Food labeling requirements in the US and Catalonia (EU). Similarities and differences

By Ester Johé Tornero

FOOD REGULATION IN THE UNITED STATES
Professor Neal Fortin
12/03/2012

TABLE OF CONTENTS

1.	INTRODUCTION	. 2
2.	LEGISLATION	3
	2.1. US food labeling legislation	3
	2.2. Catalan (EU) food labeling legislation	4
3.	GENERAL FOOD LABELING REQUIREMENTS	6
	3.1. General food labeling requirements in US	6
	3.2. General food labeling requirements in Catalonia (EU)	. 7
4.	FOOD LABELING	. 8
	4.1. Nutritional facts panel in the US	. 8
	4.2. Nutritional facts panel in Catalonia (EU)	13
	4.3. Nutrient content claims and Health claims in US	14
	4.4. Nutrient content claims and Health claims in Catalonia (EU)	16
5.	CONCLUSION	19

1. INTRODUCTION

The paper is focusing on a brief comparison on similarities and differences between United States (US) and Catalan food labeling requirements. Catalonia is a region in the north-east of Spain and its food labeling legislation is based on European Union (EU) legislation and its transposition into national legislation.

The outbreak of many diseases in the late 1980s and certainly during the 1990s in Europe, together with aspects of animal welfare, food safety scares over genetically modified food, the use of antibiotics and hormones in both Europe and North America and the environmental impacts caused by food production¹, have decreased consumer trust in food safety.

Food labels provide consumers information about ingredients, nutritional value or allergens included, among others. The US and EU are two markets with great interaction. The total flow of Foreign Direct Investment (FDI) between the EU and the US was approximately 147 billion; the EU FDI stock held in the US amounts to about 926b; total FDI stocks held in each other's countries is approximately 1.89 trillion². Consumer goods produced within its borders are exported from one country to another with ease, and food products are no exception. Is why it is important to understand the similarities and especially the differences in food labeling to provide consumers the tools needed to buy with confidence and to provide manufacturers and exporters the tools to know what requirements must be met before sell their products in the other market.

 1 Consumer demand for informative labeling. Efthalia Dimara and Dimitris Skuras. Journal of Consumer Marketing. Volume 22 \cdot Number 2 \cdot 2005 \cdot 90–100

² SYRQUIN, A. (2009, Aug 06). US-EU trade and investment barriers reviewed. Jerusalem Post. Retrieved from http://search.proquest.com/docview/319695400?accountid=15299

2. LEGISLATION

2.1. <u>US food labeling legislation</u>

In the US the Food and Drug Administration (FDA) regulates the labeling of most foods. Food labeling requirements are designed to protect against fraud and deception and to provide consumers with the information they need to make informed choices about the food.

The labeling of food products in the US derives from the Food, Drug and Cosmetic Act (FDC&A) and its amendments, and many of the statutory labeling requirements come from section 403 of this FDC&A³. The Fair Packaging and Labeling Act (FPLA) was enacted in 1966 to prevent unfair and deceptive trade practices and to provide consumers with accurate information regarding the quantity and value of products like foods, drugs and cosmetics. The Federal Trade Commission (FTC) administers the FPLA for most other consumer commodities⁴. Labeling of meat, poultry and egg products is regulated under separate laws by the USDA⁵

All required label information must appear on the food label in the English language. With a few exceptions, the label must also bear all of the required statements in the foreign language as well as in English⁶. In addition the required label information must be conspicuously displayed and in terms that the ordinary consumer is likely to read and understand under ordinary conditions of purchase and use⁷.

³https://www.angel.msu.edu/section/content/default.asp?WCl=pgDisplay&WCU=CRSCNT&ENTRY_ID=DC18A71DE C584058AE51BA2933069F30.pdf

⁴https://www.angel.msu.edu/section/content/default.asp?WCI=pgDisplay&WCU=CRSCNT&ENTRY_ID=DC18A71DE C584058AE51BA2933069F30.pdf

https://www.angel.msu.edu/section/content/default.asp?WCI=pgDisplay&WCU=CRSCNT&ENTRY_ID=DC18A71DEC584058AE51BA2933069F30.pdf

⁶ 21 C.F.R. § 101.15(c)(2). The Tariff Act of 1930, 19 U.S.C. § 1304, also requires all imported articles to be marked with the English name of the country of origin.

⁷ FD & C Act § 403(f).

4

FDA has edited a Food Labeling Guide to help manufacturers, distributors, and importers about the proper labeling of their food products⁸.

2.2. Catalan (EU) food labeling legislation

Catalonia as a part of EU must meet with the EU food law regulations.

The European Parliament and the Council provides to all EU members the regulations they all must meet so that all member states have a common regulatory framework. In Catalonia, food labeling regulation is provided both by *Ministerio de Agricultura, Alimentación y Medio Ambiente*⁹ (Agriculture, Food and Environment Ministry) which depends from the central government and *Departament d'Agricultura, Ramaderia, Pesca, Alimentació i Medi Natural*¹⁰ (Ministry of Agriculture, Livestock, Fisheries, Food and Natural Environment) which depends from the regional government.

The **Directive 2000/13/EC** of the European Parliament and of The Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs enact Community rules of a general nature applicable horizontally to all foodstuffs put on the market¹¹.

The *Council Directive 90/496/EEC* of 24 September 1990 on nutrition labeling for foodstuffs concerns nutrition labeling of foodstuffs to be delivered as such to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers¹².

Real Decreto 930/1992¹³ of July 17, by approving the standard nutrition labeling of foodstuffs, is the transposition of the previous regulation into the national legislation.

10 http://www20.gencat.cat/portal/site/DAR

 $^{^8} http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm$

⁹ http://www.magrama.gob.es/en/

¹¹ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:109:0029:0042:EN:PDF

¹² http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0496:20081211:EN:PDF

¹³ http://www.gencat.cat/salut/acsa/html/ca/dir1363/dn1363/rd%20etiquetatge%20nutritiu.pdf

Regulation (EU) No 1169/2011¹⁴ of The European Parliament and of The Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 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) No 608/2004, combine the two previous regulations into one and will apply from 13 December 2014. The obligation to provide nutrition information will apply from 13 December 2016.

This new regulation on the provision of food information to consumers considerably changes existing legislation on food labeling including:

- Nutrition information on processed foods;
- Origin labeling of fresh meat from pigs, sheep, goats and poultry;
- Highlighting allergens e.g. peanuts or milk in the list of ingredients;
- Better legibility i.e. minimum size of text;
- Requirements on information on allergens also cover non pre-packed foods including those sold in restaurants and cafés.

Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that those labeling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community¹⁵.

The compulsory labeling of food products sold in Spain should be expressed, at least in the official Spanish language of the State. In Catalonia, as a part of Spain,

_

¹⁴ http://ec.europa.eu/food/food/labelingnutrition/foodlabeling/proposed_legislation_en.htm

¹⁵ Art. 16. B.2, Directive 2000/13/EC

the compulsory labeling of food products should be expressed at least in the official Spanish language¹⁶.

Nevertheless, Article 128-1, Chapter 8 of Law 22/2010 of July 20 of Codi de Cosum de Catalunya¹⁷ says that consumers, without prejudice to the obligation of full respect for language availability, are entitled to receive at least in Catalan (Catalonia's own language), advertising, fixed information, documentation about the product and its use, the contractual information and any terms and conditions of use, among others. So this law compares the use of Catalan and Spanish in all the areas of labeling.

3. GENERAL FOOD LABELING REQUIREMENTS.

3.1. General food labeling requirements in US

All mandatory label information must be placed in packages and containers on the front label panel (the principal display panel¹⁸ or PDP); in certain cases specified label statements might be placed on the PDP and other labeling on the information panel¹⁹ (the label panel immediately to the right of the PDP, as seen by the consumer facing the product).

The mandatory label information is the following:

- the statement of identity, or name of the food
- the net quantity statement, or amount of product
- the name and address of the manufacturer, packer or distributor
- The list of ingredients, or ingredient statement, listed by their common names and in descending order by weight. It might include food allergens

¹⁶ Art. 18 RD 1334/1999 Norma General d'etiquetatge, presentació i publicitat dels productes alimentaris.

 $^{^{17}} http://www20.gencat.cat/portal/site/portaljuridic/template.PAGE/menuitem.d15a4e5dfb99396dc366ec10b0c0e1a0/?javax.portlet.tpst=ba5f51819ed19d6c56159f10b0c0e1a0&javax.portlet.prp_ba5f51819ed19d6c56159f10b0c0e1a0=action%3Dfitxa%26documentId%3D543841$

¹⁸ 21 CFR 101.1

¹⁹ 21 CFR 101.2

 Nutritional information, including serving sizes, number of serving per container, amounts of nutrients found in significant quantities and percentage of Daily Values for nutrients based on 2000 calorie-per day diet.

For information panel labeling, might be used a print or type size that is prominent, conspicuous and easy to read. Letters might be at least one-sixteenth (1/16) inch in height based on the lower case letter "o". The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read²⁰.

3.2. General food labeling requirements in Catalonia (EU)

When foodstuffs are packaged, indications of mandatory labeling information must appear on the packaging or on a label attached to the packaging²¹. In all cases, the compulsory information should be easily understandable and must be enrolled in a prominent place and in order to be easily visible, clearly legible and indelible. These indications should not be hidden, covered or separated in any way for other indications or pictures²². Indication of the following particulars shall be compulsory on the labeling of foodstuffs²³:

- The name under which the product is sold
- The list of ingredients
- The quantity of certain ingredients or categories of ingredients
- In the case of prepackaged foods, the net quantity
- The date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the 'use by' date

²⁰ 21 C.F.R. § 101.105

²¹ Article 17 (1) REIAL DECRET 1334/1999, de 31 de juliol, pel qual s'aprova la Norma general d'etiquetatge, presentació i publicitat dels productes alimentaris.

Article 17 (5) REIAL DECRET 1334/1999, de 31 de juliol, pel qual s'aprova la Norma general d'etiquetatge, presentació i publicitat dels productes alimentaris.

Article 3 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs

- Any special storage conditions or conditions of use
- The name or business name and address of the manufacturer or packager,
 or of a seller established within the Community
- Particulars of the place of origin or provenance in the cases where failure
 to give such particulars might mislead the consumer to a material degree
 as to the true origin or provenance of the foodstuff
- Instructions for use when it would be impossible to make appropriate use
 of the foodstuff in the absence of such instructions
- For beverages containing more than 1.2% by volume alcohol, the actual alcoholic strength by volume

4. FOOD LABELING

4.1. Nutritional facts panel in the US

The nutrition facts label is required on most food packaged labeled.

The Nutrition Facts may be presented on any label panel when the total surface available for labeling is 40 or less square inches²⁴. Packages with more than 40 square inches of available space must place the nutrition information on either the PDP or information panel²⁵ unless there is insufficient space (excluding vignettes, etc.), in which case the Nutrition Facts may be placed on any panel that may be seen readily by consumers²⁶.

Nutrition information must be set off in a box. The format requires that headings and nutrients be separated by "bars". Print must be in both upper and lower case in an easy to read type style and with sufficient contrast to assure readability. All nutrients listed must be printed in at least 8 point type. Column headings for

²⁴ 21 CFR 101.9(j)(13)(ii)(D)

²⁵ 21 CFR 101.2

"Amount per Serving", "% Daily Value", footnote and caloric conversion information can be no smaller than 6 point²⁷.

"Nutrition Facts" must be presented in bold print and in print larger than any other printed information in the nutrition label.

All values expressed must be in terms of the stated "Serving Size" and, except for fish or game meat, must be based on the product as packaged.

In the US the mandatory nutrients are total calories, total fat – both saturated and trans -, cholesterol, sodium, total carbohydrate – both fiber and sugar -, protein, Vitamin A, Vitamin C, calcium and iron. Other nutrients, along with calories from fat, must be shown if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too²⁸. In addition other nutrients must be included in a food's Nutrition Facts label if the nutrients are added as a nutrient supplement to the food, if the label makes a nutrition claim about them, or if advertising or product literature provides information connecting the nutrients to the food²⁹. The listing of trans fatty acids is mandatory even when mono- and polyunsaturated fatty acids are not listed³⁰.

Serving size³¹

The Serving size remains the basis for reporting each food's nutrient content. It must be expressed in both common household and metric measures. NLEA defines serving size as the amount of food customarily eaten at one time. The serving sizes that appear on food labels are based on FDA-established lists of "Reference Amounts Customarily Consumed per Eating Occasion".

²⁸https://www.angel.msu.edu/section/content/default.asp?WCI=pgDisplay&WCU=CRSCNT&ENTRY_ID=DC18A71DE C584058AE51BA2933069F30.pdf

²⁷ 21 CFR 101.9(d)

²⁹ 21 CFR 101.9(a), 21 CFR 101.9(c), 21 CFR 101.9(c)(8)(ii)

³⁰ 21 CFR 101.9(c), (c)(2)(ii), (c)(2)(iii), and (c)(2)(iv)

^{31 21} CFR 101.9(b)(1)

Amount per serving³²

Nutrients are listed in the order in which they must be listed on the nutrition label. Nutrients are listed in a column and immediately followed by the quantitative amount with a "g" for grams, "mg" for milligrams and "I.U." for International Units. % Daily Value³³

Declaration of the % DV is required for nutrients for which Daily Values (Recommended Daily Intakes (RDIs) or Daily Reference Values DRVs) have been established. That nutrients not referenced on the chart do not have Daily Values.

Calories³⁴

"Calories from Fat" must be declared unless the product contains < 0.5 g total fat.

"Calories" may be followed by the optional term "Energy" in parenthesis.

A listing of "Calories from Saturated Fat" is voluntary.

If both "Calories from Fat" and "Calories from Saturated Fat" are declared they should be indented and listed in a line under "Calories".

Fat³⁵

Saturated fat must be listed in grams, but is not required if the food contains less than 0.5 grams of total fat per serving and if no claims are made about fat or cholesterol content. If not required and not declared, the statement "Not a significant source of saturated fat" must be included at the bottom of the nutrient table.

"Polyunsaturated Fat" or "Polyunsaturated" in grams voluntary unless monounsaturated fat is declared, or a cholesterol or saturated fat claim is made and the total fat declared is greater than zero. 'Monounsaturated Fat' or 'Monounsaturated' in grams is voluntary unless polyunsaturated fat is declared, or

³² 21 CFR 101.9(c)

³³ 21 CFR 101.9(c)(7)&(8)&(9) and (d)(6)&(7)

^{34 21} CFR 101.9(c)(1)

^{35 21} CFR 101.9(c)(2)

11

a cholesterol or saturated fat claim is made and the total fat declared is greater

than zero.

Cholesterol³⁶

Is not required, if the product contains less than 2 milligrams cholesterol per serving and makes no claim about fat, saturated fat or cholesterol; and if not declared, the statement "Not a significant source of cholesterol" must be included at the bottom of the nutrient table.

Sodium³⁷

Foods for infants and children under 4 years of age may list the mg. amount, but may not list the % Daily Value for sodium.

Potassium³⁸

It is voluntary unless a claim is made about potassium. If listed it must be in bold print and listed in milligrams.

Carbohydrates and Dietary Fiber³⁹

- "Dietary Fiber" in grams is not required if the serving contains less than 1 gram. If not declared, the statement "Not a significant source of dietary fiber" must be included at the bottom of the nutrient table.
- "Soluble Fiber" in grams is voluntary unless a claim is made about soluble fiber. A Daily Value has not been established.
- "Insoluble Fiber" in grams is voluntary unless a claim is made about insoluble fiber. A Daily Value has not been established.
- "Sugars" is not required if a serving contains less than 1 gram of sugar and no claims are made about sweeteners, sugars, or sugar alcohol content, and if not declared, the statement "Not a significant source of sugars"

³⁷ 21 CFR 101.9(c)(4)

³⁸ 21 CFR 101.9(c)(5)

³⁶ 21 CFR 101.9(c)(3)

³⁹ 21 CFR 101.9(c)(6)

must be included at the bottom of the nutrient table. A Daily Value has not been established.

- "Sugar Alcohol" is voluntary unless a claim is made about sugar alcohol or sugar when sugar alcohols are present in the food. When listed and only one sugar alcohol is present in the food, the name of the sugar alcohol may be given in lieu of the term "sugar alcohol (e.g. xylitol). Daily value has not been established.
- "Other Carbohydrates" is voluntary. A Daily Value has not been established.

Protein⁴⁰

Declaration of % Daily Value is not required when the food is for adults or children over 4 years of age unless a protein claim is made.

However, when the food is for adults or children over 1 year of age and the protein is of poor quality, the label should state "0%" in % DV column or state "Not a significant source of protein."

The statement "Not a significant source of protein" is required if the food is purported to be for infants and has a Protein Efficiency Ratio (PER) of less than 40 percent of the reference standard (casein).

Declaration of Vitamins and Minerals⁴¹

Nutritional information as the percent of the Reference Daily Intake (RDI) for the following nutrients is MANDATORY and must be declared in the order listed: "Vitamin A, Vitamin C (Ascorbic Acid)⁴², Calcium, Iron". They may be listed horizontally or in two columns.

The order for listing optional vitamins and minerals is as follows:

Vitamin D

_

⁴⁰ 21 CFR 101.9(c)(7)

⁴¹ 21 CFR 101.9(c)(8)

⁴² Parenthetical listing of ascorbic acid is optional.

- Vitamin E
- Thiamin (Vitamin B1)(*)
- Riboflavin (Vitamin B2)(*)
- Niacin Vitamin B6
- Folate (Folacin)(*)
- Vitamin B12
- Biotin
- Pantothenic Acid
- Phosphorus
- Iodine
- Magnesium
- Zinc
- Copper
- (*) These parenthetical listings are optional

4.2. Nutritional Facts Panel in Catalonia (EU)

In Catalonia the nutritional labeling is optional⁴³. Where a nutrition claim appears on labeling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labeling shall be compulsory⁴⁴. The information must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit, the information shall be presented in linear form. It shall be printed in legible and indelible characters in a conspicuous place⁴⁵.

Where nutrition labeling is provided, the information given shall consist of either group 1 or group 2 in the following order⁴⁶:

 $^{^{43}}$ Article 2 (1), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

⁴⁴ Article 2 (2), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

⁴⁵ Article 7 (1), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

⁴⁶ Article 4 (1), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

- Group 1: energy value; the amounts of protein, carbohydrate and fat.
- Group 2: energy value; the amounts of protein, carbohydrate, sugars, fat, saturates, fiber and sodium.

Nutrition labeling may also include the amounts of one or more of the following⁴⁷:

- Starch
- Polyols
- Mono-unsaturated
- Polyunsaturated
- Cholesterol
- Any of the minerals or vitamins listed in the Annex and present in significant amounts as defined in that Annex

The declaration of substances which belong to or are components of one of the categories of nutrients referred above shall be compulsory where a nutrition claim is made⁴⁸. In addition, where the amount of polyunsaturates and/or monounsaturates and/or the cholesterol rate is given, the amount of saturates shall be given.

4.3. Nutrient content claims and Health claims in US

Nutrient content claims⁴⁹, are claims that expressly or implicitly characterize the level of a nutrient of the type required in nutrition labeling under section 101.9.

No nutrient content claim may be made on food offered for sale for human consumption that has not been defined in a regulation.

Core terms may be used as follows:

- 1. Free of fat, saturated fat, cholesterol, sodium, salt, sugars and calories;
- 2. Very Low in sodium;

-

⁴⁷ Article 4 (3), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

⁴⁸ Article 4 (4), Council Directive 90/496/EEC of 24 September on nutrition labelling for foodstuffs

⁴⁹ 21 CFR 101.13

- 3. 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);
- 5. High and Good Source of a beneficial nutrient with a DV;
- 6. Reduced and Less in fat, saturated fat, cholesterol, sodium, sugar and calories;
- 7. More of a beneficial nutrient with a DV;
- 8. Light for fat or calories or in sodium.

Health claims are any claim made on the label or in labeling of a food that expressly or by implication characterizes the relationship of any substance (e.g., a specific food or component of food) to a disease or health-related condition⁵⁰.

A disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension).

Authorized health claims are as follows:

- 1. Calcium and Osteoporosis;
- 2. Fat and Cancer;
- 3. Saturated Fat, Cholesterol and Coronary Heart Disease;
- 4. Fiber-Containing Grain Products, Fruits and Vegetables and Cancer;
- Fruits, Vegetables and Grain Products that Contain Fiber and Risk of Coronary Heart Disease;
- 6. Sodium and Hypertension (High Blood Pressure);
- 7. Fruits and Vegetables and Cancer.
- 8. Folic Acid and Neural Tube Defects

= 1

⁵⁰ 21 CFR 101.14

All information required to be included in the claim must appear in one place without other intervening material, except that principal display panel of the label or labeling may bear the reference statement, "See _____ for information about the relationship between ____ and ____," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling, provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim must appear in immediate proximity to such graphic material.

4.4. Nutrient content claims and Health claims in Catalonia (EU)

Nutrition claim⁵¹ means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- a) The energy (calorific value) it
 - i) Provides
 - ii) Provides at a reduces or increased rate, or
 - iii) Does not provide; and or
- b) The nutrients or other substances it
 - i) Contains
 - ii) Contains in reduced or increased proportions, or
 - iii) Does not contain

Nutrition claims shall only be permitted if they are listed in the Annex and are in conformity with the conditions set out in Regulation (EC) 1924/2006.

⁵¹ Article 2 (4) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

The following nutrition claims are permitted:

- 1. Low energy, energy-reduced, energy-free,
- 2. Low fat, fat-free, low saturated fat, saturated fat-free,
- 3. Low sugars, sugars-free, with no added sugars,
- 4. Low sodium/salt, very low sodium/salt, sodium-free or salt-free,
- 5. Source of fibre, high fibre,
- 6. 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)
- 9. Reduced (name of the nutrient), light/lite, naturally/natural
- 10. Source of omega-3 fatty acids, high of omega-3 fatty acids,
- 11. High monounsaturated fat, high polyunsaturated fat, high unsaturated fat

Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health⁵².

Any food business operator can use authorized health claims if the conditions of use and any applicable restrictions are respected. Non-authorized health claims should not be used. National authorities control the use of claims. Health claims should only be made for the nutrient, substance, food or food category for which they have been authorized, and NOT for the food product that contains them. Some flexibility of wording of the claim is possible provided its aim is to help consumer understanding taking into account factors such as linguistic and cultural

⁵² Article 2 (5) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

variations and the target population. Adapted wording must have the same meaning for the consumer as the authorized claim in the EU Register.

Health claims shall only be permitted if the following information is included in the labeling, or if no such labeling exists, in the presentation and advertising:

- a) 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 effect;
- c) where appropriate, a statement addressed to persons who should avoid using the food; and
- d) An appropriate warning for products that are likely to present a health risk if consumed to excess.

The Regulation distinguishes between different types of health claims and provides different procedures to be followed for evaluation and authorization⁵³:

"Article 13 claims" are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioral functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

"Article 14 claims" are health claims describing or referring to:

- a) reduction of disease risk claims;
- b) Claims referring to children's development and health.

Food Regulation in the United States – Professor Neal Fortin – 12/03/2012

 $^{^{53}\} http://ec.europa.eu/food/food/labelling nutrition/claims/guidance_claim_14-12-07.pdf$

5. CONCLUSION

Although general labeling requirements are quite similar between the two countries, there are some significant differences that must be taken into account when manufacturers and distributors wishing to export their products from one country to another. For example, a product made in Catalonia (EU) to be exported to U.S. must include on its label the nutritional information of the product while in the opposite case, the manufacturer or distributor may refrain from including this information – in case it does not include a nutrition claim on the label – but should include other information such as the date of minimum durability of the product or 'use by' date, or special conditions of use.

Another significant difference between one country and another is the fact that nutrition facts label in U.S. is mandatory in most packaged foods while in Catalonia (EU) is voluntary unless it meets certain requirements of the regulation. No significant differences were observed in the declaration of substances and nutrition claims permitted, always bearing in mind that this statement is mandatory in U.S. and not in Catalonia (EU).

Referring to health claims we have already seen a big difference in their definition. While in U.S. is defined as a claim made expressly or by implication that characterizes the relationship of a substance to a disease or a health-related condition in Catalonia (EU) is considered a health claim that states, suggests or implies food that has beneficial nutritional properties. It is perhaps for this reason that in the U.S. authorized health claims associates a nutrient with an illness, disability or healthy condition and in Catalonia (EU) approved health claims are associated with beneficial nutrients for the health of consumers and not related to any disease or nutrient deficiency.

In short, from my point of view, differences in food labeling between one country and another one are related to the cultural background of each country and do not affect the safety of the product itself. Also, being quite similar, manufacturers, distributors

and importers must not make excessive changes to their labeling to market their products in the other market and consumers have a good source of information for safely buy and to compare some food with other and decide which one to buy.