



Scientific Substantiation of Health Claims Made on Foods in the European Union and the United States

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Health Claims in the EU and USA

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Table of contents

- 1** Health Claims on foods – why they are important?
- 2** Health Claims in the United States
- 3** Health Claims in the European Union
- 4** EFSA's scientific scrutiny of Article 13.1 Health Claims
- 5** Summary



1 Health Claims on foods – why they are important?



1. Health claims – why they are important?

Health claims can be used...

- ✓ to provide information about the health benefits of foods and food constituents
- ✓ to show important results of nutritional research on food labels
- ✓ to provide information to consumers that will help maintain health and/or reduce the risk of diseases
- ✓ as a marketing tool in order to draw attention to products and increase product sales



2

Health Claims in the United States



2. Health claims in the United States

Competent Authorities

Food and Drug Administration (FDA)



- ✓ Center for Food Safety and Applied Nutrition (CFSAN)
- ✓ oversees labeling claims

Federal Trade Commission (FTC)



- ✓ oversees advertising claims
- ✓ FTC has filed one hundred and twenty cases challenging health claims made for supplements





2. Health claims in the United States

Classification of Claims

Allowed categories of claims in food labeling

- 1) Nutrient content claims
- 2) Structure/function claims and
- 3) Health claims





2. Health claims in the United States

Nutrient Content Claims

- ✓ are used to describe the percentage of a nutrient in a product relative to the daily value
- ✓ are limited to those authorized by FDA regulation
- ✓ Examples: “good source of calcium” or “sodium free”
(less than 5 mg sodium per serving)





2. Health claims in the United States



Structure and Function Claims

- ✓ describe the effect that a substance has on the structure or function of the body
- ✓ Example: “Calcium builds strong bones”
- ✓ S/F Claims are not pre-reviewed or authorized by FDA
- ✓ Must be accompanied by the following disclaimer:

“This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”



2. Health claims in the United States



Health Claims – Definition

- ✓ Health claim means any claim made [...] in labeling of a food that [...] **characterizes the relationship of any substance to a disease or health-related condition**
- ✓ cannot be a claim about the diagnosis, cure, mitigation, or treatment of disease
- ✓ are pre-authorized by FDA





2. Health claims in the United States



Health Claims – SSA Health Claims

- ✓ require a Significant Scientific Agreement (SSA) standard
- ✓ new and evolving sciences do not meet the criteria of the SSA standard
- ✓ Example: Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors



2. Health claims in the United States



Health Claims – Qualified Health Claims

- ✓ based on less science evidence than on the standard of Significant Scientific Agreement (SSA)
- ✓ must be accompanied by a disclaimer or otherwise qualified
- ✓ Example: “**Supportive but not conclusive research** shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease”



2. Health claims in the United States



Health Claims – Ranking System

| Level of scientific evidence | FDA Category | Proposed qualifying language |
|------------------------------|--------------|--|
| High | A | Category A health claims are unqualified health claims that meet the significant scientific agreement |
| Moderate/Good | B | "Although there is some scientific evidence supporting [the claim], the evidence is not conclusive." |
| Low | C | "Some scientific evidence suggests [the claim], Evidence is limited and not conclusive." |
| Lowest | D | "Very limited and preliminary scientific research suggests [the claim]. There is little scientific evidence supporting the claim" |



2. Health claims in the United States



Health Claims – FDAMA Health Claims

- ✓ based on authoritative statements by a scientific body of the US government, such as the National Institutes of Health
- ✓ claims are authorized by FDA as a result of the notification from a stakeholder
- ✓ Examples:
 1. Whole Grains & Risk of Heart Disease and Certain Cancers
 2. Potassium & Risk of High Blood Pressure and Stroke



3

Health Claims in the European Union



3. Regulation of health claims in the EU



Regulation (EC) on nutrition and health claims made on foods (NHCR)

- ✓ came into force on 1st July 2007
- ✓ should provide a high level of consumer protection
- ✓ any health claim made on foods must be authorized and based on generally accepted scientific evidence
- ✓ is intended to stimulate innovation in the European food industry



3. Regulation of health claims in the EU



Health Claims – Definition

- ✓ A health claim means a claim (including pictorial, graphic or symbolic representation) that states, suggests or implies a **relationship between a food, food constituent or food category and health.**



3. Regulation of health claims in the EU



Competent Authorities

European Food Safety Authority (EFSA) 

- ✓ Panel on Dietetic Products, Nutrition and Allergies (NDA Panel)
- ✓ responsible for the scientific assessment of health claims
- ✓ gives advices to the European Commission for the authorisation of health claims by publishing scientific opinions

European Commission (EC)



- ✓ responsible for the authorisation of health claims
- ✓ determines the condition of use and the wording of the claims



3. Regulation of health claims in the EU

EFSA's assessment of health claims

Evaluation steps

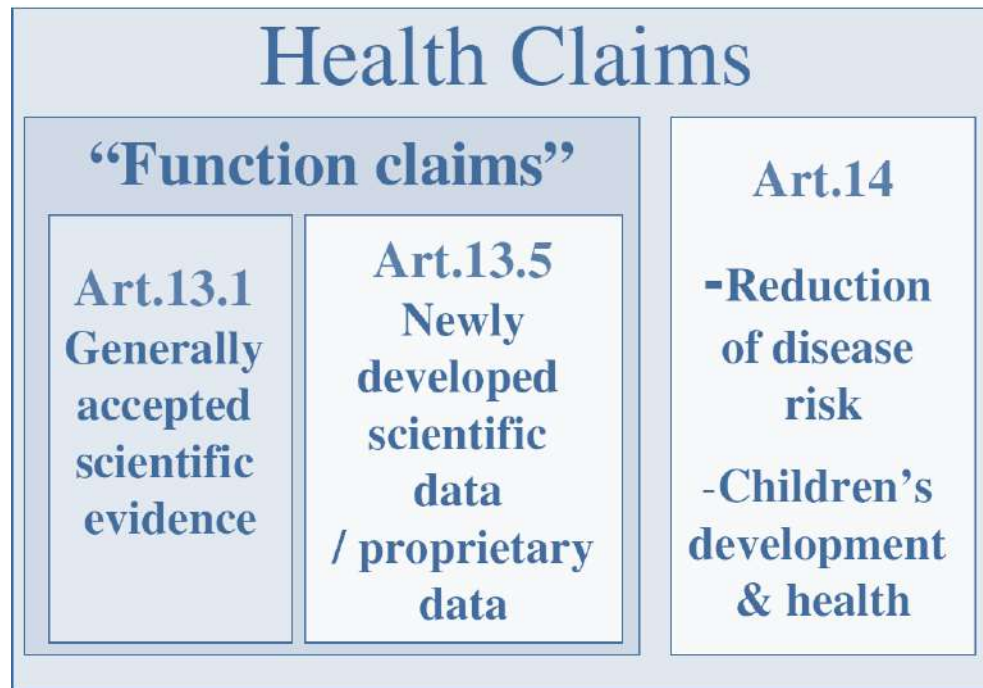
- 1) Is the the food/constituent properly **defined** and **characterised**?
- 2) Is the claimed effect sufficiently defined and does it have a **beneficial physiological** effect?
- 3) **Is a cause and effect established** between the consumption of the food/constituent and the claimed effect





3. Regulation of health claims in the EU

Classification of Health Claims





3. Regulation of health claims in the EU



Definition of “Function Health Claims”

- ✓ the role of a nutrient or other substance in growth, development and the functions of the body, or
- ✓ psychological and behavioral functions, or
- ✓ slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety
- ✓ Examples: “Vitamin A contributes to the maintenance of normal vision.”
“Iron contributes to normal oxygen transport in the body.”



3. Regulation of health claims in the EU



European Community list of “Function Health Claims”

- ✓ 44,000 claims submitted by Member States to EC (January 2008)
- ✓ 4,185 claims submitted by EC to EFSA (Jul/Nov/Dec 2008)
- ✓ EFSA had carried out the scientific scrutiny of “Function health claims” as part of the establishment of the European Community list of permitted health claims
- ✓ **341 scientific opinions by EFSA** in the period from 1st October 2009 to 28th July 2011

**OUTCOME OF
EFSA'S
ASSESSMENTS?**



4 EFSA's Scientific Scrutiny of Article 13.1 Health Claims



4. EFSA's scientific scrutiny of Article 13.1 Health Claims

Main Objective

Quantifying the positive and negative assessments of “Function
Health Claims”

- ✓ at the level of the individual evaluation steps of the EFSA's assessment procedure
- ✓ for the different evaluated constituent components of foods





4. EFSA's scientific scrutiny of Article 13.1 Health Claims

Methods – Content Analysis



- ✓ Content analysis of 341 EFSA opinions and in total 1,921 relationships between the consumption of a food/constituent and a claimed health effect (food-health relationships)
 1. Determination of the sample material
 2. Definition of evaluation and coding units
 3. Development of a category system and coding plan
 4. Pretesting and completing the category system
 5. Text encoding and
 6. Statistical analysis (e.g. comparative analysis by using frequency counts)



4. EFSA's scientific scrutiny of Article 13.1 Health Claims

| Category | Number of food-health relationships | Number of food-health relationships in % |
|---|-------------------------------------|--|
| 1. Vitamins | 155 | 8.1 |
| 2. Minerals/ Trace elements | 139 | 7.2 |
| 3. Aminoacids/Peptides/Proteins | 120 | 6.2 |
| 4. Probiotics (single) | 164 | 8.5 |
| 5. Probiotics (combinations) | 49 | 2.6 |
| 6. Lipids | 104 | 5.4 |
| 7. Carbohydrats and dietary fibres | 148 | 7.7 |
| 8. Plants and plant extracts | 511 | 26.6 |
| 9. Secondary plant compounds | 142 | 7.4 |
| 10. Foods, food categories and diets | 184 | 9.7 |
| 11. Combinations of nutrients, other substances and foods | 112 | 5.8 |
| 12. Other substances | 93 | 4.8 |
| In total | 1,921 | 100% |



4. EFSA's scientific scrutiny of Article 13.1 Health Claims

Results



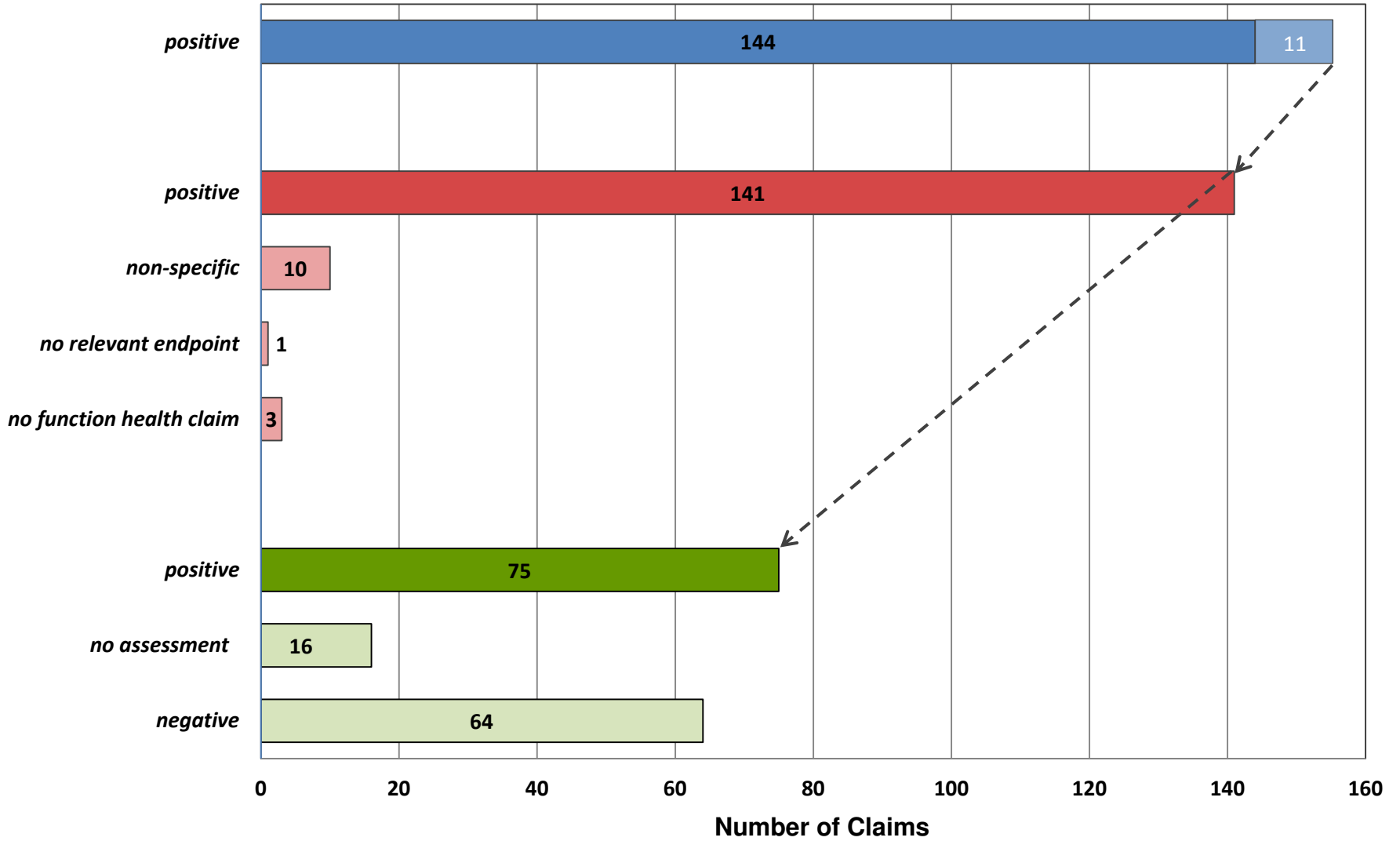
- ✓ 221 food and health relationships (11.5%) have been positively assessed
- ✓ 1,700 food and health relationships (88.5%) could not be scientifically confirmed
- ✓ discrepancy between vitamins, minerals as well as trace elements and the remaining classes of foods/constituents



4. EFSA's scientific scrutiny of Article 13.1 Health Claims

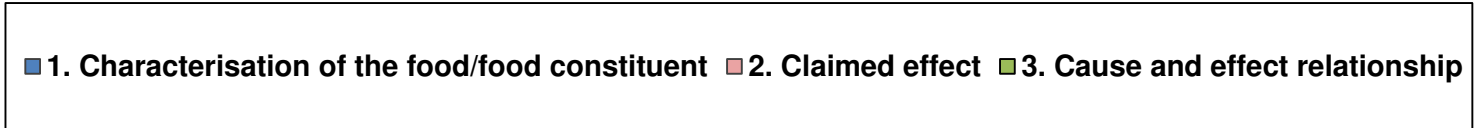
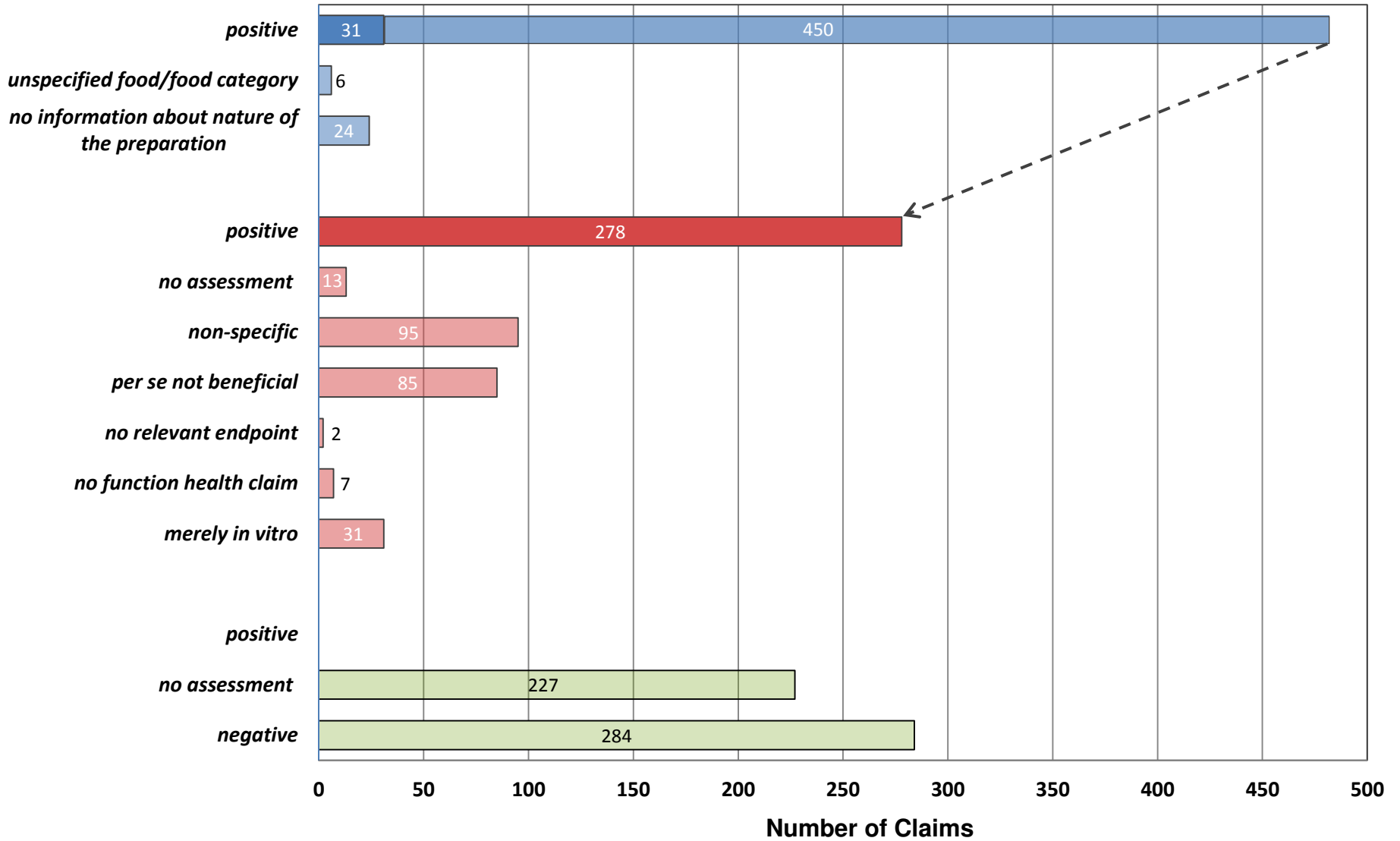
| Category | Number of positive assessed food relationships | Number of positive assessed food relationships within the categories in % |
|--|--|---|
| 1. Minerals/Trace elements | 71 | 51.1 |
| 2. Vitamins | 75 | 48.4 |
| 3. Carbohydrats and dietary fibres | 20 | 13.5 |
| 4. Foods, food categories and diets | 21 | 11.4 |
| 5. Other substances | 10 | 10.8 |
| 6. Secondary plant compounds | 7 | 7.4 |
| 7. Lipids | 7 | 6.7 |
| 8. Amino acids/Peptides/Proteins | 5 | 4.2 |
| 9. Combinations of nutrients, other substances and foods | 4 | 3.6 |
| 10. Probiotics (combinations) | 1 | 2.0 |
| 11. Probiotics (single) | 0 | 0 |
| 12. Plants and plant extracts | 0 | 0 |
| In total | 221 | |

Assessed Claims related to Vitamins



■ 1. Characterisation of food/food constituent
 ■ 2. Claimed effect
 ■ 3. Cause and effect relationship

Assessed Claims related to plants and plant extracts





4. EFSA's scientific scrutiny of Article 13.1 Health Claims

Results – Main reasons for rejections

- ✓ claimed effects are non-specific or not beneficial
- ✓ inappropriate scientific data
- ✓ no pertinent studies/no human studies
- ✓ flaws in study design or statistics
- ✓ inappropriate target population





4. EFSA's scientific scrutiny of Article 13.1 Health Claims

Conclusions for Consumers and the Food Industry



- ✓ Will there be less unsubstantiated health claims???
- ✓ Many manufacturers have enriched their products with vitamins and minerals with the aim of using authorized health claims
- ✓ More incentive for use of vitamins/minerals than for doing research
- ✓ Only conclusive proof were accepted, no qualified claims are allowed
- ✓ Future health claims application dossiers should include better scientific data, for example high-quality human intervention studies, in particular in the fields of botanicals and probiotics



5

Summary



5. Summary

- ✓ Three different subtypes of health claims in the United States could be used in food labeling (SSA Claims, Qualified Claims and FDMA Claims)
- ✓ European Regulation (EC) on nutrition and health claims made on foods (NHCR) stipulates that any health claim made on foods must be authorized and based on generally accepted scientific evidence
- ✓ EFSA had carried out the scientific scrutiny of “Function health claims” as part of the establishment of the European Community list of permitted health claims
- ✓ Most food and health relationships have not been scientifically confirmed, none of the proposed claims related to plant/plant extracts and probiotics have been positively assessed
- ✓ Future health claims application dossiers should include better scientific data, for example high-quality human intervention studies



**Many thanks for your
attention!**

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6

Supplements



6.1

Health Claims in the United States



2. Health claims in the United States

Nutrient Content Claims

- ✓ placed on labels for USDA-regulated products must always be submitted for USDA approval
- ✓ can be made for both conventional foods and dietary supplements
- ✓ are not allowed on products for infants and children less than two years of age
- ✓ must be accompanied by the following disclosure when fat, cholesterol, saturated fat or sodium threshold levels are exceeded:

SEE NUTRITION PANEL FOR (NAME OF NUTRIENT) CONTENT



2. Health claims in the United States

Nutrients that qualify for nutrient content claims include:

- ✓ total calories, total fat, saturated fat, cholesterol, sodium, potassium
- ✓ dietary fibre, sugars, protein, vitamin A, vitamin C, calcium, iron,
- ✓ vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6,
- ✓ folate, vitamin B12, biotin, pantothenic acid, iodine, magnesium, zinc,
- ✓ selenium, copper, manganese, chromium, molybdenum, chloride, choline
- ✓ and ALA & DHA omega-3 fatty acids



2. Health claims in the United States



Structure and Function Claims

- ✓ must be truthful and must not be misleading
- ✓ Manufacturers of **dietary supplements** that make structure/function claims on labels or in product labeling **must submit a notification** to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim



2. Health claims in the United States



Health Claims

- ✓ can be used only on foods that contain, without fortification, 10% or more Daily Value for Vitamin A, Vitamin C, calcium, iron or fiber
- ✓ require that the manufacturer of a dietary supplement submit a notification to FDA no later than 30 days after the product goes to market
- ✓ the notification must include the text of the claim (conventional foods do not require this notification)
- ✓ must use tightly-controlled wording as set forth in the Code of Federal



Differences and similarities in USA and European Union

Similarities

- ✓ prohibition of using misleading claims in advertising and labeling
- ✓ prohibition of claims which relates to the diagnosis, treatment, cure and mitigation (Linderung) of diseases (disease claims)
- ✓ high scientific standard for the substantiation of health claims (but in EU exists only one scientific standard exists)
- ✓ time- and cost-intensive approval procedure (usually over 1 year)



Differences and similarities in USA and European Union

Differences

- ✓ NHCR includes direct requirements for the use of health claims
- ✓ in the EU no qualified health claims are allowed
- ✓ the introduction of Nutrient Profiles in the EU is still in discussion
- ✓ In USA Health claims are forbidden when products contain less than 10% of the Reference Daily Value of Vitamin A, C, Calcium, Proteins, Iron or dietary fibre
- ✓ in contrast to EU no pre-approval is needed for claims used in advertising in USA



2. Health claims in the United States

Number of approved Qualified Health Claims



Currently, 16 qualified substance/ disease relationships are approved in 5 different disease categories for foods and dietary supplements, including

- heart disease [B vitamins, certain tree nuts, walnuts, (n-3) fatty acids, olive oil, canola oil, corn oil]
- cancer (tomato products, calcium, green tea, selenium, certain antioxidant vitamins)
- cognitive function (phosphatidylserine)
- diabetes (chromium picolonate)
- hypertension (calcium); and neural tube defects (folate).



2. Health claims in the United States



Number of approved Qualified Health Claims

Cancer

- Antioxidant Vitamins & Certain Cancers
- Calcium & Colon/Rectal Cancer and Recurrent Colon/Rectal Polyps
- Green Tea & Certain Cancers
- Selenium & Certain Cancers
- Tomatoes & Certain Cancers

Cognitive Function

- Phosphatidylserine & Cognitive Dysfunction and Dementia

Diabetes

- Chromium Picolinate & Insulin Resistance and Type 2 Diabetes

Neural Tube Defects

- Folic Acid & Neural Tube Defects

Cardiovascular Disease

- Certain B Vitamins & Vascular Disease
- Nuts & Coronary Heart Disease
- Walnuts & Coronary Heart Disease
- Omega-3 Fatty Acids & Coronary Heart Disease
- Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
- Corn Oil & Heart Health
- Monounsaturated Fatty Acids from Olive Oil & Coronary Heart Disease

Hypertension

- Calcium & Hypertension, Pregnancy-Induced Hypertension and Preeclampsia



2. Health claims in the United States



Number of approved Unqualified Health Claims

- During the original implementation of NLEA, 7 claims were allowed based on monographs produced and reviewed by experts in the field
- Subsequently 5 additional claims, as well as amendments to existing claims, that meet the standard of SSA have been authorized through petitions to the FDA



2. Health claims in the United States



Number of approved Unqualified Health Claims

1. Adequate calcium throughout life, as part of a well-balanced diet, may reduce their risk of osteoporosis later in life.
2. Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
3. Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
4. While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
5. 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.
6. Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
7. Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. [Name of food] is high in vitamins A and C, and it is a good source of dietary fiber.
8. Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.
9. Frequent between-meal consumption of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.
10. Diets low in saturated fat and cholesterol that include [X grams] of soluble fiber per day from [name of soluble fiber source] may reduce the risk of heart disease. One serving of [name of food] provides X grams of this soluble fiber.
11. 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. One serving of [food name] provides X grams of soy protein.
12. Foods containing at least 0.65g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies X grams of plant sterol esters.

† Adapted from U.S. Code of Federal Regulations



2. Health claims in the United States

Number of approved FDMA Health Claims



1. Whole Grains & Risk of Heart Disease and Certain Cancers (authorized via authoritative statement from National Academies of Science)
2. Potassium & Risk of High Blood Pressure and Stroke (authorized via authoritative statement from National Academies of Science)
3. Fluoride & Risk of Dental Caries (authorized via authoritative statement from multiple sources including U.S. Surgeon General)
4. Saturated Fat, Cholesterol and Trans Fat & Risk of Heart Disease (authorized via authoritative statement from 2005 Dietary Guidelines for Americans)
5. Substitution of Saturated Fat with Unsaturated Fatty Acids & Risk of Heart Disease (authorized via authoritative statement from National Academies of Science)



2. Health claims in the United States



What do consumers think about health claims?

- The 2007 Food & Health Survey from the International Food Information Council showed that consumers are relying **less on health and nutrition information** on package labels when they make purchase decisions.
- The IFIC evaluated the consumer understanding of qualified health claims in a webbased survey of 5642 U.S. adults in 2005. They found that consumers had trouble distinguishing the 4 distinct levels of science behind the FDA-proposed 4 levels of health claims regardless of which of several language options were used to describe them. More specifically, **78% of consumers could not correctly sort 4 levels of claims as to the scientific evidence**, e.g., unqualified, “B” claim, “C” claim, “D” claim



2. Health claims in the United States



What do consumers think about health claims?

- In conclusion, the intent of label claims is to provide consumers more scientifically valid information about the foods they eat to improve their health and well-being.
- However, evidence to date suggests that this mode of communication **has had limited success** and **in fact may be misleading to consumers** with regard to understanding of scientific evidence as well as overall diet choices.



2. Health claims in the United States



Scientific evaluation of health claims by FDA

- In order to meet its statutory responsibility for evaluation of health claims, the agency has developed guidelines for review of scientific evidence in support of a health claim. These guidelines include
- Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, which was published December 22, 1999
- Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data as a part of the Consumer
- Health Information for Better Nutrition Initiative, which was published July 10, 2003.



2. Health claims in the United States



Scientific evaluation of health claims by FDA

- Letters of enforcement discretion for qualified health claims, which have been released since 2004 (provide information on the examination criteria used and how the criteria are applied)
- Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims (final version 2009)
- This document outlines the process by which the FDA systematically reviews the scientific literature to determine the level of scientific agreement in support of a claim



2. Health claims in the United States



Scientific evaluation of health claims by FDA

- The FDA goes through several steps to review scientific evidence in support of a claim. The process involves the following steps:
 1. define the substance-disease relationship that is the subject of the claim
 2. identify relevant studies
 3. classify the studies
 4. rate the studies on the basis of quality
 5. rate the studies on the basis of the strength of their body of evidence
 6. and report the studies' rank order.



2. Health claims in the United States



Scientific evaluation of health claims by FDA

- Evidence to support a health claim should be based on studies in humans
- Only studies conducted in “healthy populations” are considered, because health claims are directed to the general population or designated subgroups (e.g., elderly persons) and
 - are intended to assist the consumer in maintaining healthful dietary practices
- A healthy population can be one at high risk for but without a diagnosis of the disease that is the subject of the health claim
- Animal and *in vitro* studies are useful but not sufficient on their own to substantiate a claim.



2. Health claims in the United States



Scientific evaluation of health claims by FDA

- Among studies in humans, the randomized, placebo-controlled, double-blind intervention study provides the strongest evidence
- FDA's review examines whether the studies are controlled for confounders and bias, the appropriateness of the study population, and soundness of the experimental design and analysis, including the use of appropriate statistical analysis and estimates of intake
- Observational data can be supportive of a claim but often are less persuasive scientifically based on the nature of the study and its design
- Research syntheses such as meta-analysis or review articles are primarily useful for identifying studies for further examination



2. Health claims in the United States



How to distinguish between dietary supplements and foods? Dietary supplements

- The Dietary Supplement Health and Education Act requires that the phrase “dietary supplement” appear as part of the product name on the front panel of product labels (**products sold as dietary supplements must be clearly labeled as a dietary supplement**)
- the term “dietary” can be replaced by a descriptive phrase, such as “multivitamin and mineral”
- are labeled with Supplement Facts
- The Dietary Supplement Health and Education Act also defines what a dietary supplement is



2. Health claims in the United States



How to distinguish between dietary supplements and foods? Dietary supplements

- A dietary supplement is a ***product taken by mouth that contains a dietary ingredient intended to supplement the diet***
- Dietary ingredients include vitamins, minerals, herbs, botanicals, amino acids, enzymes, organ tissues, glandulars, metabolites, extracts or concentrates. Dietary supplements have many forms that include tablets, capsules, softgels, gelcaps, liquids, bars and powders
- Regardless of the form, the information on the label must not represent the product as a conventional food or a sole item of a meal or diet



2. Health claims in the United States



How to distinguish between dietary supplements and foods? Dietary supplements

- A new dietary ingredient or a product containing a new dietary ingredient to submit **pre-market notification** to the FDA. This notification, which must be submitted at least 75 days before the product is introduced into interstate commerce, must contain information that provides a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement will “reasonably be expected to be safe.”



2. Health claims in the United States



How to distinguish between dietary supplements and foods? Conventional foods

- are labeled with Nutrition Facts
- there is not a regulated FDA definition for conventional food
- Conventional foods are commonly understood to be all foods, beverages and chewing gums for human consumption that do not qualify as dietary supplements



2. Health claims in the United States



Disclosure Statement Requirement

- When claims are made about a product's nutrition or health benefits on FDA-regulated products, a **disclosure statement is required if one or more of the four nutrients shown in the chart below exceed threshold levels** for the product's reference amount or labeled serving size if larger, or per 50 grams for small servings

| Nutrient | Individual Foods ³ (includes small servings) | Main Dishes ⁴ | Meals ⁵ |
|---------------|--|--------------------------|--------------------|
| Total Fat | 13.0 g | 19.5 g | 26.0 g |
| Saturated Fat | 4.0 g | 6.0 g | 8.0 g |
| Cholesterol | 60 mg | 90 mg | 120 mg |
| Sodium | 480 mg | 720 mg | 960 mg |



2. Health claims in the United States



Disclosure Statement Requirement

- 1 Reference Amounts are Reference Amounts Customarily Consumed per eating occasion (RACC).*
- 2 Small Servings are those with reference amounts of 30 grams or less, or 2 Tablespoonful or less.*
- 3 Individual Foods are those with reference amounts of more than 30 grams, or more than 2 Tbsp.*
- 4 Main Dishes are products that weigh at least 6 oz per serving, contain not less than 40 grams each of at least two different foods from at least two specified food groups, and are represented as main dishes.*
- 5 Meals are products that weigh at least 10 oz per serving, contain not less than 40 grams each of at least three different foods from at least two specified food groups, and are represented as meals.*



2. Health claims in the United States



Disclosure Statement Requirement

- The disclosure statement must be placed adjacent to the claim without intervening material, and generally must be presented in a type size at least as large as the Net Contents statement, but never less than half of the size of the claim

LOW SODIUM
SEE NUTRITION PANEL
FOR FAT CONTENT

Example of a disclosure statement for a product low in sodium and high in fat



6.2

Health Claims in the European Union

