

# **CONTRASTS AND SIMILARITIES: STRUCTURE-FUNCTION CLAIMS IN THE US AND EU**

## **PROS AND CONS FOR REGULATORS, INDUSTRY, AND CUSTOMERS**

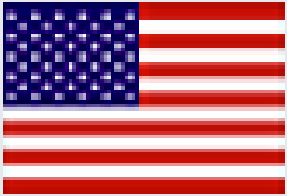
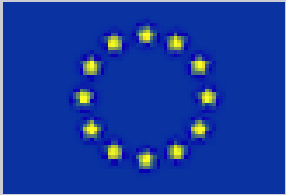


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# DO STRUCTURE/FUNCTION CLAIMS REQUIRE APPROVAL?

	YES	NO
	Authorized Health Claims, Qualified Health Claims	S/F Claims*
	Article 13(1), 13(5), 14(1)(a), 14(1)(b) claims	Not applicable
<p>DRR=Disease Risk Reduction; S/F=Structure/Function * For dietary supplements, a notification to the FDA is required no later than 30 days following market introduction.</p>		



# STRUCTURE-FUNCTION CLAIMS IN THE US

- ❖ Describe role of nutrient or functional component in affecting or maintaining normal body structure or function or general well-being; are not health claims
- ❖ Cannot describe or imply that a nutrient or functional component affects a disease or health-related condition (that is, diagnose, cure, mitigate, treat, or prevent)
- ❖ Can be used on FDA-regulated conventional foods, medical foods and dietary supplements
- ❖ Are not pre-approved by FDA but the manufacturer must have substantiation on file (clinical studies or other research, published or unpublished) to show that the claim is truthful and not misleading



# STRUCTURE-FUNCTION CLAIMS IN THE US

- ❖ **Require the manufacturer of a dietary supplement to 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)**
- ❖ **Require the label of a dietary supplement to have disclaimer\* placed adjacent to the S/F statement, or enclosed in a box and linked to the statement with an asterisk or other symbol (labels for conventional foods do not require this disclaimer)**

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

# Examples of Allowable Structure/Function Claims\* in US



Component Category	Component Sub-category	Structure or Function
Vitamins (Fat-Soluble)	Vitamin A	may contribute to maintenance of healthy vision may contribute to maintenance of healthy immune function may contribute to bone health may contribute to cell integrity
	Vitamin D	helps regulate calcium and phosphorus helps contribute to bone health may contribute to healthy immune function helps support cell growth
	Vitamin E	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of heart health
	Beta carotene	may neutralize free radicals may increase cellular antioxidant defense
Carotenoids	Lutein, Zeaxanthin	may help maintain healthy vision
	Lycopene	may help maintain prostate health
Fatty Acids	ALA, DHA/EPA (Omega-3 fatty acids)	may contribute to maintenance of heart health may contribute to maintenance of mental and visual function
	Conjugated linoleic acid	may contribute to maintenance of desirable body composition may contribute to maintenance of healthy immune function

\* Adapted from "Functional Foods" by International Food Information Council Foundation ([www.ific.org](http://www.ific.org))

# Types of Claims US FDA Found on Food labels in its Survey of Grocery Stores



*Are we cowboys in the food industry who make outlandish claims that are not supported by science?*

Claim type	Percentage of labels with claim type
Qualified health claim	0.4
Health claim (based on significant scientific agreement or an authoritative source)	4.3
Structure/function claim	5.5
Other implied nutrient content claim <sup>a</sup>	5.6
"Healthy" claim (an implied nutrient content claim) <sup>a</sup>	7.6
Significant source claim <sup>a</sup>	20.5
Nutrient content claim	53.2

Source: FDA survey conducted in 2006-2007.

# CAN CAKE STOP JOINT PAIN?





Is this blend or brand of vegetables likely to improve one's immune system than somebody else's vegetables?







## FOR STRUCTURE/FUNCTION CLAIMS IN US

- ❖ **No requirement that substantiation must be publicly available**
- ❖ **Many companies keep their substantiation information confidential so they can achieve or maintain a competitive advantage (competitors must develop their own substantiation)**
- ❖ **The information is regarded as confidential commercial information that is not subject to public disclosure under the Freedom of Information Act**
- ❖ **While FDA may ask a company to provide its scientific support for a claim, FDA does not have express legal authority to compel the company to provide such information**



## **COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE**

**Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area**

**That have been conducted and evaluated in an objective manner by persons qualified to do so**

**Using procedures generally accepted in the profession to yield accurate and reliable results**



## CURRENT QUESTIONS IN US

**Should the FDA establish a comprehensive regulatory framework for prohibiting misleading claims that a substance in a food can affect the structure or function of a bodily system?**

**Or instead should FDA continue to rely only on case-by-case enforcement actions?**

# GAO Recommendations for Executive Action

GAO-11-102, Jan 14, 2011

- ❖ **Provide guidance to industry on the type and strength of scientific evidence needed to prevent false or misleading information in a structure/function claim**
- ❖ **Identify and request from Congress the authorities needed to access evidence from food companies regarding potentially false or misleading structure/function or other claims on food that would allow the agency to establish whether there is scientific support for the claims**
- ❖ **Amend the "Compliance Program Guidance Manual" instructions to FDA inspectors for reviewing food labels during inspections of food facilities, to include steps for identifying potentially false or misleading structure/function claims for further review**



# GENERAL FUNCTION CLAIMS IN EUROPE

- ❖ Regulation (EC) No 1924/2006 focuses on precaution and consumer understanding; one of the most controversial pieces of legislation of the last decade in the area of EU food law
- ❖ “General function” claims are health claims under Article 13.1; refer to the role of a nutrient or substance in growth, development and body functions; psychological and behavioral functions; slimming and weight control, satiety or reduction of available energy from the diet
- ❖ Article 13.1 claims do not include those related to child development or disease risk reduction
- ❖ EFSA's scientific evaluation helps to ensure that claims made on food labeling and advertising regarding nutrition and health are meaningful and accurate, and can thereby help consumers in making healthy diet choices

# GENERAL FUNCTION CLAIMS IN EUROPE



**EFSA finalized the evaluation of the “general function” health claims prioritized by the Commission by the end of June 2011 and has published 341 opinions providing scientific advice on 2,758 “general function” health claims**



**The updated final list of 4,637 claims was the result of a consolidation process carried out by the Commission, after examining over 44,000 claims supplied by the MS. The complete list was published on the EFSA website in May 2010**

**There are only 222 authorized, ‘general function’ health claims on the “list” that apply to 70 foods and ingredients**



## **“New” or Emerging Function Health Claims**

- ❖ **Claims under article 13/5 are those based on newly developed scientific evidence and/or for which protection of proprietary data is requested**
- ❖ **For these health claims authorization is required on a case-by-case basis, following the submission of a scientific dossier to EFSA for assessment**
- ❖ **For confidentiality reasons, and in accordance with the claim regulation, summaries of these Article 13.5 claims applications are not published**



# AUTHORIZED CLAIMS ARE IN BLACK AND WHITE



The screenshot displays the European Commission's website for Health and Consumers, specifically the Food section. The page is titled "EU Register of nutrition and health claims made on foods". The left sidebar contains a navigation menu with the following items: "Health & Nutrition Claims", "EU Register On Nutrition & Health Claims" (which is expanded to show "Overview", "Health claims", and "Nutrition claims"), and a button for "Commissioner Dalli". The main content area lists the following information:

- The EU Register is for information only, showing:
  - » Permitted nutrition claims and their conditions of use
  - » Authorised health claims, their conditions of use and applicable restrictions, if any;
  - » Non-authorised health claims and the reasons for their non-authorisation;
  - » EU legal acts for the specific health claims;
  - » National measures mentioned in Art. 23(3) of Regulation EC 1924/2006
- The Commission will update the EU Register when required, namely upon adoption of EU decisions on applications for claims or on changes to conditions of use and restrictions.

At the bottom of the main content area, there is a button labeled "EU Register of Nutrition and Health claims" with a right-pointing arrow.



# **EFSA: HIGHEST SCIENTIFIC STANDARD IN ASSESSING HEALTH CLAIMS INCLUDING GENERAL FUNCTION CLAIMS**

- ❖ **In Europe the health relationship has to be proven in healthy persons via clinical (intervention) trials; the scientific assessment is of the highest possible substantiation standard**
- ❖ **Vast majority of general function claims in the US are recognized as unsubstantiated in the EU**
- ❖ **Scores of products sold in the US feature claims EU regulators believe are not supported by science**

# STRUCTURE-FUNCTION CLAIMS

## PROS:



- Companies can make claims with credible and reliable evidence in hand; claims must be “fair and not misleading” and they do not need to be shared with FDA or be made publicly available
- No pre-market approval process for structure/function claims, FDA can focus on food safety
- Opportunity for innovation, speed to market, and confidentiality
- Regulatory oversight and action only if claims promote food as drug
- US consumers generally understand the language of or implied meaning of structure/function claims
- The “system” generally works and has been in effect almost 20 years

## PROS:



- Harmonized regulatory framework and EFSA guidance available for making and applying for general function claims
- Register of claims is available and ready for use by customers and manufacturers
- Same approved language for a claim if conditions are met (except if proprietary claim)
- Highest scientific standard used; European consumers protected from the false or misleading claims

# STRUCTURE-FUNCTION CLAIMS

## CONS:



- Marketplace chaos and unfair play?
- No regulatory framework for structure/function claims for conventional foods
- Can consumers distinguish structure/function claims from health claims that require FDA approval and must be supported by “significant scientific agreement”?
- Is the customer healthier? Is there a safety risk with no regulatory framework? Is the customer protected from unsafe and ineffective claims?
- Does “enhance” or “strengthen” actually “improve”?

## CONS:



- Very costly and time-consuming process with accompanying legislative procedure
- Do consumers consider products with health claims to be a uniform category of foodstuffs?\*
- Questionable economic impact – will it/does regulation stimulate R & D, protect innovation, encourage small-medium enterprises, facilitate fair competition and achieve a high level of consumer protection \*\*?
- Costs to remove unapproved health claims; then inspection and enforcement

\*Fiona Lalor, Jean Kennedy, Patrick G. Wall, (2011) "Impact of nutrition knowledge on behaviour towards health claims on foodstuffs", British Food Journal, Vol. 113 Iss: 6, pp.753 – 765

\*\*Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU food supplement sector and market For the European Health Claims Alliance (EHCA) by September 2010

# CONCLUSIONS: IS THERE A BETTER WAY ?



## ❖Consider:

Costs and national  
scientific and regulatory  
capabilities

Culture

Prescriptive or flexible

Enforcement options and  
implications

Consumer safety

## ❖Remember the goal:

Protect consumers

Better and more informed food/diet  
choices

Respect fair competition and trade

Promote and protect innovation

## A Global Codex Register of S/F Claims?

**C O D E X**

International Food Standards

**A L I M E N T A R I U S**



World Health  
Organization



Food and Agriculture  
Organization of  
the United Nations



# THANK YOU !

