G. ARES, A. GÁMBARO, Influence of gender, age and motives underlying food choice on perceived healthiness and willingness to try functional foods, *Appetite* 49(1), 2007, pp. 148-158.

¹⁹⁷ G. ARES, A. GÁMBARO, *op. cit.*, 2007, p. 667; E. VAN KLEEF, H.C.M. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299-308.

¹⁹⁸ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 231; LÄHTEENMÄKI, P. LAMPILA, K. GRUNERT, Y. BOZTUG, Ø. UELAND, Impact of health-related claims on the perception of other product attributes, *Food Policy* 35, 2010, pp. 230-239; E. VAN KLEEF, H.C.M. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299-308; A. SABA, M. VASSALLO, R. SHEPHERD *et al.*, Countrywise differences in perception of health-related messages in cereal-based food products, *Food Qual. Prefer.* 21, 2010, pp. 385-393.

¹⁹⁹ B. WANSINK, S.T. SONKA, and C.M. HASLER, Front-Label Health Claims: When Less is More, *Food Policy* 29(6), December 2004, pp. 659-667.

²⁰⁰ B. WANSINK, S. T. SONKA, and C.M. HASLER, *op. cit.*, 2004, p. 665.

²⁰¹ L. SINGER, P.G. WILLIAMS, L. RIDGES, S. MURRAY, A. MCMAHON, Consumer reactions to different health claim formats on food labels, *Food Australia* 58(3), 2006, pp. 92-97.

²⁰² K.G. GRUNERT, L. LÄHTEENMÄKI, Y. BOZTUG *et al.*, Perception of health claims among nordic consumers, *J. Consum. Policy* 32, 2009, pp. 269-287.

As label inspection remains limited to the front-label package, the best way to satisfy the different group of consumers would be to state a short claim on the front-package, with more detailed information appearing elsewhere (on the back)²⁰³. Split claims have been proved to produce more positive responses and to create a higher level of satisfaction and a greater trust in the claim²⁰⁴.

The research underlines that policy-makers should take these preferences into account to accomplish their purposes of consumer education, and when dressing a list of authorized claims²⁰⁵. In the US, the authorized claims are sometimes very long and complex. Food manufacturers have interest in putting the claims on the front of the package and in using simpler wording. However, they have to keep in mind that the presence of too much information on the package can confuse consumers²⁰⁶.

c. Types of Health Claims, Alleged Benefits, and Country

The framing in which the claim is communicated influences the understanding of the claim. Certain kinds of claims are better perceived depending on the type of benefit associated and the country where they are made. This is a fact relevant for food manufacturers and for regulators as well.

The importance of this frame was demonstrated in the study of van Trijp and van der Lans, directed in four countries (UK, Italy, Germany and US)²⁰⁷. Different types of claims were used in this study: nutrient content claim, function claim, disease-risk reduction claim, taste claim and marketing claim. Six health benefits were claimed for each claim type: cardiovascular disease, stress, infections, fatigue, overweight and concentration²⁰⁸.

The results showed that the understanding differs substantially by type of the alleged benefits, but much less by various claims types. Consumers do not distinguish the subtle

²⁰³ B. ROE, A.S. LEVY, B.M. DERBY, The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data, *Journal of Public Policy and Marketing* 18(1), 1999, pp. 89–105.

²⁰⁴ B. WANSINK, S.T. SONKA, and C.M. HASLER, *op. cit.*, 2004, pp. 659-667; L. SINGER, P.G. WILLIAMS, L. RIDGES, S. MURRAY, A. MCMAHON, Consumer reactions to different health claim formats on food labels, *Food Australia* 58(3), 2006, pp. 92-97; WILLIAMS P.G., *op. cit.*, 2005, pp. 256-264.

²⁰⁵ B. WANSINK, S.T. SONKA, C.M. HASLER, *op. cit.*, 2004, p. 665.

²⁰⁶ H.C.M. VAN TRIJP, I.A. VAN DER LANS, Consumer perceptions of nutrition and health claims, *Appetite* 48(3), May 2007, p. 319; B. WANSINK, How do front and back package labels influence beliefs about health claims?, *Journal of Consumer Affairs* 37, 2003, pp. 305–316.

²⁰⁷ H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op. cit.*, 2007, p. 319.

²⁰⁸ *Id.*

differences between the types of health claims²⁰⁹. “Apparently for consumers it is more about the benefit (health) than about the precise way in which it is delivered”²¹⁰. This study confirms other studies having concluded that consumers do not make clear distinctions between nutrition content claims, structure-function claims, and health claims²¹¹. Nutrient content claims have been said to have similar effects to health claims²¹².

If the distinction between the diverse type claims is not clear in the mind of the consumers, some claims can confuse them more than others. Nutrition claims seem to be better understood than health claims²¹³. This may be because these claims are communicated in a simpler wording, facilitating the understanding²¹⁴. However, concerning the preference, studies all over the world concluded that consumers prefer health claims to content claims²¹⁵. Also, disease-risk reduction claims would lead to a higher purchase intention than function claims, because the alleged benefits of these claims are preferred²¹⁶. However, according to other studies, consumers prefer general mentions of health benefits rather than specific claims concerning reduction of disease-risk with alarming warning and words. Disease-risk reduction claims are perceived as less friendly towards consumers²¹⁷. Consumers do not like alarming words such as “cancer” and they prefer function claims. There is thus unanimity among the studies about this point. Nonetheless, disease-risk reduction claims are more attractive and convincing for the consumers with a personally relevant health problem, than for the others²¹⁸. Anyway, the consumer impact of one or the other claim type would be greatly depending on the alleged benefits²¹⁹.

The claim type does not make a relevant difference. However, the understanding of the claim varies substantially with the benefit being claimed and the interaction between benefit and country”²²⁰.

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ P.G. WILLIAMS, *op. cit.*, 2005, p. 262; H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op. cit.*, pp. 306-324.

²¹² B. ROE, A.S. LEVY, B.M. DERBY, The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data, *Journal of Public Policy and Marketing* 18(1), 1999, p. 99.

²¹³ EdComs, Review and analysis of current literature on consumer understanding of nutrition and health claims made on food, 2007, p. 24.

²¹⁴ D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, *op. cit.*, p. 478.

²¹⁵ WILLIAMS P.G., *op. cit.*, 2005, p. 258.

²¹⁶ E. VAN KLEEF, H.C.M. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299-308.

²¹⁷ P.G. WILLIAMS, *op. cit.*, pp. 256-264

²¹⁸ E. VAN KLEEF, H.C.M. VAN TRIJP, P. LUNING, *op. cit.*, 2005, p. 307.

²¹⁹ E. VAN KLEEF, H.C. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299-308.

²²⁰ H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op. cit.*, 2007, p. 318.

Depending on the benefit claimed, the perception of the claim is different. For instance, claims on weight and concentration are more easily understood than cardiovascular disease claims²²¹. The combination of the benefit with the claim type is important²²². It does not seem to be contested that certain benefits interact better with certain claim types. Certain combinations are better understood and perceived by the consumer than others. This is something that manufacturers should verify when making a claim²²³.

The understanding and preference in benefits also varies to a large extent among the studied countries²²⁴. Health claims are regulated differently in different countries, and are still prohibited in many countries. Cultural differences and the fact that consumers are differently exposed to health claims explain the difference in understanding and preference²²⁵. Thus, disease related claims are better understood by Americans than by Europeans, and the American consumers differentiate comparatively more between both kinds of claims. This “may be explained by American consumers having experience of both types of claims, whereas EU consumers only have marginal experience of physiological claims and not at all of prevention claims”²²⁶. This explains the presence of numerous disease-risk reduction claims on the American cereals. Yet, it was also shown that American consumers do not differentiate between function claims and disease-risk reduction claims²²⁷.

Differences do not only exist between the US and the EU. Even inside the EU, the understanding of the claims differs per country²²⁸. For instance, compared to taste claims, nutrition and health claims are more difficult to understand in the UK and the US than in Italy and Germany²²⁹. Also, while 60% of the respondents in a study in Germany said they understood a claim on a probiotic yogurt, this proportion raise to 25% in Spain²³⁰. Particularly in Belgium, health claims are perceived as more convincing and more attractive than nutrition claims, but there would exist no difference concerning the intention to buy²³¹.

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*, pp. 305-324.

²²⁴ *Id.*

²²⁵ P.G. WILLIAMS, *op. cit.*, 2005, p. 258.

²²⁶ T. BECH-LARSEN, K.G. GRUNERT, *op. cit.*, 2003, p. 13.

²²⁷ K.R. FRANCE, P.F. BONE, Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Label, *Journal of Consumers Affairs* 39 n°1, 2005, pp. 27-51.

²²⁸ H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op. cit.*, 2007, p. 313.

²²⁹ *Id.*, p. 318.

²³⁰ *Id.*, p. 313.

²³¹ W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, *op. cit.*, 2009, p. 688.

D. Consumer's Perception of the Credibility of the Claim

Food policy-makers assume that the consumers trust the claims since they want to protect them against misleading claims. Actually, there is a high level of skepticism among the consumers towards the credibility of the nutrition and health claims²³². Consumers consider the claims as sales tools used by the manufacturers²³³. This can be explained by the lack of trustful information²³⁴. However, when the nutrition information is confirmed by an independent and trusted body, the claim is perceived as more believable²³⁵. For instance, in the UK, a heart leading charity approved the heart benefits alleged on 100% wholegrain breakfast, which results in a better perception of the claim by the consumers²³⁶. The credibility also increases when the messages are frequently repeated by trusted sources²³⁷.

The credibility of the nutrition and health claims differs by alleged benefits and by country²³⁸. "On average, the infections and weight claims are more credible than claims for other benefits"²³⁹. The type claim can also have an impact on the credibility. Content claims that mention the particular ingredient responsible for the benefit are generally more credible and convincing²⁴⁰. Also, consumers rely more on the nutrition panel than on health claims²⁴¹. The choice of the carrier product influences the trust of the consumers as well²⁴².

In general, consumers strongly think that claims should be allowed by government authorities²⁴³. This is not always the case; function claims in the US do not have to be authorized in order to be made. The role of educators is here important in order to reinforce the trust in the claims.

²³² P.G. WILLIAMS, *op. cit.*, 2005, p. 259; W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, *op. cit.*, 2009, p. 686; G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 577.

²³³ P.G. WILLIAMS, *op. cit.*, p. 259.

²³⁴ W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, *op. cit.*, 2009, p. 686

²³⁵ P.D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, Consumer understanding of nutrition and health claims: source of evidence, *British Journal of Nutrition* 98, 2007, p. 477.

²³⁶ *Id.*

²³⁷ P.G. WILLIAMS, Consumer understanding and use of health claims for foods, *Nutrition Reviews* 63(7), 2005, p. 259; National Consumer Council, Messages on food consumer's use and understanding of health claims on food packs, London, 1997.

²³⁸ H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op.cit.*, 2007, p. 318.

²³⁹ *Id.*

²⁴⁰ H.C.M. VAN TRIJP, I.A. VAN DER LANS, *op.cit.*, 2007, p. 318; C.M. HASLER, Health claims in the United States: An aid to the public or a source of confusion?, *J. Nutr.* 138, 2008, p. 1219S, available at http://comenius.susqu.edu/biol/010/tobinjanzen/healthclaimsintheunitedstatesanaidtothepublicorasourceofconfusion_sol2012.pdf ; W. VERBEKE, J. SCHOLDERER, L. LÄHTEENMÄKI, *op. cit.*, 2009, pp. 684–692.

²⁴¹ J.A. GARRETSON and S. BURTON, Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease-related risks, and trust, *Journal of Public Policy & Marketing* 19(2), 2000, pp. 213-227.

²⁴² J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, pp. 229-236.

²⁴³ P.G. WILLIAMS, *op. cit.*, 2005, p. 259.

E. Consumer's Understanding of the Scientific Evidence of Health Claims

As seen in the second part about the US regulations, there exist different levels of scientific evidence of health claims. This categorization is deemed to be clear for consumer. However, a study showed that respondents were not able to range the claims in the four levels (A, B, C and D)²⁴⁴. Also, consumers do not make the difference between qualified and non-qualified health claims where a disclaimer is used²⁴⁵. The disclaimers, having a role of information of a lack of scientific evidence, do thus not diminish the expectations of the consumers towards the benefits of the health claims²⁴⁶. It is thus very difficult to communicate the strength of the science supporting the claim to consumers²⁴⁷.

F. Consumer's Perception of the Product

In general, the presence of a nutrition health claim increases the perceived healthiness of the product, but some studies showed the opposite²⁴⁸. As for understanding of the claim, the perceived overall healthiness differs substantially by benefits and country, but not by claim type. Both physiological claims (structure/function) and disease-risk reduction claims have a positive influence on consumer's perception of the healthiness of foods²⁴⁹. However, as for the perception of the claim, the overall healthiness perceived from certain benefits claim is affected by the relation benefits-claim type²⁵⁰.

The perception of the product depends on how the consumers understand the claim. According to an American study, more than one fifth of respondents did not notice that a

²⁴⁴ W.R. KAPSAK, D. SCHMIDT, N.M. CHILDS, J. MEUNIER, C. WHITE, Consumer perceptions of graded, graphic and text label presentations for qualified health claims, *Critical Reviews in Food Science and Nutrition* 48, 2008, pp. 248–256.

²⁴⁵ FDA website, <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>

²⁴⁶ B.M. DERBY, A.S. LEVY, Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Working Paper No. 1, Center of Food Safety and Applied Nutrition – US Food and Drugs Administration, September 2005, p. 34, available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>; K.R. FRANCE and P.F. BONE, Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Label, *Journal of Consumers Affairs* 39 n°1, 2005, pp. 27-51; N.H. HOOKER, R.P. TERATANAVAT, Qualified Health Claims, FDA Public Meeting, Assessing Consumers' Perceptions of Health Claims, 2005, available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>; W.R. KAPSAK, D. SCHMIDT, N.M. CHILDS, J. MEUNIER, C. WHITE, Consumer perceptions of graded, graphic and text label presentations for qualified health claims, *Critical Reviews in Food Science and Nutrition* 48, 2008, pp. 248–256.

²⁴⁷ B.M. DERBY, A.S. LEVY, Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Working Paper No. 1, Center of Food Safety and Applied Nutrition – US Food and Drugs Administration, September 2005, p. 34, available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>

²⁴⁸ L. LÄHTEENMÄKI, P. LAMPILA, K. GRUNERT, Y. BOZTUG, Ø. UELAND, Impact of health-related claims on the perception of other product attributes, *Food Policy* 35, 2010, pp. 230–239.

²⁴⁹ T. BECH-LARSEN, K.G. GRUNERT, *op. cit.*, 2003, p. 12.

²⁵⁰ H.C.M. VAN TRUIP, I.A. VAN DER LANS, *op. cit.*, 2007, p. 317.

product had any health benefits, even when it carried an explicit claim²⁵¹. As showed, consumers sometimes do not understand or interpret the claim very well. This results in some bias²⁵².

The first bias is known as the “halo effect”. Consumers rate the product higher on attributes not mentioned in the claim²⁵³. The phenomenon occurs even when warning statements about risk-increasing nutrients appear on the label²⁵⁴. A significant proportion of the consumers overlook the statement in the presence of a health claim²⁵⁵. Due to the halo effect, ‘*Low cholesterol*’ claim may lead consumers to extend the positive perception to the level of fat and to believe that the product contains low fat²⁵⁶. Lähteenmäki moderated this effect by demonstrating that the halo effect can be negative when consumers are confronted with ingredients and benefits new for them²⁵⁷.

Another effect of the claim on the product’s perception is the called “magic bullet” effect. It means that consumers attribute inappropriate health benefits to the product²⁵⁸. For instance, consumers may deduct from a ‘*Low cholesterol*’ claim that the product will help against cardio-vascular disease²⁵⁹.

The overgeneralization phenomenon is restricted to the non-featured nutrient content and not to the disease risks possibilities²⁶⁰.

²⁵¹ P.G. WILLIAMS, Can health claims for food help consumers choose better diets?, *CML – Clinical Nutrition* 15(2), 2006, pp. 25–30.

²⁵² E. VAN KLEEF, H.C.M. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299–308; H.C.M. VAN TRIJP, I.A. VAN DER LANS, Consumer perceptions of nutrition and health claims, *Appetite* 48, 2007, pp. 305–324; D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, *op. cit.*, p. 479.

²⁵³ J.C. ANDREWS, R.G. NETEMEYER, S. BURTON, Consumer generalization of nutrient content claims in advertising, *Journal of Marketing* 62, 1998, pp. 62–75; G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574; H.C.M. VAN TRIJP, I. A. VAN DER LANS, *op. cit.*, 2007, p. 324; W.R. KAPSAK, D. SCHMIDT, N.M. CHILDS, J. MEUNIER, C. WHITE, Consumer perceptions of graded, graphic and text label presentations for qualified health claims, *Critical Reviews in Food Science and Nutrition* 48, 2008, pp. 248–256.

²⁵⁴ D. MURPHY, T. HOPPCOCK, M. RUSK, Generic Copy Test of Food Health Claims in Advertising. Washington, DC: Federal Trade Commission, 1998, available at <http://www.ftc.gov/opa/1998/11/food.shtm>

²⁵⁵ *Id.*

²⁵⁶ H.C.M. VAN TRIJP, I. A. VAN DER LANS, *op. cit.*, 2007, p. 324; G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574.

²⁵⁷ L. LÄHTEENMÄKI, P. LAMPILA, K. GRUNERT, Y. BOZTUG, Ø. UELAND, Impact of health-related claims on the perception of other product attributes, *Food Policy* 35, 2010, pp. 230–239.

²⁵⁸ B. ROE, A.S. LEVY, and B.M. DERBY, *op. cit.*, 1999, pp. 89–105.

²⁵⁹ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574.

²⁶⁰ D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, *op. cit.*, 2007, p. 479. J.C. ANDREWS, S. BURTON, R.G. NETEMEYER, Are some comparative nutrition claims misleading? The role of nutrition knowledge, and claim type and disclosure conditions, *Journal of Advertising* 29, 2000, pp. 29–43.

G. Influence of Nutrition and Health Claims on the Consumers Purchase Choice of Food Products

Consumers consider the healthiness of a food product to be an important factor contributing to their food choice²⁶¹. As mentioned, consumers' perceptions of healthiness depend on multiple variables. The link between the perceived healthiness and the intention to buy the product is not so clear. In general, researchers recognize the positive impact of health claims on the intention to try the product²⁶². However, there is no real agreement on the extent of the influence of the claims on the final purchase choice.

Reports of marketers relate that health messages influence purchase choices of one-third of consumers at best²⁶³. Consumers admit that they are influenced by such claims and that they sometimes purchase product because of the alleged benefits. "When a product features a health or content claim, respondents view the product as healthier and state they are more likely to purchase it, independent of their information search behavior²⁶⁴". Studies related that people are maybe more willing to avoid a negative outcome than gaining a benefit²⁶⁵. The lack of clarity among the studies can be explained by the existence of multiple variables influencing consumers' choices.

The intention to buy functional food largely depends on the nutritional quality of the base product, the relevance, and the familiarity that the consumer has with it²⁶⁶. "[P]eople are unlikely to buy a new type of product because of a claim"²⁶⁷. Specific carrier-ingredient

²⁶¹ K.G. GRUNERT, Food quality and safety: Consumer perception and demand, *Eur. Rev. Agric. Econ.* 32, 2005, pp. 369-391; A. KRYSTALLIS, G. MAGLARAS, and S. MAMALIS, Motivations and cognitive structures of consumers in their purchasing of functional foods, *Food Qual. Prefer.* 19, 2008, pp. 525-538.

²⁶² E. VAN KLEEF, H.C. VAN TRIJP, P. LUNING, *op. cit.*, 2005, p. 302; M. DEAN, P. LAMPILA, R. SHEPHERD, A. ARVOLA, A. SABA, M. VASSALLO, E. CLAUPEIN, M. WINKELMANN, L. LAHTENMAKI, *op. cit.*, 2012, pp. 129-135.

²⁶³ P.G. WILLIAMS, *op. cit.*, 2005, p. 257.

²⁶⁴ B. ROE, A.S. LEVY, B.M. DERBY, *op. cit.*, 1999, p. 99.

²⁶⁵ L. LÄHTENMÄKI, Claiming health in food products, *Food Quality and Preference*, 2013, p. 107.

²⁶⁶ T. BECH-LARSEN, K.G. GRUNERT, *op. cit.*, 2003, p. 10; J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 234; A.S. LEVY, B.M. DERBY, B. ROE, Consumer Impacts of Health Claims: An Experimental Study, Washington, DC: Center for Food Safety and Applied Nutrition, 1997; G. ARES, A. GÁMBARO, Influence of gender, age and motives underlying food choice on perceived healthiness and willingness to try functional foods, *Appetite* 49(1), 2007, pp. 148-158; E. VAN KLEEF, H.C. VAN TRIJP, P. LUNING, *op. cit.*, 2005, pp. 299-308; M. DEAN, P. LAMPILA, R. SHEPHERD, A. ARVOLA, A. SABA, M. VASSALLO, E. CLAUPEIN, M. WINKELMANN, L. LAHTENMAKI, *op. cit.*, 2012, pp. 129-135; J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 234.

²⁶⁷ P.G. WILLIAMS, *op. cit.*, 2005, p. 259.

combinations influence the willingness to try the products²⁶⁸. The willingness to try a functional product is also driven by its attractiveness, the credibility and the uniqueness²⁶⁹.

There is a paradox in the purchase behavior of consumers. Consumers purchase food with nutrition and health claims even when they think the claim is not trustworthy. In a study of the CRIOC in Belgium²⁷⁰, 78% of the respondents are aware that the claims could be unfounded, and 52% say they are influenced when purchasing²⁷¹. The same consumers thinking that the nutrition and health claims are not always true admit that they prefer to buy products with such claims.

The real consumers' behavior in a supermarket does not always correspond to what respondents and participants report in surveys when they advance their intention to buy²⁷². According to sales data, the presence of health claims on a product can increase the consumption of the product compared to a situation in which no claims was made²⁷³.

Finally, the impact of nutrition and health claims on purchase behavior cannot be overestimated. On their own, health claims are not sufficient to guarantee the success of a product²⁷⁴. Other more relevant elements are taken into account when purchasing a product. The taste, brand, price, attractiveness and packaging are elements that remain more important than nutrition and health claims when taking the decision to purchase²⁷⁵. Thus, consumers are not ready to compromise taste to try food bearing health claims²⁷⁶. However, the consumers with a general interest in health are inclined to compromise the taste for the alleged

²⁶⁸ E. VAN KLEEF, H.C. VAN TRIJP, P. LUNING, *op. cit.*, 2005, p. 302.

²⁶⁹ *Id.*

²⁷⁰ The CRIOC is the Belgian Centre de recherche et d'information des organisations de consommateurs.

²⁷¹ Communication de l'Education permanente du Ministère de la Communauté Française, La santé fait vendre, document available at <http://www.questionsante.be/outils/alicaments.pdf>

²⁷² P.G. WILLIAMS, *op. cit.*, 2005, p. 260.

²⁷³ L. MARQUART, K. WEIMER, B. JACOB, Solid science and effective marketing of health claims, *Nutrition Today* 36, 2001, pp. 107-111.

²⁷⁴ P.G. WILLIAMS, *op. cit.*, 2005, p. 261.

²⁷⁵ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, Symposium 2: Nutrition and health claims: Help or hindrance: European consumers and health claims: Attitudes, understanding and purchasing behavior, *Proceedings of the Nutrition Society* 71(2), May 2012, p. 230; G. ARES, A. GIMÉNEZ and R. DELIZA, Influence of three non-sensory factors on consumer choice of functional yogurts over regular ones, *Food Qual. Prefer.* 21, 2010, pp. 361-367.

²⁷⁶ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 232; VERBEKE W., Functional foods: Consumer willingness to compromise on taste for health?, *Food Qual. Prefer.* 17, 2006, pp. 126-131.

benefits²⁷⁷. Other factors involved in the final consumer choices are the habits and the personal relevance²⁷⁸.

H. Conclusion

Consumer's perceptions, understanding, attitudes towards nutrition and health claims depend on numerous determinants, and factors influencing consumer's food choices are multiple. There exist different consumer segments and a study in a certain country does not necessary hold in another one. This explains the contradictions between the studies, and their limitations. Most of them have only investigated a few of the variables²⁷⁹.

Hence, there is still a lot of work to do in this field to determine to which extent the consumers are influenced by the nutrition and health claims. Further studies are necessary that incorporate different variables and examine consumers' perception in terms of percentage and proportion²⁸⁰. This need has been underlined in the majority of the analyzed research reviews. Additional studies are also necessary due to the fact that our nutritional knowledge and claims understanding evolves. Studies concerning consumers' behaviors should be regularly renewed and regulators should follow this evolution.

²⁷⁷ S. SABBE, W. VERBEKE, R. DELIZA et al., Effect of a health claim and personal characteristics on consumer acceptance of fruit juices with different concentrations of açai, (*Euterpe oleracea* Mart.), *Appetite* 53 (1), 2009, pp. 84–92.

²⁷⁸ J.M. WILLS, S. STORCKSDIECK GENANNT BONSMANN, M. KOLKA, K.G. GRUNERT, *op. cit.*, 2012, p. 234.

²⁷⁹ *Id.*

²⁸⁰ The study of van Trijp and van der Land is a good example of a study including multiple variables, but the application field of the study is limited to a particular product (yogurt).

Part IV. Relevance of the regulations

1. Introduction

Some issues about the relevance of the regulations were raised in the second part of this paper. Differences between the two regulations mainly concern the established categories of claims, the absence of prior authorization for function claims in the US, and the possibility of a class action in the US. These issues and differences can be examined from the point of view of the consumer attitudes towards nutrition and health claims. Since the consumer's attitudes have been analyzed in the third part of this paper, the relevance of some points of the regulations can now be discussed.

2. The Authorization of Food Claims

It has been shown that consumers do not understand claims very well and that claims do not constitute one of the most important criteria that they take into account when purchasing food products. Added to the fact that there is a risk of misleading consumers, one can wonder if it would not be better to forbid health claims in general. Many countries continue to prohibit health claims or at least reduction of disease risk claims²⁸¹. Both the EU and US decided to authorize and regulate them.

Authorizing nutrition and health claims presents benefits to both manufacturers and consumers. The food manufacturers' interests are clear since claims partially contribute to the final purchase choice of the consumers. But food manufacturers are not the only group involved in nutrition and health claims. Studies have demonstrated that consumers have a particular interest in healthy food products. Health claims play a minor role in their final decision, but are still an element that can help consumers to make an informed choice. Moreover, it has been proved consistently that health claims contribute to the nutritional education of consumers by improving nutrition awareness and better food selection²⁸². A study showed that the American consumers' knowledge of the fiber-cancer relationship increased after the dissemination of so-labeled All-Bran products in the US, which caused the appearance of new high-fiber products on the market²⁸³. Nutrition and health claims can thus

²⁸¹ P.G. WILLIAMS, *op. cit.*, 2005, p. 256.

²⁸² *Id.*

²⁸³ P. IPPOLITO, A. MATHIOS, Health claims on food marketing: evidence on knowledge and behavior in the cereal market, *Journal of Public Policy and Marketing* 10, 1991, pp. 15-32; G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 574; P.G. WILLIAMS, *op. cit.*, 2005, p. 261.

increase competition and constitute an incentive for the food manufacturers to offer healthy food, which is beneficial for the consumers.

Nutrition and health claims should therefore remain allowed, but still in a framework that allows the consumers to trust the alleged benefits. The intervention of regulators should not be limited to controlling the claims, but to encourage accurate, pertinent and comprehensive health claims.

3. Differences of Receptiveness Between the Countries

The receptiveness of the different kinds of claims and the preferences in the alleged benefits differs by country. Adopting a binding international law is thus not desirable, since it will be extremely difficult to incorporate the consumers' attitudes towards food claims into the law. EU policy-makers should also consider this disparity and freedom should be allowed to the Member States in terms of health education. Additional voluntary education could be particularly relevant in a state if it responds to particular needs of the population.

4. Nutrition Information

Many consumers do not look at the nutritional table. Moreover, it seems that health claims may discourage consumers to look for further information in the nutrition facts. They would look at the nutrition facts more often if there was no claim. Yet, under the actual EU regulation, nutrition information is mandatory only if nutrition or health claims are present. This constitutes an inappropriate discrepancy made by the EU policy-maker. The new Regulation 1169/2011 (making the nutrition information mandatory) can only be welcomed, even if the proportion of consumers that look at the nutrition information is limited²⁸⁴.

5. The “Average Consumer” in the EU Regulation

The EU Regulation 1924/2006 uses the concept of “average consumer”. It is defined in the preamble as a consumer that is reasonably well-informed, reasonable observant and circumspect taking into account social, cultural and linguistic factors²⁸⁵. The use of nutrition and health claims shall only be permitted if the average consumer can be expected to

²⁸⁴ G. COWBURN, L. STOCKLEY, Consumer understanding and use of nutrition labelling: a systematic review, *Public Health Nutrition* 8, 2004, pp. 21–28

²⁸⁵ Regulation n°1924/2006, Preamble 16.

understand the beneficial effects as expressed in the claim²⁸⁶. One of the conditions under which a health claim can be made is that it should be well understood by the average consumer²⁸⁷. However, it is not clear to which extent the “average consumer” can be expected to understand them²⁸⁸. Some specific health claims only are useful for a very small part of the population²⁸⁹. “For a health claim applying only to a specific group of intended consumers defined by their health status, their lifestyle or their socio-demographic status, these are the only ones likely to be ‘reasonably well informed’ on the benefits expressed in the claim”²⁹⁰.

The EU policy-makers should take this into account when regulating this matter and should proceed to a segmentation of the consumers. As Nocella, Kennedy and Leathwood *et al.* propose, policy-makers should refer to the “intended consumer”, the consumer that is looking for specific benefits in health claims in order to satisfy its particular needs²⁹¹. Disease-related claims are particularly relevant for a particular group of people. Focus on the intended or targeted consumers necessitates further qualitative research²⁹².

Again, education is very important in order to give sense to the image of the average consumer and to help people to make their choices.

6. Different Kinds of Claims in Regulations

The EU and US regulators have made a regulation based on the different category of claims. Each kind of claim must comply with particular conditions.

This discrepancy is reflected to a larger extent in the US. Function claims are not submitted to the FDA control, but health claim (related to a disease) are. Consumers do not clearly distinguish both types. Having two different types of claims is thus too confusing and the FDA should treat both claims in the same manner. Function claims should meet the same standards as health claims, and be authorized before appearing on the labels. The Center for

²⁸⁶ Regulation n°1924/2006, art. 5.2.

²⁸⁷ Regulation n°1924/2006, art. 13.1.

²⁸⁸ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, p. 572

²⁸⁹ K.G. GRUNERT, J. SCHOLDERER, M. ROGEAUX, Determinants of consumer understanding of health claims. *Appetite* 56, 2011, pp. 269–277.

²⁹⁰ P.D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, Consumer understanding of nutrition and health claims: source of evidence, *British Journal of Nutrition* 98, 2007, pp. 474–484.

²⁹¹ G. NOCELLA, O. KENNEDY, *op. cit.*, 2012, pp. 571–580.

²⁹² D. LEATHWOOD, D.P. RICHARDSON, P. STRÄTER, P.M. TODD, C.M. VAN TRIJP, *op. cit.*, 2007, p. 482.

Science in the Public Interest agrees with this²⁹³. American regulators should take this into account by standardizing the differences in the conditions.

The EU regulation is not really concerned by this issue since authorized claims are listed. The problem arises in the other direction. Health claims on reduction of disease risk are still submitted to a strict and costly process. Since it does not guarantee that it will be relevant for a large amount of consumers, food manufacturers can be discouraged to introduce such claims, to the dismay of those for which these claims are particularly relevant. This may be one of the reasons why disease related claims are almost nonexistent in our supermarkets.

As the type of claim does not strongly affect consumer appeal, the question of the relevance of the current regulatory framework can be raised. All the claims should be treated in the same way. The best way is to have a general list of authorized claims.

7. Bias

Due to misunderstanding, consumers may overgeneralize claims by perceiving the other components or the product as healthier. In the EU, food should respect a nutrient profile in order to be allowed to bear any claims. This would attenuate the bias. Nonetheless, these nutrient profiles have not been established yet. Food with a high level of salt can still claim a low level of fat for instance. In the US, some claims can only appear with a disclosure if the food does not comply with some prescribed levels. Regulators could take into account this overgeneralization process more, which might always be reduced by clear disclosures indicating the level of the other nutrients.

8. Class Actions

Class actions allow consumers to be reimbursed if the claim alleging benefits was not true or misleading. However, a majority of consumers do not trust claims and health claims are only one small element in the flurry of criteria that influence food choices. The purchase of the product was not only justified by the presence of the health claim. Did the consumers that complain buy the food because of the claim? Can they be misled if they don't trust the claim? Or can they be misled because they did not understand the claim? As a consequence, the justification of such a legal action is not so obvious. How can one justify that all consumers can recover the money of their purchase? The form to fill out for participation in a

²⁹³ B. SILVERGLADE, I.R. HELLER, *Food Labeling Chaos. The case for reform*, Center for Science in the Public Interest, 2010, part VI.9.

class action does not ask if the consumer has been misled by the claim. It is thus easy to participate in class actions for people who were not really misled. This might lead us to think that the actions of federal authorities or consumers associations could be more appropriate and justifiable than a class actions system where consumers can be reimbursed according to their number of bought boxes.

9. Scientific Evidence Level

As already mentioned, there exist various levels of scientific evidence in the US regulations. The consumers do not make a difference between the A, B, C and D levels. However, this is important, since the requirements are different depending on the level. How to make this clear for consumers? A solution could be to provide visual aids, such as report cards that express explicitly the level of scientific evidence²⁹⁴.

The EU is currently not concerned by this issue, because there is no such distinguishing in the scientific evidence. Nonetheless, it could be interesting to mention the scientific evidence of the claim to reinforce the trust the consumers can have towards the claim. Since they are true and not misleading, they should be trusted. So far, it is not clear whether or not consumers are aware of this control.

10. Influence of Nutrition and Health Claims on Diet

Consumers might expect from product labels displaying nutrition and health claims that the products in question have a good impact of their health. But is this so in reality?

The misunderstanding of the consumers can lead them not to use the product adequately. Actually, claims as '*Light*' and '*Low fat*' can have a perverse effect on consumers.

According to the EU regulation, a '*Low fat*' claim is authorized in the EU when the product contains no more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100 ml for

²⁹⁴ B.M. DERBY, A.S. LEVY, Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Working Paper No. 1, Center of Food Safety and Applied Nutrition – US Food and Drugs Administration, September 2005, p. 34, available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>; N.H. HOOKER, R.P. TERATANAVAT, Qualified Health Claims, FDA Public Meeting, Assessing Consumers' Perceptions of Health Claims, 2005, Available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>; W.R. KAPSAK, D. SCHMIDT, N.M. CHILDS, J. MEUNIER, C. WHITE, *op. cit.*, 2008, pp. 248–256.

liquids²⁹⁵. This claim is allowed to appear in the US when the product contains 3 g or less per reference amount customarily consumed²⁹⁶.

Consumers eat in greater quantity (about 50% more) a food product when the product is labeled '*Low fat*'. Brian Wansink and Pierre Chandon, in their study led in the US, analyzed how '*Low fat*' nutrition claims may influence food consumption²⁹⁷. The authors advance two reasons of this influence: '*low fat*' claims increase perceptions of the appropriate serving size and reduce anticipated consumption guilt²⁹⁸. In order to arrive to this conclusion, scientists concluded three studies. The first study shows that all people, and particularly those who are overweight, eat more calories of snack food when it is labeled as '*low fat*' than when it is labeled as '*regular*'²⁹⁹. "Study 2 shows that low-fat nutrition claims lead all consumers in a lab to increase the amount they believe to be an appropriate serving size, regardless of whether the snack is relatively hedonic (chocolate candies) or relatively utilitarian (granola). It further demonstrates that low-fat claims reduce guilt, especially for people who are overweight. Study 3 shows how relative nutrition claims and objective serving-size information jointly influence the consumption of granola by overweight and normal-weight moviegoers"³⁰⁰.

The same reasoning could be applied for the claim '*Light*'. This allegation can appear in the EU when the reduction in content is at least 30%, compared to a similar product. In the US, '*Light*' means that the product contains at least 33% fewer calories or 50% less fat than a similar food. This mention does not mean that the product contain a few calories; it works by comparison. '*Light*' can as such be present on strongly caloric products as ice-cream, chips, or butter labels.

What can the EU policy-makers do to change this? Should they prohibit these kinds of claims? Anyways, this would not settle the problem of misunderstanding and misinterpretation of nutrition and health claims. Regulators have to take into account consumer's behavior but they cannot totally replace the role of nutritional educators. Regulators can try to make the nutrition information more visible. The voluntary traffic-light

²⁹⁵ Regulation (EC) n° 1924/2006, Annex.

²⁹⁶ C.F.R. §101.62(b)(2).

²⁹⁷ B. WANSINK, P. CHANDON, Can "Low Fat" Nutrition Labels Lead to Obesity?, *Journal of Marketing Research*, Vol. XLIII, November 2006, pp. 605-617, available at http://foodpsychology.cornell.edu/pdf/permission/2006/LowFat-JMR_2006.pdf

²⁹⁸ *Id.*

²⁹⁹ *Id.*, pp. 605-606.

³⁰⁰ *Id.*

systems launched for instance in UK could indicate the high level of a nutrient still present in a '*Light*' labeled food³⁰¹. Moreover, the Green Keyhole in Sweden that requires food “to fulfill certain nutrient profiling criteria before being eligible to carry the logo on pack” could also help the consumers.

³⁰¹ In the traffic-light system, the level of fat, saturates, sugar and salt is indicated by a color. Red indicates a high level, orange a medium level and green a low level of the nutrient in the food.

CONCLUSION

We are strongly exposed to nutrition and health related claims on product labels in supermarkets in the EU and US. Nutrition claims appear to be more frequent than health claims. The fact that health claims are more recurrent on American food products can be explained by the difference in the regulations and in the consumer attitudes towards food claims.

As nutrition and health claims have an impact, be it limited, on the consumer's purchasing, it is necessary to regulate the conditions under which nutrition and health claims can be made³⁰². Regulators must find the proper balance between the promotion of healthy products and consumer protection. The EU and the US have adopted different rules and requirements for nutrition and health claims. With all these regulations, consumers should be able to assume that the claims are true. The EU law system is stricter than the American system and more protective of consumers. Categories of claims are clearer and all the claims, if not listed, have to be approved by the European authority. It is also more in line with the consumer perception of the claims and closer to the international standards. For all these reasons, the EU legislation is considered to be preferable in general.

One of the main issues resulting from this EU-US comparison and the review of the literature is the existence of different categories of claims understood similarly by the consumers. A list of function claims should be drawn up by the US regulators in order to attenuate this discrepancy. This might also reduce the number of lawsuits led in the US.

From their side, the EU regulators should find a nutrient profile system that is easily understood by the consumer. Scientific studies should precede the use of such a system to determine effective implementation. Moreover, for a more accurate legal language, EU policy-makers should replace the reference of the "average consumer" with the notion of "intended consumer".

This study has underlined the advantages of nutrition and health claims. They interest consumers that are looking for healthier products, but can also increase the market share of products and stimulate competition between the manufacturers. Food manufacturers should continue to promote the benefits of their products if they comply with the conditions for

³⁰² EdComs, Review and analysis of current literature on consumer understanding of nutrition and health claims made on food, 2007, p. 39.

making claims. The research mentioned in this study should inform manufacturers who seek to attract customers with nutrition and health claims. Displaying a claim is a significant investment for food manufacturers, and they should be knowledgeable of how consumers react to it and how effective it is. Generally, they should prefer short claims with simple wording, and an appropriate combination between benefit, type of claim and carrier product.

Consumer education remains essential. A public program of nutrition information is necessary to help consumers to better understand the claims and to make an informed choice. In particular, the importance of the nutrition facts must not be minimized.

Food claims are a matter affecting many disciplines: law, but also dietetics, psychology and marketing. This study was limited to examining the regulations on food claims and their relevance for the consumers. It focused mainly on the legal aspect, but it also incorporated the key elements of the other areas. Nonetheless, it would also be interesting to investigate further the other aspects of this matter.

Other legal questions about food labeling regulations could have been raised as well. Recent food scandals have shown that a strict regulation is not sufficient to protect the consumers and that the control of food labeling can be problematic. The exact composition of the food product is difficult to control, particularly in an international food market, where the traceability of food becomes cumbersome. This again demonstrates that adopting rules is not sufficient but that an effective control by the competent authorities is also essential.

BIBLIOGRAPHY

1. Legislation

a. European Law

- Directive 1979/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, *O.J.*, 1979, L. 33/1.
- Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising, *O.J.*, 19 September 1984, L. 250.
- Council Directive n° 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs, *O.J.E.C.*, 6 October 1990, L. 276.
- White Paper on Food Safety of the Commission of the European Communities, COM (1999) 719 final, 12 January 2000.
- Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, *O.J.U.E.*, 27 December 2006, L. 376.
- Consolidated version of the treaty establishing the European Community of 24 December 2006, *O.J.E.U.*, 29 December 2006, C. 321.
- Regulation (EC) n° 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, *O.J.E.U.*, 18 January 2007, L.12.
- Commission Regulation (EU) n°116/2010 of 9 February 2010 amending Regulation (EC) n°1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims, *O.J.E.U.*, 10 February 2010, L. 37/16.
- Regulation (EU) n°1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) n°1924/2006 and (EC) n°1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) n°608/2004, *O.J.E.U.*, 22 November 2011, L. 304.
- Commission Regulation (EU) n°432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health, *O.J.E.U.*, 25 May 2012, L. 136.

b. American Law

- Federal Food, Drug and Cosmetic Act (FDCA)
- Nutrition Labeling and Education Act

- Code of Federal Regulations: 21 C.F.R. §101.18; §101.13(b),(f), (h); §101.14; §101.54; §101.62(b),(e),(d); §101.65(d)(2); §101.72(e),(f); §101.73(e)(1); §101.75(e)(1); §101.76(e); §331; §343.
- Federal Rules of Civil Procedure Rule 23
- 28 U.S.C.A. §1332(d)

c. Others

- General Guidelines on Claims, Codex Guidelines 1/1979.
- Codex Guidelines for use of nutrition and health claims, 23/1997 revised and amended.
- Art. 140bis of the Italian Consumer Code

2. Doctrine

a. Books

- HOLLAND D., POPE H., *EU Food Law and Policy*, The Hague, Kluwer Law International, 2004.
- MCMAOLAIN C., *EU Food Law-Protection Consumers and Health in a Common Market*, Portland, Hart Publishing, 2007.
- O’ROURKE, *European Food Law*, 3rd Ed., London, Sweet and Maxwell, 2005.

b. Articles

- ALLEN D.M., “Validity, under Commerce Clause (Art I, § 8, Cl 3), of state statutes regulating labeling of food”, 79 *A.L.R. Fed.*, 1986, pp. 246-275.
- AUSTIN R.W., “The federal food legislation of 1938 and the food industry”, *Law and Contemporary problems*, 1939, pp.129-143, available at <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1942&context=lcp>
- BROOKES G., “Economic Impact Assessment of the European Union (EU)’s Nutrition & Health Claims Regulation on the EU Food Supplement Sector and Market. European Health Claim Alliance”, GBC Ltd., UK, 2010.
- BUREAU J.-C., VALCESCHINI E., “European Food-Labeling Policy: Successes and Limitations”, *Journal of Food Distribution Research* 34, November 2003, pp. 70-76.
- DICKERSON B.E., “Recent developments in food and drug law: Leading lawyers on dealing with increased enforcement, keeping up-to-date with FDA requirements, and developing compliance practices”, *Aspatore*, 2011, p. 3.
- EMORD J.W., “Pearson v. Shalala: The Beginning of the End for FDA Speech Suppression”, *Journal of Public Policy & Marketing* 19(1), Spring 2000, pp. 139-143, available at <http://www.jstor.org/stable/30000494>

- ENDRES A.B., JOHNSON N.R., TARR M.N., “United States food law update: health care reform, preemption, labeling claims and unpain interns: the latest battles in food law”, *Journal of Food Law & Policy*, Fall 2010, pp. 311-337.
- LEGAULT L., BRANDT M.B., MCCABE N., ADLER C., BROWN A.M., BRECHER S., “2000-2001 food label and package survey: an update on prevalence of nutrition labeling and claims on processed, packaged foods”, *J. Am. Diet Assoc.* 104(6), 2004, pp. 952-958.
- MCCOLL D.B., BUMP C.P., “Qualified Health Claims: Creatures of Case Law”, *FDLI*, November/December 2005, pp. 33-36, available at http://www.hpm.com/pdf/MCCOLL_BUMP.pdf
- ROWLANDS J. C., HOADLEY J. E., “FDA perspectives on health claims for food labels”, *Toxicology* 221, Elsevier, 2006, pp. 35-43.
- SILVERGLADE B.A., “The Nutrition Labeling and education Act-Progress to Date and Challenges for the Future”, *Journal of Public Policy & Marketing* 15(1), American Marketing Association, Spring 1996, pp. 148-150.
- SILVERGLADE B., HELLER I.R., *Food Labeling Chaos. The case for reform*, Center for Science in the Public Interest, 2010, part VI.1.
- Am. Jur. 2d, Commerce §11.

c. Studies and Reviews of studies

- ANDREWS J.C., NETEMEYER R.G., BURTON S., Consumer generalization of nutrient content claims in advertising, *Journal of Marketing* 62, 1998, pp. 62–75.
- ANDREWS J.C., BURTON S., NETEMEYER R.G., Are some comparative nutrition claims misleading? The role of nutrition knowledge, ad claim type and disclosure conditions, *Journal of Advertising* 29, 2000, pp. 29–43.
- ARES G., GÁMBARO A., Influence of gender, age and motives underlying food choice on perceived healthiness and willingness to try functional foods, *Appetite* 49(1), 2007, pp. 148–158.
- ARES G., GIMÉNEZ A., GÁMBARO A., Influence of nutritional knowledge on perceived healthiness and willingness to try functional foods, *Appetite* 51, 2008, pp. 663–668.
- ARES G., GIMÉNEZ A., GÁMBARO A., Consumer perceived healthiness and willingness to try functional milk desserts. Influence of ingredient, ingredient name and health claim, *Food Quality and Preference* 20, 2009, pp. 50–56.
- ARES G., GIMÉNEZ A. and DELIZA R., Influence of three non-sensory factors on consumer choice of functional yogurts over regular ones, *Food Qual. Prefer.* 21, 2010, pp. 361–367.
- BECH-LARSEN T., and GRUNERT K. G., The perceived healthiness of functional foods: A conjoint study of Danish, Finnish and American consumers’ perception of functional foods, *Appetite* 40, 2003, pp. 9-14.
- BOGUE J., COLEMAN T., SORENSON D., Determinants of consumers’ dietary behaviour for health-enhancing foods, *British Food Journal* 107, 2005, pp. 4–16.

- BRENNAN R., CZARNECKA B., DAHL S., EAGLE L., MOUROT O., Regulation of nutrition and health claims in advertising, *Journal of Advertising Research* 1, 2008, pp. 57–70.
- Communication de l'Education permanente du Ministère de la Communauté Française, La santé fait vendre, available at <http://www.questionsante.be/outils/aliments.pdf>
- COWBURN G., STOCKLEY L., Consumer understanding and use of nutrition labelling: a systematic review, *Public Health Nutrition* 8, 2004, pp. 21–28.
- DEAN M., SHEPHERD R., ARVOLA A., et al., Consumer perceptions of healthy cereal products and production methods, *J. Cereal. Sci.* 46, 2007, pp. 188–196.
- DEAN M., LAMPILA P., SHEPHERD R., ARVOLA A., SABA A., VASSALLO M., CLAUPEIN E., WINKELMANN M., LAHTENMAKI L., Perceived relevance and foods with health-related claims. *Food Quality and Preference* 24, 2012, pp. 129–135.
- DERBY B.M., LEVY A.S., Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims. Working Paper No. 1, Center of Food Safety and Applied Nutrition – US Food and Drugs Administration, September 2005, available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>
- EdComs, Review and analysis of current literature on consumer understanding of nutrition and health claims made on food, 2007.
- Food Standards Agency, Review and Analysis of Current Literature on Consumer Understanding of Nutrition and Health Claims Made on Food, 2007, London.
- FRANCE K.R., BONE P.F., Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Label, *Journal of Consumers* 39 (1), 2005, pp. 27–51.
- GRUNERT K.G., LÄHTENMÄKI L., BOZTUG Y., et al., Perception of health claims among nordic consumers, *J Consum Policy* 32, 2009, pp.269–287.
- GRUNERT K.G., SCHOLDERER J., ROGEAUX M., Determinants of consumer understanding of health claims. *Appetite* 56, 2011, pp. 269–277.
- HOOKER N.H., TERATANAVAT R.P., Qualified Health Claims, FDA Public Meeting, Assessing Consumers' Perceptions of Health Claims, 2005, Available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>
- LÄHTENMÄKI, P. LAMPILA, K. GRUNERT, Y. BOZTUG, Ø. UELAND, Impact of health-related claims on the perception of other product attributes, *Food Policy* 35, 2010, pp. 230–239.
- LÄHTENMÄKI L., Claiming health in food products, *Food Quality and Preference*, 2013, pp. 106–201.
- LALOR F., KENNEDY J., WALL P., The impact, among third-level students, of nutrition knowledge on behavior towards products with health claims. *Proc. Nutr. Soc.* 68, 2009, E131.
- LALOR F., MADDEN C., MCKENZIE K. et al., Health claims on foodstuffs: A focus group study of consumer attitudes, *J. Funct. Foods* 3, 2011, pp. 56–59.

- LEATHWOOD P.D., RICHARDSON D.P., STRÄTER P., TODD P.M., VAN TRIJP C.M., Consumer understanding of nutrition and health claims: source of evidence, *British Journal of Nutrition* 98, 2007, pp. 474–484.
- LEVY A.S., FEIN S.B., Consumers' ability to perform tasks using nutrition labels, *Journal of Nutrition Education* 30, n°4, 1998, pp. 210–217.
- LOUREIRO M. L., YEN S. T., NAYGA R. M., The effects of nutritional labels on obesity, *Agricultural economics* 43(3), 2012, pp. 333–342.
- FORD G.T., HASTAK M., MITRA A., RINGOLD D. J., Can consumers interpret nutrition information in the presence of health claim? A Laboratory investigation, *Journal of publicity & Marketing* 15, 1996, pp. 16–27.
- GARRETSON J.A. and BURTON S., Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease-related risks, and trust, *Journal of Public Policy & Marketing* 19(2), 2000, pp. 213–227.
- GRUNERT K.G., Food quality and safety: Consumer perception and demand, *Eur. Rev. Agric. Econ.* 32, 2005, pp. 369–391;
- HASLER C.M., Health claims in the United States: An aid to the public or a source of confusion?, *J. Nutr.* 138, 2008, pp. 1216S–1220S, available at http://comenius.susqu.edu/biol/010/tobinjanzen/healthclaimsintheunitedstatesanaidtothepublicorasourceofconfusion_sol2012.pdf
- HOOKER N.H., TERATANAVAT R.P., Qualified Health Claims, FDA Public Meeting, Assessing Consumers' Perceptions of Health Claims, 2005, Available at <http://www.fda.gov/ohrms/dockets/dockets/05n0413/05n-0413-ts00008-hooker.pdf>
- IPPOLITO P., MATHIOS A., Health claims on food marketing: evidence on knowledge and behavior in the cereal market, *Journal of Public Policy and Marketing* 10, 1991, pp. 15–32.
- KAPSAK W.R., SCHMIDT D., CHILDS N.M., MEUNIER J., WHITE C., Consumer perceptions of graded, graphic and text label presentations for qualified health claims, *Critical Reviews in Food Science and Nutrition* 48, 2008, pp. 248–256.
- KRYSTALLIS A., MAGLARAS G., and MAMALIS S., Motivations and cognitive structures of consumers in their purchasing of functional foods, *Food Qual. Prefer.* 19, 2008, pp. 525–538.
- LEATHWOOD P.D., RICHARDSON D.P., STRÄTER P., TODD P.M., VAN TRIJP C.M., Consumer understanding of nutrition and health claims: source of evidence, *British Journal of Nutrition* 98, 2007, pp. 474–484.
- LEVY A.S., DERBY B.M., ROE B., Consumer Impacts of Health Claims: An Experimental Study, Center for Food Safety and Applied Nutrition, Washington DC, 1997.
- MARQUART L., WEIMER K., JACOB B., Solid science and effective marketing of health claims, *Nutrition Today* 36, 2001, pp. 107–111.
- MURPHY D, HOPPCOCK T, RUSK M., Generic Copy Test of Food Health Claims in Advertising. Washington, DC: Federal Trade Commission, 1998, available at <http://www.ftc.gov/opa/1998/11/food.shtm>

- National Consumer Council, Messages on food consumer's use and understanding of health claims on food packs, London, 1997.
- NOCELLA G., KENNEDY O., Food health claims – What consumers understand, *Food Policy* 37(5), October 2012, pp. 571-580.
- ROE B., LEVY A.S., DERBY B.M., The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data, *Journal of Public Policy and Marketing* 18(1), 1999, pp. 89–105.
- SABBE S., VERBEKE W., DELIZA R. et al., Effect of a health claim and personal characteristics on consumer acceptance of fruit juices with different concentrations of açai, (*Euterpe oleracea* Mart.), *Appetite* 53(1), 2009, pp. 84–92.
- SABA A., VASSALLO M., SHEPHERD R. et al., Countrywise differences in perception of health-related messages in cereal-based food products, *Food Qual. Prefer.* 21, 2010, pp. 385–393.
- SINGER L., WILLIAMS P.G., RIDGES L., MURRAY S., MCMAHON A., Consumer reactions to different health claim formats on food labels, *Food Australia* 58(3), 2006, pp. 92-97.
- STORCKSDIECK GENANNT BONSMANN S., CELEMIN L.F., LARRANAGA A., et al., Penetration of nutrition information on food labels across the EU-27 plus Turkey, *Eur. J. Clin. Nutr.* 64, 2010, pp. 1379–1385.
- VAN TRIJP H.C.M., VAN DER LANS I.A., Consumer perceptions of nutrition and health claims, *Appetite* 48(3), May 2007, pp. 305–324
- VAN KLEEF E., VAN TRIJP H.C.M., LUNING P., Functional foods: health claim-food product compatibility and the impact of health claim framing on consumer evaluation, *Appetite* 44, 2005, pp. 299-308.
- VERBEKE W., Functional foods: Consumer willingness to compromise on taste for health?, *Food Qual. Prefer.* 17, 2006, pp. 126-131.
- VERBEKE W., SCHOLDERER J., LÄHTEENMÄKI L., Consumer appeal of nutrition and health claims in three existing product concepts, *Appetite* 52, 2009, pp. 684–692.
- WILLIAMS P.G., Consumer understanding and use of health claims for foods, *Nutrition Reviews* 63(7), 2005, pp. 256-264.
- WILLIAMS P.G., Can health claims for food help consumers choose better diets?, *CML – Clinical Nutrition* 15(2), 2006, pp. 25–30.
- WILLS J.M., STORCKSDIECK GENANNT BONSMANN S., KOLKA M., GRUNERT K.G., Symposium 2: Nutrition and health claims: Help or hindrance: European consumers and health claims: Attitudes, understanding and purchasing behavior, *Proceedings of the Nutrition Society* 71(2), May 2012, pp. 229-236.
- WANSINK B., How do front and back package labels influence beliefs about health claims?, *Journal of Consumer Affairs* 37, 2003, pp. 305–316.

- WANSINK B., SONKA S.T., HASLER C.M., Front-Label Health Claims: When Less is More, *Food Policy* 29(6), December 2004, pp. 659-667.
- WANSINK B. and CHANDON P., Can "Low Fat" Nutrition Labels Lead to Obesity?, *Journal of Marketing Research*, Vol. XLIII, November 2006, pp. 605-617.

d. Articles Online

- AISBITT B., "Nutrition and Health Claims: the Facts on your Food", Synthesis report n°5, EuroFIR, British Nutrition Foundation, 2007, available at http://www.eurofir.net/sites/default/files/EuroFIR%20synthesis%20reports/Synthesis%20Report%205_Nutrition%20and%20health%20claims_the%20facts%20on%20your%20food.pdf
- ECKHARDT J., "No Slow Down to Class Action Lawsuits in California Regarding Food Labeling and Marketing", October 2011, <http://www.foodliabilitylaw.com/joseph-eckhardt.html>
- GAUTHIER C., "Food health claims: challenges for ASEAN manufacturers", 12 November 2012, <http://www.lexology.com/library/detail.aspx?g=76fa4d5d-1ae4-46bf-a04c-3fca7657b08c>
- HOSKIN J.M., "Contrasts and similarities: structure-function claims in the US and EU. Pros and cons for regulators, industry, and customers", Regional Symposium 2012, http://www.cfs.gov.hk/english/rc/sci_events/files/Symposium_2012/Symposium_2012_Free_Paper_3.pdf
- O'FLAHERTY M.J., "Class Action Consumer Litigation : A Rising Enforcement Risk for Aggressive Food Labeling Claims", 2 October 2012, available at <http://agfdablog.com/2012/10/02/class-action-consumer-litigation-a-rising-enforcement-risk-for-aggressive-food-labeling-claims/>
- PRINCIPE G., "Italian class actions. An update", March 2012, available at <http://globalclassactions.stanford.edu/sites/default/files/documents/Italian%20Class%20Actions%20Principe.pdf>
- ABCnews website, "Nutella: Consumer Class Action Settlement", 29 April 2012, available at <http://abcnews.go.com/blogs/business/2012/04/nutella-consumer-class-action-settlement/>
- American Bar Association website, "Confusion in Court over "All Natural"", 30 April 2012, available at <http://apps.americanbar.org/litigation/committees/classactions/articles/spring2012-0412-all-natural-labels-mean-marketing.html>

- Consommation, logement et cadre de vie website, “Publicité trompeuse : Candia condamnée”, 21 November 2012, available at <http://www.clcv.org/nos-actions-en-justice/publicite-trompeuse-candia-condamne.html>
- FDA, Guidance for Industry: A Food Labeling Guide, 12. Appendix D, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064923.htm>
- FDA, “Claims that can be made for Conventional Foods and Dietary Supplements”, September 2003, <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>
- FDA, “Health Claim Notification for the Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease”, <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073631.htm>
- Foodnavigator website, “Nutri-Grain legal challenge has ‘no merit’ says Kellogg”, 4 February 2010, available at <http://www.foodnavigator-usa.com/Business/Nutri-Grain-legal-challenge-has-no-merit-says-Kellogg>
- IFT13 website, “Is there a definition for natural food?”, June 2008, available at <http://www.am-fe.ift.org/cms/?pid=1000744>
- Natural Society website, “Lawsuit Slams “All Natural” Snack Makers for Containing Harmful GMO Ingredients”, 31 January 2012, available at <http://naturalsociety.com/lawsuit-slams-all-natural-snack-makers-for-containing-harmful-gmo-ingredients/>
- Nutraceuticals World website, “Nutrient Profiles Back on the EU Agenda”, 16 April 2012, available at http://www.nutraceuticalsworld.com/contents/view_breaking-news/2012-04-16/nutrient-profiles-back-on-the-eu-agenda/
- Nutraingredients website, “US structure/function claims under scrutiny as EFSA ups the ante”, September 2011, available at <http://www.nutraingredients-usa.com/Regulation/US-structure-function-claims-under-scrutiny-as-EFSA-ups-the-ante>
- Nutraingredient website, “Nutrient profiling back on EU agenda says policy expert”, 16 April 2012, available at <http://www.nutraingredients.com/Regulation/Nutrient-profiling-back-on-EU-agenda-says-policy-expert>
- Nomos website, “Candia condamnée pour les publicités sur son produit ‘Silhouette Active’ ”, available at http://www.nomosparis.com/index.php?option=com_content&view=article&id=554:candia
- Nomos website, “Andros condamnée pour son allégation ‘recette moins sucrée’ », available at http://www.nomosparis.com/index.php?option=com_content&view=article&id=553:andros-condamnee-pour-son-allegation-l-recette-moins-sucree-r&catid=45&Itemid=169

- North Dakota State University website, <https://www.ndsu.edu/pubweb/~saxowsky/aglawtextbk/chapters/foodlaw/USagencies.html>
- Nutritional Outlook website, “EU Nutrient Profiles: Back on the Table ?”, 9 October 2012, available <http://www.nutritionaloutlook.com/article/eu-nutrient-profiles-back-table-3-10531>
- The Globe and Mail website, “Nutella backs off ‘balanced breakfast’ claims after hit with \$3 million lawsuit”, 27 April 2012, available at <http://www.theglobeandmail.com/news/world/nutella-backs-off-balanced-breakfast-claims-after-hit-with-3-million-lawsuit/article4103025/>
- The Wall Street Journal website, “Cheerios’ Health Claims Break Rules, FDA says”, 13 May 2009, available at <http://online.wsj.com/article/SB124216077825612187.html>

e. Other Documents

- Discussion Paper on nutrition claims and functional claims of the European Commission, prepared by the Directorate General Health and Consumer Protection (SANCO D4)
- European Commission. Strategy for Europe on nutrition, overweight and obesity related health issues – Implementation Progress Report 2010. Brussels, 2010.
- Food Standards Agency, Review and Analysis of Current Literature on Consumer Understanding of Nutrition and Health Claims Made on Food, 2007, London, p. 13, citing the 2004 research of Institute of Grocery Distribution
- Agreement containing consent order, FTC, n° 082 3158, available at <http://www.ftc.gov/os/caselist/0823158/101215dannonagree.pdf>

3. Jurisprudence

a. French Cases

- TI Paris, 13 Nov. 2012.
- T. Com. Paris, 24 Octobre 2012.

b. American Cases

- *Pearson v. Shalala*, 164 F.3d 650 (D.C Cir. 1999)
- *Wiener et al. v. Dannon Company*, 255 F.R.D. 658 (C.D. California 2009).
- In the Matter of Kellogg Company, a corporation, FTC, WL 2402679, Docket n° C-4262, July 2009.
- *Fitzpatrick v. General Mills*, 263 F.R.D. 687 (S.D. Florida 2010).
- In re Ferrero Litigation, 278 F.R.D. 552 (S.D. California 2011).
- In re Frito-Lay North America, Inc. All Natural Litigation, WL 6554657, 2012.

4. **Visited Websites**

- Europa, <http://europa.eu>
- EFSA, <http://www.efsa.europa.eu>
- European Commission, <http://ec.europa.eu>
- European Parliament, <http://www.europarl.europa.eu>
- SPF, <http://www.health.belgium.be>
- Centers for Disease Control and Prevention, <http://www.cdc.gov/nchs/data/databriefs/db82.htm>
- American National Standards Institute, http://www.standardsportal.org/usa_en
- Food Trade Commission, <http://www.ftc.gov>
- FDA, <http://www.fda.gov>
- FTC, <http://www.ftc.gov>
- <http://www.topclassactions.com>
- <https://nutellaactionsettlement.com>
- <http://consumerist.com/2011/06/27/get-15-in-rice-krispies-cereal-class-action>