Cómo soportar la evidencia en las declaraciones de propiedades saludables. El ejemplo de la industria

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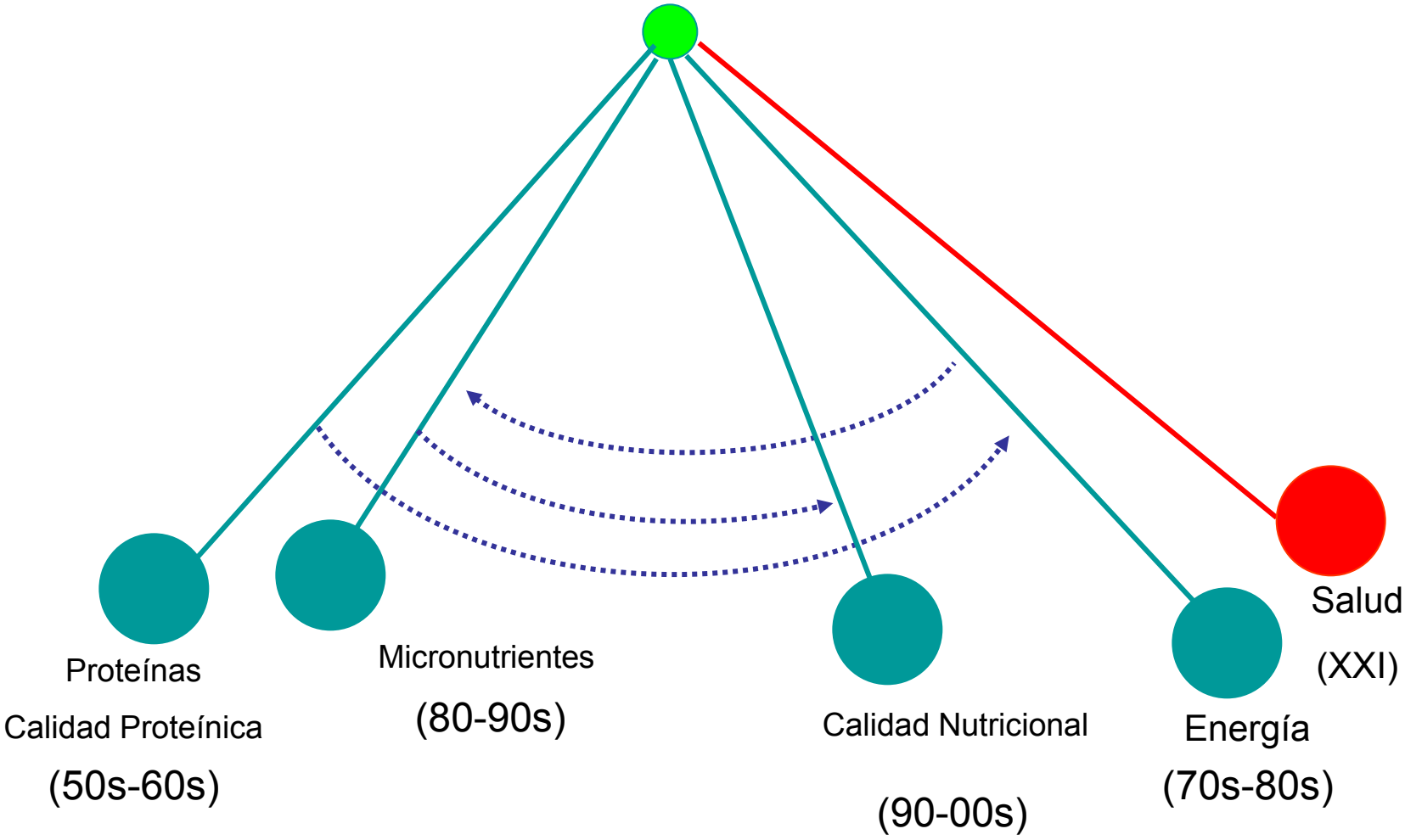
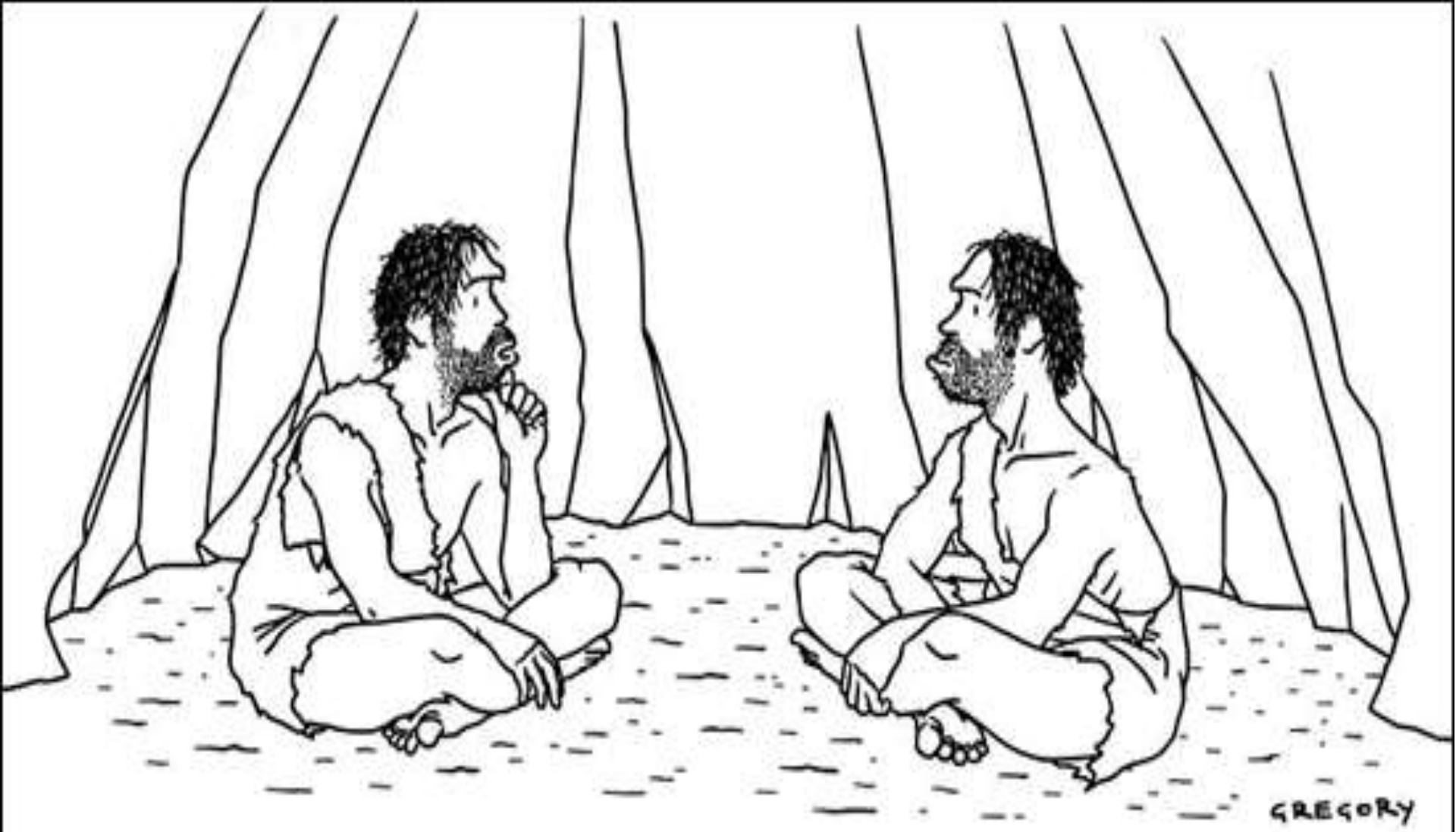
MENAJE
BUENAS ¿DÓNDE TIENEN LA LECHE SEMIDESCREMADA CON OMEGA 3 Y NUTRIENTES PARA CABELLOS GRASOS PERMANENTADOS CON RETROGUSTO AFRUTADO A ROBLE Y RECUERDOS FLORALES?
SOPAS
OFERTA PAELLERA DE 70 RACIONES SÓLO 350€
LUIS JOSÉ: SERENATE, ESTÁS HABLANDOLE A UNA PAELLERA

El cambio de paradigma





"Something's just not right—our air is clean, our water is pure, we all get plenty of exercise, everything we eat is organic and free-range, and yet nobody lives past thirty."

Evolución de las tendencias del consumidor en alimentación

Supervivencia

Hambre / Sed

Placer/Variedad

Alimentos **Sin**

Alimentos **Con**

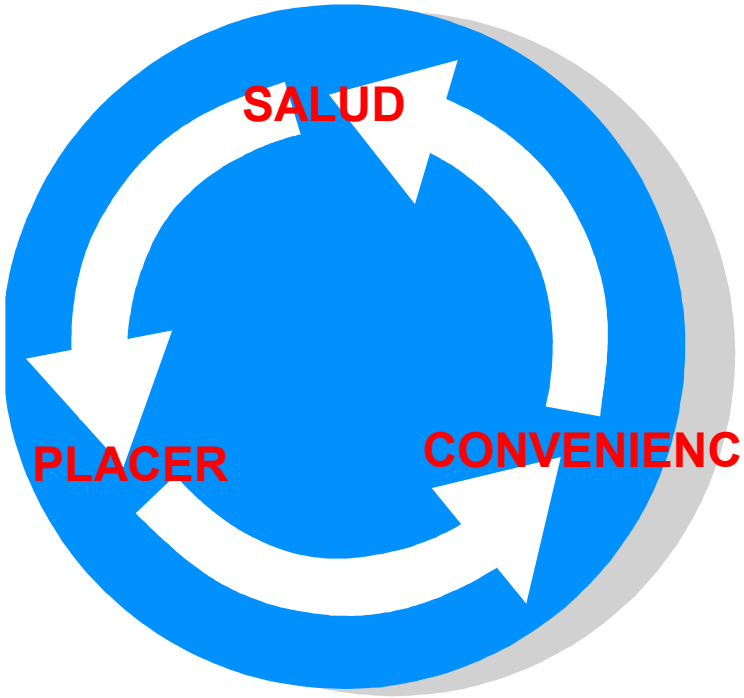
Le quitamos algo para evitar un efecto no deseable

Le ponemos algo que produzca un efecto saludable

La industria alimentaria del Siglo XXI: Salud, placer y conveniencia

Nutrición eficiente

Factor hipocondríaco



Factor tiempo

Indulgencia

Plus de conveniencia

Experiencia sensorial

“We need to put our faith in consumer ignorance”

"We need to put our faith in consumer ignorance."

COUNTERTHINK

ART - DAN BERGER - CONCEPT - MIKE ADAMS

www.NewsTarget.com

Hill & Knowlton (2000)
European study on nutritional, health and ethical claims - 2000

HILL AND KNOWLTON

STUDY ON NUTRITIONAL, HEALTH AND ETHICAL CLAIMS IN THE EUROPEAN UNION

FOR THE EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND CONSUMER PROTECTION

April 2000

Recommendations

"Our overall conclusion is that to safeguard consumer protection, claims, whether they are nutritional, health or ethical, need to be better regulated at the EU level. The very large majority of the key stakeholders agree that solutions are to be found at the EU level and all look to the European Commission to propose legislation".

Hawkes, Corinna
Nutrition labels and health claims: the global regulatory environment. WHO, 2004

Alimentos Funcionales: Oportunidades y retos
IFT (Expert Report), 2007

IFT
EXPERT REPORT

Functional Foods:
Opportunities and Challenges

Bringing Functional Foods to Market

The Expert Report presents a seven-step process that addresses critical aspects in the design, development, and marketing of functional foods. Although all seven steps will be undertaken for each new bioactive substance and the resulting functional foods, the specific requirements within each step will vary depending on the physical, chemical, and biological characteristics of the functional component, the applicable regulatory requirements, and the health claims to be made.

Step 1: Identify the relationship between the food component and the health benefit. The future success of functional foods relies on establishing a sound scientific basis for the relationship between a functional food and the claimed health benefit(s). A wealth of scientific literature describes the types of research that can be used to identify potential relationships between functional components and health benefits.

Step 2: Demonstrate efficacy and determine the intake level necessary to achieve the desired effect. First, researchers attempt to identify the bioactive components that result in the health benefit observed in Step 1. In some cases, the bioactive component may be unidentified or partially identified. Sometimes the chemical identity is unknown, and a defined surrogate compound is used to establish efficacy.

Next, the stability and bioavailability of the component(s) must be demonstrated. This analysis includes the physical and chemical form of the food component, the effects of the total diet, the effects of food processing, and the effects of environmental factors during crop production. Stable and bioavailable components also must produce the identified health benefit.

To establish a credible health claim, the evidence of efficacy must be critically evaluated for adequacy based on the following: strength of association; consistency of the observed association; specificity of the association; temporal relationship of the observed association; dose–response relationship; biological plausibility; and coherence of the evidence. In applying each of these criteria to the research findings, consider also the amount and type of evidence, the quality of the evidence, the totality of the evidence, and the relevance of the evidence to the specific claim.

To receive a health benefit from consuming a functional food, the food must be consumed in adequate quantities to achieve the desired effect. Dietary intake assessments must address intake levels for the targeted population, potential high- and low-intake consumers, and population subgroups with special risks or benefits.

Step 3: Demonstrate safety at efficacious levels. Functional components must be determined to be safe at their projected use levels, using an objective, science-based evaluation process. The assessment of safety should be based on the long-standing principle that foods are safe. As such, the prior safe use of the component should play an important role in the demonstration of safety. Substances new to food use must undergo a safety assessment, including the potential for allergenicity.

Step 4: Develop a suitable food vehicle for the bioactive component. The food vehicle must be appropriate for the intended consumer and deliver the bioactive component at the desired compliance levels. The food vehicle must be consumed at the level necessary to achieve the benefit, but not consumed at amounts so great as to be toxic. In addition, the selection of a vehicle depends on the stability and bioavailability of the bioactive components in that particular food.

Step 5: Demonstrate scientific sufficiency of the evidence for efficacy. The evaluation of efficacy will be most effective and cost-efficient if undertaken by panels of independent scientists with appropriate expertise. This approach has been successfully applied to Generally Recognized as Safe (GRAS) determinations for many substances. A parallel process should be used to establish efficacy by conducting a review of the evidence demonstrating efficacy. The process could be called a Generally Recognized as Efficacious (GRAE) determination.

A GRAE determination would achieve public confidence while conserving government resources. The FDA should establish a procedure for GRAE notification similar to that used for GRAS substances.

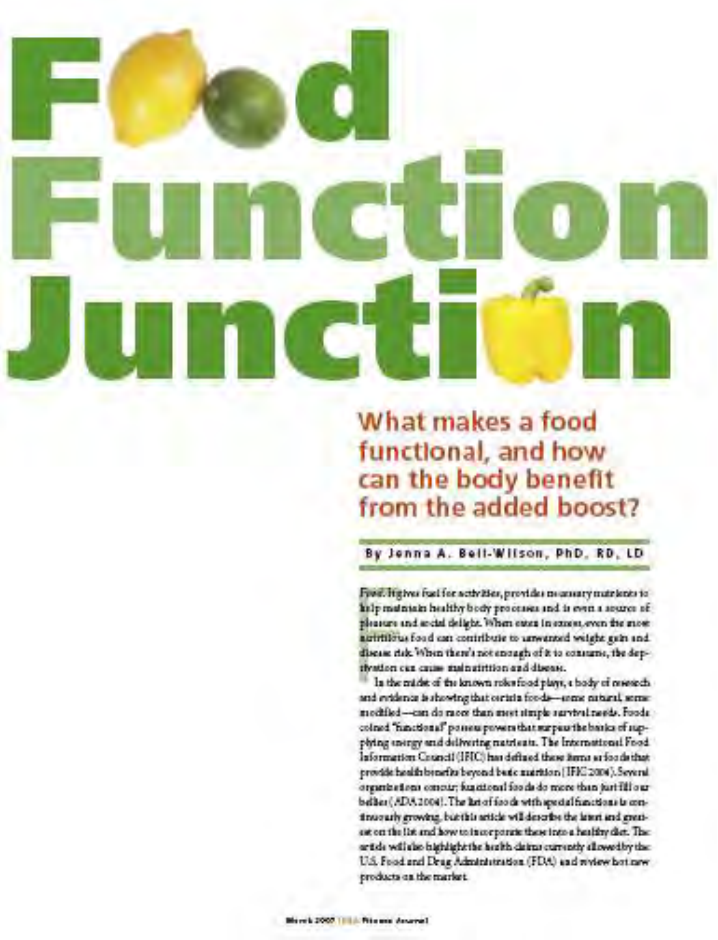
Step 6: Communicate benefits to consumers. The results of steps 1–5 should form the basis of the messages used to inform consumers of the relationship between the consumption of the functional food and its intended benefits. The health claims should be accurate and not misleading. Guidelines developed by the International Food Information Council Foundation and IFT (http://www.ific.org/nutrition/functional/guidelines/index.cfm) provide information about how to appropriately communicate scientific information to consumers.

Step 7: Conduct in-market surveillance to confirm efficacy and safety. Once the functional food is on the market, its manufacturer should monitor the actual consumption patterns and, when possible, the resulting health benefit. In addition, information about any adverse effects should be collected.

Recognizing the tremendous health benefits offered by functional foods, the Institute of Food Technologists commissioned an expert panel to review the available scientific literature related to functional food development. The panel's report is divided into nine sections: Definitions, Introduction, Food and Genes, Current Legal Standards, Scientific Standards, Policy Limitations, Bringing Functional Foods to Market, Role of Research, and Conclusions. Copies of the report are available at www.ift.org. Founded in 1939, the Institute of Food Technologists is a 28,000-member international not-for-profit scientific society for food science and technology.

1. Identificar las relaciones entre ingrediente y beneficios de salud.
2. Demostrar la eficacia y determinar el nivel de ingesta del ingrediente necesaria para conseguir el efecto pretendido.
3. Demostrar los niveles de seguridad y eficacia.
4. Desarrollar un apropiado vehículo alimentario para contener el ingrediente.
5. Demostrar la suficiencia científica de la evidencia para la eficacia.
6. Comunicar los beneficios a los consumidores.
7. Realizar un seguimiento post-comercialización para confirmar seguridad y eficacia.

Food Function Junction
Bell-Wilson, 2007



Food Function Junction

What makes a food functional, and how can the body benefit from the added boost?

By Jenna A. Bell-Wilson, PhD, RD, LD

Food. It gives fuel for activities, provides necessary nutrients to help maintain healthy body processes and is even a source of pleasure and social delight. When eaten in excess, even the most nutritious food can contribute to unwanted weight gain and disease risk. When there's not enough of it to consume, the deprivation can cause malnutrition and disease.

In the midst of the known roles food plays, a body of research and evidence is showing that certain foods—some natural, some modified—can do more than meet simple survival needs. Foods coined "functional" possess powers that surpass the basics of supplying energy and delivering nutrients. The International Food Information Council (IFIC) has defined these items as foods that provide health benefits beyond basic nutrition (IFIC 2004). Several organizations concur; functional foods do more than just fill our bellies (ADA 2004). The list of foods with special functions is continuously growing, but this article will describe the latest and greatest on the list and how to incorporate these into a healthy diet. The article will also highlight the health claims currently allowed by the U.S. Food and Drug Administration (FDA) and review hot new products on the market.

- La idea básica de los alimentos funcionales es la bioactividad de los ingredientes utilizados.
- La demostración de los efectos beneficiosos debe ser la base fundamental para la comercialización de los alimentos funcionales.

La regulación de las declaraciones de salud no es algo nuevo

Ministerio de Sanidad y Consumo y Federación Española de Industrias de la Alimentación y Bebidas: Acuerdo Interpretativo sobre la Publicidad de las Propiedades de los Alimentos en relación con la Salud (1998)

ACUERDO INTERPRETATIVO SOBRE LA PUBLICIDAD DE LAS PROPIEDADES DE LOS ALIMENTOS EN RELACIÓN CON LA SALUD.

MINISTERIO DE SANIDAD Y CONSUMO – FEDERACIÓN ESPAÑOLA DE INDUSTRIAS DE LA ALIMENTACIÓN Y BEBIDAS,

FINALIDAD Y AMBITO DE APLICACIÓN

El presente Acuerdo se aplica a la publicidad de las propiedades de los alimentos en relación con la salud.

La publicidad de las propiedades de los alimentos en relación con la salud se encuentra regulada por el Real Decreto 212/92, Norma General de Etiquetado, presentación y publicidad de los productos alimenticios y por el Real Decreto 1907/96 sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria.

El Real Decreto 212/92 (Norma General de Etiquetado) en su artículo 4. establece:

> "El etiquetado y las modalidades de realizarlo no deberán:
>
> 1. Ser de tal naturaleza que induzcan a error al comprador, especialmente:
>
> (...)
>
> 4. atribuyendo a un producto alimenticio propiedades preventivas, terapéuticas o curativas de una enfermedad humana, ni mencionando dichas propiedades sin perjuicio de las disposiciones aplicables a las aguas minerales y a los productos alimenticios destinados a una alimentación especial".

De acuerdo con este artículo a los productos alimenticios no se les pueden atribuir indicaciones preventivas, terapéuticas o curativas de una enfermedad humana. Los productos alimenticios pueden poseer propiedades fisiológicas o nutritivas y declararlas, siempre que respeten los principios del Real Decreto 212/92.

Quedan excluidas del campo de aplicación de este Acuerdo Voluntario:

- Las alegaciones que atribuyan a un producto alimenticio propiedades preventivas, terapéuticas, o curativas de una enfermedad humana o que las mencionen.

- Las alegaciones relativas a los preparados alimenticios para regímenes dietéticos y/o especiales, en sus diversas categorías, que se regirán por el Real Decreto 2685/76, por el que se aprueba la RTS, así como por la legislación específica que se establezca mediante Reglamentaciones Técnico-Sanitarias de acuerdo con lo dispuesto en el anexo del Real Decreto 1808/91 que modifica la RTS citada.

CLAUSULA DE REVISIÓN

El presente Acuerdo será objeto de revisión periódica con la finalidad de adaptarlo a la experiencia que se adquiera del funcionamiento de la Comisión de Seguimiento.

El presente acuerdo, aceptado y ratificado por las partes, se firma por triplicado en la sede del Ministerio de Sanidad y Consumo, en Madrid, a 20 de marzo de 1998.

Por la Federación Española de Industrias de Alimentación y Bebidas
Fdo: Jorge Jordana Buñuel de Pozas
SECRETARIO GENERAL

Por la Dirección General de Salud Pública del Ministerio de Sanidad y Consumo
Fdo: Juan José Francisco Polledo
DIRECTOR GENERAL DE SALUD PUBLICA

Confederation of the Food and Drink Industries of the EU (CIAA): Code of practice on the use of health claims (2001)

Purpose of this document

This document has been developed to help manufacturers to prepare the documentation necessary for the substantiation of health claims and to establish guidelines for the communication of health claims to consumers.

CIAA recognises that the present legal framework governing claims is incomplete and inflexible. Regulations are applied differently from one Member State to the next. Codes of Practice exist in some Member States. In order to achieve a level playing field throughout the EU, CIAA believes that the use of a single set of guidelines, adhered to by the whole European Food and Drink Industry, will contribute to reducing barriers to trade pending clarification of or changes to the legislation.

CIAA wishes to highlight that the present document does not concern safety aspects. The safety of all foodstuffs must be established whether or not claims are made for them.

Scope

This *Code* applies to the use of health claims, as defined in *"Definitions"*, page 3, in labelling, advertisement and promotion of foods without prejudice to specific regulations which exist for certain categories of food.

This code addresses neither nutrition claims, already defined by *Codex Alimentarius*[1], nor dietetic claims, as defined by EU legislation and *Codex Alimentarius*[1], nor medical claims.

Código de Conducta Publicitaria de Autocontrol (2002)

Código De Conducta Publicitaria

El presente Código de Conducta Publicitaria fue aprobado en la Asamblea General Extraordinaria celebrada el 19 de diciembre de 1995, según lo establecido en los Estatutos de la Asociación para la Autorregulación de la Comunicación Comercial. Última versión, con las modificaciones aprobadas por la Asamblea General Ordinaria el día 3 de abril de 2002.

I.- ÁMBITO DE APLICACIÓN Y NORMAS GENERALES

1.- Ámbito de aplicación

Estas normas deontológicas se aplican a toda actividad de comunicación publicitaria tendente a fomentar, de manera directa o indirecta y sean cuales fueren los medios empleados, la contratación de bienes o servicios, o el posicionamiento de marcas y nombres comerciales.

También serán aplicables las presentes normas deontológicas a cualquier anuncio emitido por cuenta de cualesquiera personas físicas o jurídicas, de carácter privado, con el fin de promover determinadas actitudes o comportamientos.

No serán de aplicación a la publicidad política.

2.- Objeto y fines de la Asociación para la Autorregulación de la Comunicación Comercial

2.1.- El objeto de la Asociación es contribuir a que la publicidad constituya un instrumento particularmente útil en el proceso económico, velando por el respeto a la ética publicitaria y a los derechos de los destinatarios de la publicidad, con exclusión de la defensa de intereses profesionales.

2.2.- A título simplemente enunciativo se considerarán como fines de la Asociación los siguientes:

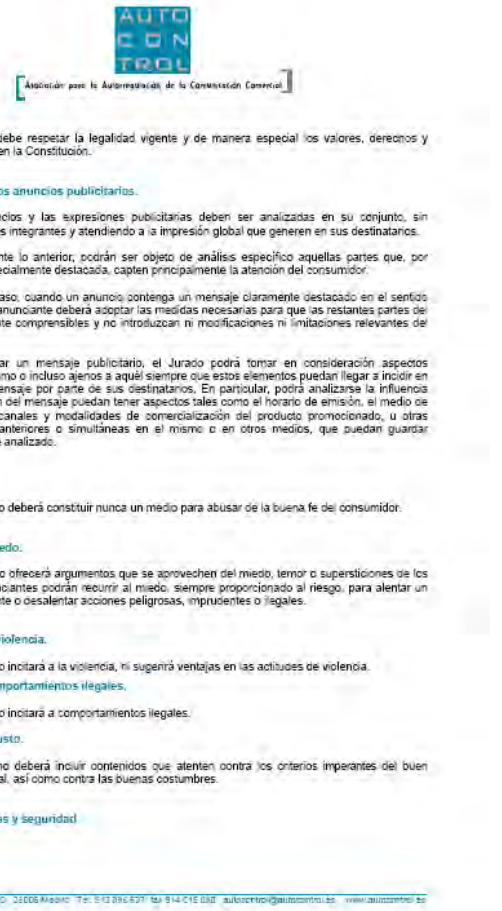
a) La elaboración de códigos de ética publicitaria, tanto de carácter general como de carácter sectorial, que recojan las normas básicas de conducta que deberán ser respetadas en la actividad publicitaria.

b) Dirimir las controversias y conflictos que puedan suscitarse por la realización de una determinada publicidad y que le sean sometidos por sus sponsors o por terceros.

c) Elaborar dictámenes, informes, estudios de cualquier clase o naturaleza sobre cuestiones concernientes a la publicidad, cuando le sean solicitados, bien por un asociado, bien por las Administraciones Públicas, bien por cualquier tercero.

d) Constituirse en parte procesal para defender los objetivos de la Asociación y el interés general en el cumplimiento de las disposiciones publicitarias que rijan en España.

e) Coordinar activamente con las Administraciones Públicas, Organismos Públicos e Instancias Internacionales para conseguir que la publicidad se ajuste a las normas por las que se rige, así como en general dirigir instancias, formular propuestas, remitir sugerencias o emitir informes para esos organismos y autoridades en materias que afecten a la publicidad.



La publicidad debe respetar la legalidad vigente y de manera especial los valores, derechos y principios reconocidos en la Constitución.

3.- Interpretación de los anuncios publicitarios.

3.1.- Los anuncios y las expresiones publicitarias deben ser analizadas en su conjunto, sin descomponer sus partes integrantes y atendiendo a la impresión global que generen en sus destinatarios.

3.2.- No obstante lo anterior, podrán ser objeto de análisis específico aquellas partes que, por aparecer de forma especialmente destacada, capten principalmente la atención del consumidor.

3.3.- En todo caso, cuando un anuncio contenga un mensaje claramente destacado en el sentido del párrafo anterior, el anunciante deberá adoptar las medidas necesarias para que las restantes partes del anuncio sean claramente comprensibles y no introduzcan ni modificaciones ni limitaciones relevantes del mensaje principal.

3.4.- Al analizar un mensaje publicitario, el Jurado podrá tomar en consideración aspectos relacionados con el mismo o incluso ajenos a aquél siempre que estos elementos puedan llegar a incidir en la interpretación del mensaje por parte de sus destinatarios. En particular, podrá analizarse la influencia que en la interpretación del mensaje puedan tener aspectos tales como el horario de emisión, el medio de difusión utilizado, los canales y modalidades de comercialización del producto promocionado, u otras acciones publicitarias anteriores o simultáneas en el mismo o en otros medios, que puedan guardar relación con el mensaje analizado.

4.- Buena fe.

La publicidad no deberá constituir nunca un medio para abusar de la buena fe del consumidor.

5.- Explotación del miedo.

La publicidad no ofrecerá argumentos que se aprovechen del miedo, temor o supersticiones de los destinatarios. Los anunciantes podrán recurrir al miedo, siempre proporcionado al riesgo, para alentar un comportamiento prudente o desalentar acciones peligrosas, imprudentes o ilegales.

6.- No incitación a la violencia.

La publicidad no incitará a la violencia, ni sugerirá ventajas en las actitudes de violencia.

7.- No incitación a comportamientos ilegales.

La publicidad no incitará a comportamientos ilegales.

8.- Respeto al buen gusto.

La publicidad no deberá incluir contenidos que atenten contra los criterios imperantes del buen gusto y del decoro social, así como contra las buenas costumbres.

9.- Prácticas peligrosas y seguridad

International Chamber of Commerce (ICC). Department of Policy & Business Practices. ICC Framework for responsible food & beverage communications (2004)

International Chamber of Commerce
The world business organization

Department of Policy and Business Practices

ICC framework for responsible food and beverage communications

Introduction
The increasing worldwide attention to diet, nutrition and physical activity is of great significance to the international food and beverage community and to the broader business community of which it is a part. The following framework has been prepared by the Commission on Marketing and Advertising of the International Chamber of Commerce (ICC) to address some of the issues raised by these concerns.

The International Chamber of Commerce (ICC), as the world business organization, promotes high standards of business ethics through the development and dissemination of rules, including codes and guidelines on how business should direct its efforts to assure that commercial communications to consumers are responsible.

World business supports the notion that responsible commercial communications can assist consumers in making appropriate choices about food and beverage products, and in understanding the role of nutrition, diet and physical activity in healthy lifestyles. By conveying commercial communications consistent with principles of good nutrition, diet, physical activity and personal choice, business can play an important role.

ICC's longstanding view is that commercial communications are best regulated by effective self-regulation within a legal framework that protects consumers from false and misleading claims. In this way, self-regulation best serves the consumer's interest in receiving truthful and accurate communications. More broadly, advertisers and marketers should be guided by self-regulatory principles and participate in self-regulatory processes.

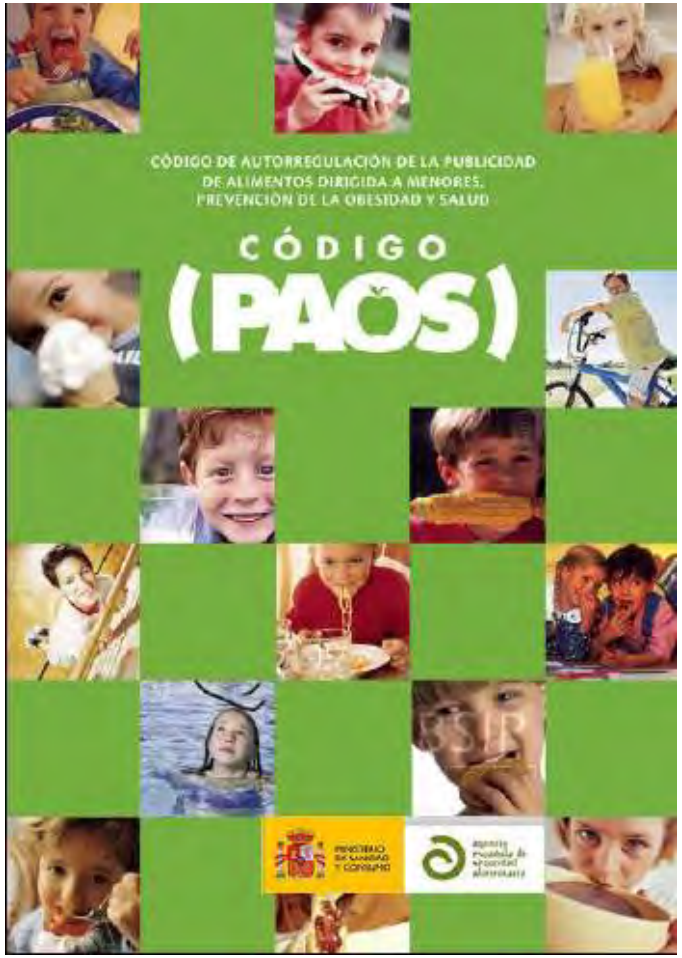
As a multi sectoral organization, ICC recognizes that its codes serve as an international standard and that they are used to develop regional and national codes by industry sector groups and by regional and national self-regulatory bodies.

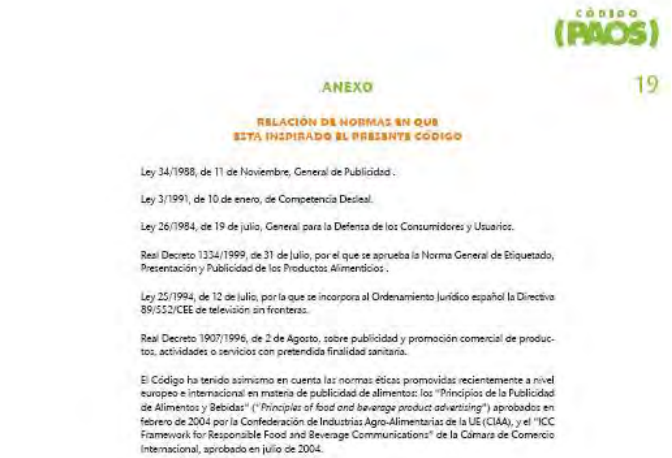
To be effective, marketing self-regulatory systems bring together advertisers, advertising agencies and the media to develop standards, evaluate advertising for compliance with those standards, and take appropriate action to enforce them. World business agrees that effective self-regulation is the system that, through a combination of best practices and determined enforcement, can best inspire consumer confidence in advertising.

ICC welcomes the adoption by regional and national self-regulatory advertising bodies around the world of the general principles expressed in ICC's own codes. Furthermore, world business values the enforcement mechanisms such bodies have put in place to sanction or amend advertisements that do not meet applicable self-regulatory requirements.

ICC PRINCIPLES	APPLICATION TO FOOD AND BEVERAGE ADVERTISING
ICC International Code of Advertising Practice Article 1 All advertising should be legal, decent, honest, and **truthful.**	Application in the context of food and beverage advertising of this principle means that claims about nutrition and health benefits should have a sound scientific basis. The claims should be conveyed consistent with the nature and scope of the evidence, providing the consumer with supportable information. The claim should also be judged by the likely perception of the reasonable consumer, especially where children and young people are concerned.
Article 1 continued Every advertisement should be prepared with a due sense of **social responsibility**....	Food and beverage advertisements should not encourage or condone excess consumption and portion sizes should be appropriate to the setting portrayed. Advertising should not undermine the importance of healthy lifestyles.
Article 1 continued No advertisement should be such as to impair **public confidence** in advertising.	Advertisements should respect the spirit of ICC, local and sectoral self-regulatory codes, in order to maintain confidence both in advertising and in the self-regulation system.
ICC International Code of Advertising Practice Article 3 Advertisements should be so framed as not to abuse the trust of consumers or **exploit their lack of experience or knowledge.**	Where claims or terminology used in advertisements might reasonably be interpreted by a consumer as health or nutrition claims, they should be supportable with appropriate scientific evidence.

Acuerdo sobre la autorregulación de la publicidad de alimentos y bebidas dirigidas a menores entre el Ministerio de Sanidad y Consumo (MSC), la Federación de Industrias de Alimentación y Bebidas (FIAB) y la Asociación para la Autorregulación de la Comunicación Comercial (Autocontrol) (2005)




CÓDIGO (PAOS)

ANEXO 19

RELACIÓN DE NORMAS EN QUE ESTÁ INSPIRADO EL PRESENTE CÓDIGO

Ley 34/1988, de 11 de Noviembre, General de Publicidad .

Ley 3/1991, de 10 de enero, de Competencia Desleal.

Ley 26/1984, de 19 de julio, General para la Defensa de los Consumidores y Usuarios.

Real Decreto 1334/1999, de 31 de Julio, por el que se aprueba la Norma General de Etiquetado, Presentación y Publicidad de los Productos Alimenticios .

Ley 25/1994, de 12 de Julio, por la que se incorpora al Ordenamiento Jurídico español la Directiva 89/552/CEE de televisión sin fronteras.

Real Decreto 1907/1996, de 2 de Agosto, sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria.

El Código ha tenido asimismo en cuenta las normas éticas promovidas recientemente a nivel europeo e internacional en materia de publicidad de alimentos: los "Principios de la Publicidad de Alimentos y Bebidas" ("*Principles of food and beverage product advertising*") aprobados en febrero de 2004 por la Confederación de Industrias Agro-Alimentarias de la UE (CIAA), y el "ICC Framework for Responsible Food and Beverage Communications" de la Cámara de Comercio Internacional, aprobado en julio de 2004.

Repercusiones de las declaraciones de salud: La seguridad de los alimentos y su eficacia

MAD SCIENTIST SUPERMARKETS

La importancia de evidenciar las promesas de los alimentos funcionales
Katan, 2004

Critical Reviews in Food Science and Nutrition, 44:369–377 (2004)

ISSN: 1040-8398
DOI: 10.1080/10408690490489387

Taylor & Francis

Promises and Problems of Functional Foods

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"Functional" foods are branded foods, which claim, explicitly or implicitly, to improve health or well being. We review typical functional foods and their ingredients, efficacy, and safety. We also review regulations for health claims for foods worldwide. These regulations often allow manufacturers to imply that a food promotes health without providing proper scientific evidence. At the same time, regulations may ban claims that a food prevents disease, even when it does. We offer a plea for regulations that will permit all health claims that are supported by the totality of scientific evidence, and ban all claims that suggest an unproven benefit.

Keywords functional foods, health claims, regulation, supplements, Nutraceuticals

INTRODUCTION

Functional foods are the food industry's response to the consumers' demand for foods that are both attractive and healthy. Healthy diets offer a number of proven benefits: epidemiological and clinical studies show that a diet rich in fruits, vegetables, unrefined grains, fish, and low-fat dairy products, and low in saturated fats and sodium can reduce the risk of coronary heart disease and hypertension and perhaps even of some types of cancer (www.health.gov/dietaryguidelines). Some people have changed their diet accordingly, and have benefited from it with a much lower risk of heart disease (Hu et al., 2000). However, for most consumers it is a struggle to meet dietary guidelines. This is where industry steps in with special foods that promise to improve health and well-being with less effort and sacrifice. Such 'functional' foods match the spirit of our time. The 1970s saw an upsurge of 'natural' and 'organic' foods, and the 1980s saw the introduction of 'low' and 'light' foods with less calories, cholesterol, or salt. Not all of them were palatable, but consumers were willing to make a sacrifice, because at that time, eating for long-term prevention of disease fitted the prevailing mood. Although by 1998 94% of US shoppers still said they sometimes select food for health reasons, only 24% ate healthy for long-term prevention of disease, which is down from 45% in a 1990 survey (Consumer Motivation, 2000). By 1998, 41% are motivated by expectation of short-term benefits. Thus, consumers are less willing to sacrifice taste or convenience for long-term health. This has created a market for foods that combine taste and convenience with the suggestion of short- or long-term health benefits, i.e., for functional foods.

It is often questioned whether individual foods can be healthy or unhealthy, as it is the composition of the entire diet that determines nutritional status. However, changes in diet necessarily involve adding certain foods and leaving out others. We, therefore, suggest that certain foods could be called healthy, but only for, a defined population. For instance, increased consumption of whole-grain foods might prevent constipation and possibly heart disease in adults, but an excess of whole-grain foods may cause malnutrition in rapidly growing infants.

WHAT ARE FUNCTIONAL FOODS?

The definition of functional foods is a contentious issue. Regulatory agencies do not recognize 'functional food' as a nutritional entity. Even in Japan, where functional foods originated, the term itself was not adopted because it was agreed that all foods are already functional (Baily, 1999). The International Food Information Council (IFIC), which is supported primarily by food, beverage, and agricultural industries, defines

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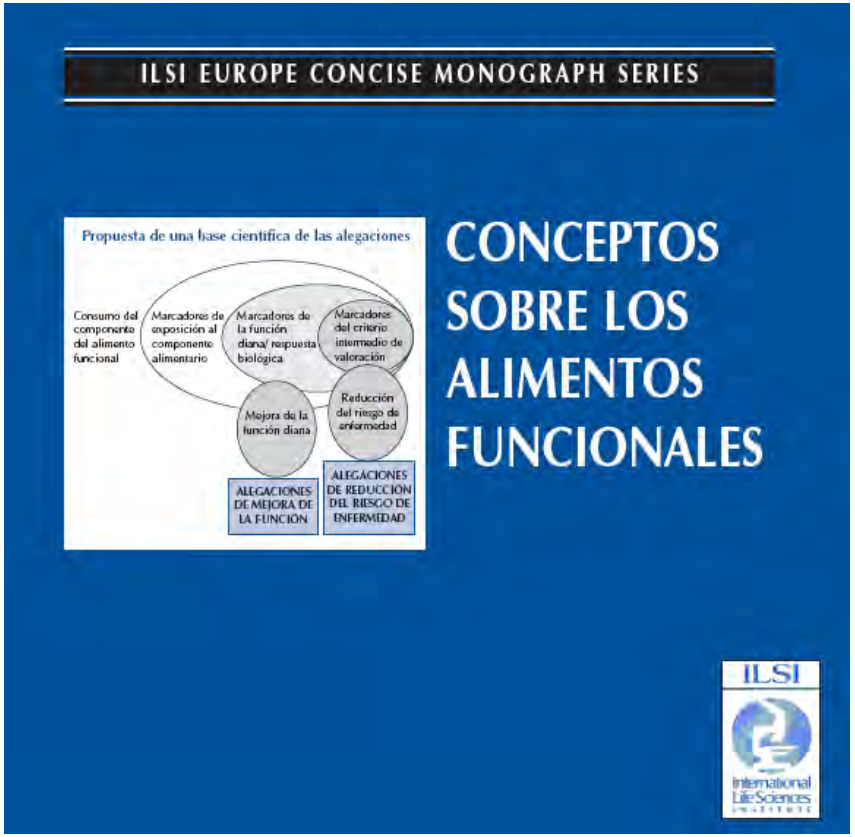
- A menudo se cuestiona si los alimentos individuales pueden ser saludables o no así como si es la composición de la dieta completa la que determina el status nutricional.
- En todo caso, las promesas de los alimentos funcionales deberán basarse en la evidencia científica.

International Life Sciences Institute
ILSI, 2002



- ILSI recomienda que la funcionalidad de los ingredientes se teste en diferentes grupos poblacionales así como en diferentes situaciones al objeto de comprobar su bioactividad.

Un ejemplo: El CLA no funciona en obesos y si en sujetos con sobrepeso

Conjugated linoleic acid supplementation for 1 y does not prevent weight or body fat regain[1–3]

Thomas Meinert Larsen, Søren Toubro, Ola Gudmundsen, and Arne Astrup

ABSTRACT

Background: Conjugated linoleic acid (CLA) is marketed as a safe, simple, and effective dietary supplement to promote the loss of body fat and weight. However, most previous studies have been of short duration and inconclusive, and some recent studies have questioned the safety of long-term supplementation with CLA.

Objective: Our aim was to assess the effect of 1-y supplementation with CLA (3.4 g/d) on body weight and body fat regain in moderately obese people.

Design: One hundred twenty-two obese healthy subjects with a body mass index (in kg/m²) > 28 underwent an 8-wk dietary run-in with energy restriction (3300–4200 kJ/d). One hundred one subjects who lost >8% of their initial body weight were subsequently randomly assigned to a 1-y double-blind CLA (3.4 g/d; $n = 51$) or placebo (olive oil; $n = 50$) supplementation regime in combination with a modest hypocaloric diet of −1250 kJ/d. The effects of treatment on body composition and safety were assessed with the use of dual-energy X-ray absorptiometry and with blood samples and the incidence of adverse events, respectively.

Results: After 1 y, no significant difference in body weight or body fat regain was observed between the treatments. The CLA group ($n = 40$) regained a mean (±SD) 4.0 ± 5.6 kg body weight and 2.1 ± 5.0 kg fat mass compared with a regain of 4.0 ± 5.0 kg body weight and 2.7 ± 4.9 kg fat mass in the placebo group ($n = 43$). No significant differences in reported adverse effects or indexes of insulin resistance were observed, but a significant increase in the number of leukocytes was observed with CLA supplementation.

Conclusion: A 3.4-g daily CLA supplementation for 1 y does not prevent weight or fat mass regain in a healthy obese population. *Am J Clin Nutr* 2006;83:606–12.

KEY WORDS Conjugated linoleic acid, dietary supplement, obesity, body fat, safety

INTRODUCTION

The long-term effects of conventional weight-management programs are unsatisfactory, and alternative therapies, including dietary supplements, are repeatedly called for by obese persons and society. Although the use of dietary supplements is widespread, the documentation on their efficacy and safety is not convincing (1). Conjugated linoleic acid (CLA) is a mixture of linoleic acid isomers with conjugated double bonds that has been studied intensively (2). CLA is sold commercially as dietary supplements for weight and fat loss. The products often have a 40%:40% content of *cis*-9, *trans*-11 (*c*9,*t*11) and *trans*-10,*cis*-12 (*t*10,*c*12) fatty acids, and the remaining 20% is usually composed of ≈1–4% other conjugated fatty acids and 15–19% other nonconjugated fatty acids (3). The CLA *c*9,*t*11 isomer is a natural constituent in the human diet, and the average daily intake of the *c*9,*t*11 isomer in Western societies is between 150 and 200 mg/d (4), whereas the intake of the *t*10,*c*12 isomer is negligible.

In humans, a dose-response study of CLA supplementation (a mixture of *c*9,*t*11 and *t*10,*c*12) over 3 mo reported a decrease in body fat, which was assessed by dual X-ray absorptiometry (DXA) scanning, at CLA doses ≤3.4 g/d without additional effects at doses ≥3.4 g/d (5). The only published long-term (>6 mo) placebo-controlled human study provided subjects with CLA (a mixture of *c*9,*t*11 and *t*10,*c*12, as either free fatty acids or triacylglycerols) for 12 mo and induced significant losses of 2.0 kg body weight (in the CLA triacylglycerol group only) and 2.2 kg body fat mass (in both CLA supplementation regimens) compared with placebo (6). An open label 1-y extension of that study showed not only that the placebo group lost body fat mass when given CLA, but also that a 2-y treatment did not add more loss of fat mass than did the 1-y treatment (7).

To our knowledge, only 2 studies have investigated the effect of CLA during weight gain in humans, and both found no effect on body weight or body fat regain after a 3- or ≈6-mo treatment with CLA (as a mixture of *c*9,*t*11 and *t*10,*c*12) after an initial loss of body weight (8, 9). However, the 3-mo study found that CLA did increase the amount of lean body mass compared with placebo (8).

In the present study, we investigated whether 1-y supplementation with CLA (3.4 g/d of a mixture of *c*9,*t*11 and *t*10,*c*12 as triacylglycerols) could decrease body weight and body fat mass regain in moderately obese persons after a low calorie diet (LCD)–induced weight loss (primary endpoint). In addition, we assessed the safety of the treatment [by monitoring adverse events, vital signs, electrocardiograms (ECGs), and blood variables, including indexes of insulin resistance] and the influence

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[2] Supported by Cognis Corporation, Nutrition & Health, Functional Ingredients, IL (previously Natural ASA, Sandvika, Norway).

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Conjugated linoleic acid supplementation for 1 y reduces body fat mass in healthy overweight humans[1–3]

Jean-Michel Gaullier, Johan Halse, Kjetil Høye, Knut Kristiansen, Hans Fagertun, Hogne Vik, and Ola Gudmundsen

ABSTRACT

Background: Short-term trials showed that conjugated linoleic acid (CLA) may reduce body fat mass (BFM) and increase lean body mass (LBM), but the long-term effect of CLA was not examined.

Objective: The objective of the study was to ascertain the 1-y effect of CLA on body composition and safety in healthy overweight adults consuming an ad libitum diet.

Design: Male and female volunteers ($n = 180$) with body mass indexes (in kg/m²) of 25–30 were included in a double-blind, placebo-controlled study. Subjects were randomly assigned to 3 groups: CLA–free fatty acid (FFA), CLA-triacylglycerol, or placebo (olive oil). Change in BFM, as measured by dual-energy X-ray absorptiometry, was the primary outcome. Secondary outcomes included the effects of CLA on LBM, adverse events, and safety variables.

Results: Mean (± SD) BFM in the CLA-triacylglycerol and CLA-FFA groups was 8.7 ± 9.1% and 6.9 ± 9.1%, respectively, lower than that in the placebo group ($P < 0.001$). Subjects receiving CLA-FFA had 1.8 ± 4.3% greater LBM than did subjects receiving placebo ($P = 0.002$). These changes were not associated with diet or exercise. LDL increased in the CLA-FFA group ($P = 0.008$), HDL decreased in the CLA-triacylglycerol group ($P = 0.003$), and lipoprotein(a) increased in both CLA groups ($P < 0.001$) compared with month 0. Fasting blood glucose concentrations remained unchanged in all 3 groups. Glycated hemoglobin rose in all groups from month 0 concentrations, but there was no significant difference between groups. Adverse events did not differ significantly between groups.

Conclusion: Long-term supplementation with CLA-FFA or CLA-triacylglycerol reduces BFM in healthy overweight adults. *Am J Clin Nutr* 2004;79:1118–25.

KEY WORDS Conjugated linoleic acid, body fat mass, lean body mass, weight, body mass index, dual-energy X-ray absorptiometry, overweight, humans

INTRODUCTION

Conjugated linoleic acid (CLA) is a mixture of linoleic acid isomers with conjugated double bonds. CLA was first identified when extracts from fried beef were found to be anticarcinogenic (1). This effect was confirmed in animal and in vitro models of carcinogenesis (2–7). Later studies in animals showed other beneficial health roles for CLA, including protection against arteriosclerosis (8, 9), immune stimulation (10, 11), and the normalization of impaired glucose tolerance and improvement of hyperinsulinemia in ZDF rats (12). Numerous studies in mice, rats, hamsters, rabbits, and pigs showed that CLA supplementation causes changes in body composition, such as a reduction in body fat mass (BFM) and an increase in lean body mass (LBM; 13–23).

In humans, only short-term clinical studies with small numbers of subjects have been conducted with CLA (24). Some CLA studies performed with a mixture of the bioactive isomers *cis*-9, *trans*-11 and *trans*-10, *cis*-12, showed reductions in BFM and in some cases increases in LBM (25–27). Other short-term studies performed with the use of different methods and technology, such as body-composition measurements, daily dosage, CLA composition, and study design, did not show any effects on body composition (28–32), which raises questions about the consistency of the effects of CLA on BFM and LBM in humans. After correction for differences in metabolic rate, similar effects are observed in humans and in mice, which suggests that the mechanisms for reducing BFM in animals and humans may be similar (33).

Previous short-term studies concluded that CLA supplementation was safe. The only adverse events (AEs) reported in these studies were gastrointestinal complaints (25, 27). Two published clinical studies showed that CLA may induce lipid peroxidation (34, 35). Riserus et al (32, 36) showed that a preparation with high concentrations of the *trans*-10, *cis*-12 CLA isomer causes increases in F_2-isoprostane excretion and in insulin resistance in men with the metabolic syndrome. Men with the metabolic syndrome receiving a mixture of the 2 isomers (*cis*-9, *trans*-11 and *trans*-10, *cis*-12) had greater F_2-isoprostane excretion than did those in the placebo group, but the CLA mixture had no effect on insulin resistance (32, 36).

The present study was designed primarily to investigate the long-term effects of CLA (as a 50:50 mixture of *cis*-9, *trans*-11 and *trans*-10, *cis*-12 isomers) on BFM and LBM in a randomized, double-blind, placebo-controlled study. Because CLA is mar-

[1] From the Scandinavian Clinical Research AS (JMG, KK, and OG) and the Scandinavian Statistical Services AS (HF), Kjeller, Norway; the Betanien Medical Center, Oslo (JH); the Helsetorget Medical Center, Elverum, Norway (KH); and the Matforsk (Norwegian Food Research Institute), Ås, Norway (HV).

[2] Supported by Natural LTD and Cognis Nutrition and Health.

[3] Address reprint requests to J-M Gaullier, Scandinavian Clinical Research AS, Gleerupsvei 8, PO Box 135, 2027 Kjeller, Norway. E-mail: j-m@scr.no.

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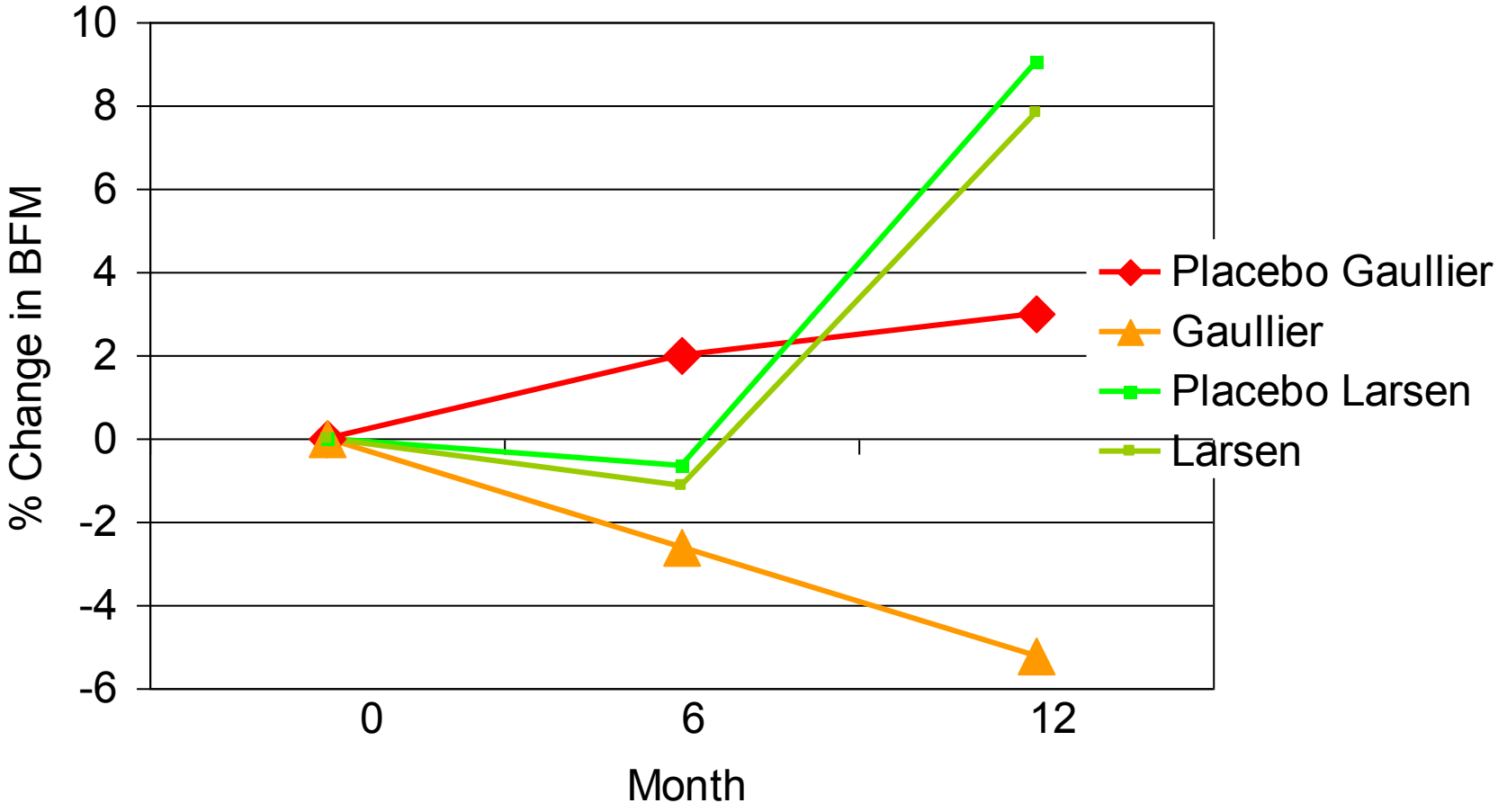
% Change in BFM in Overweight/Obese Adults with 3,4g CLA for 12 months



Otro ejemplo: El CLA funciona mejor cuando su ingesta se acompaña de ejercicio

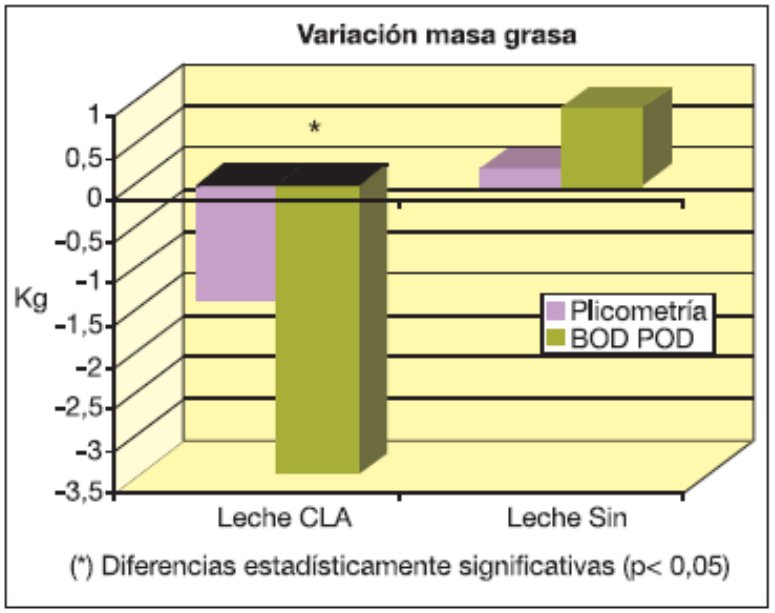
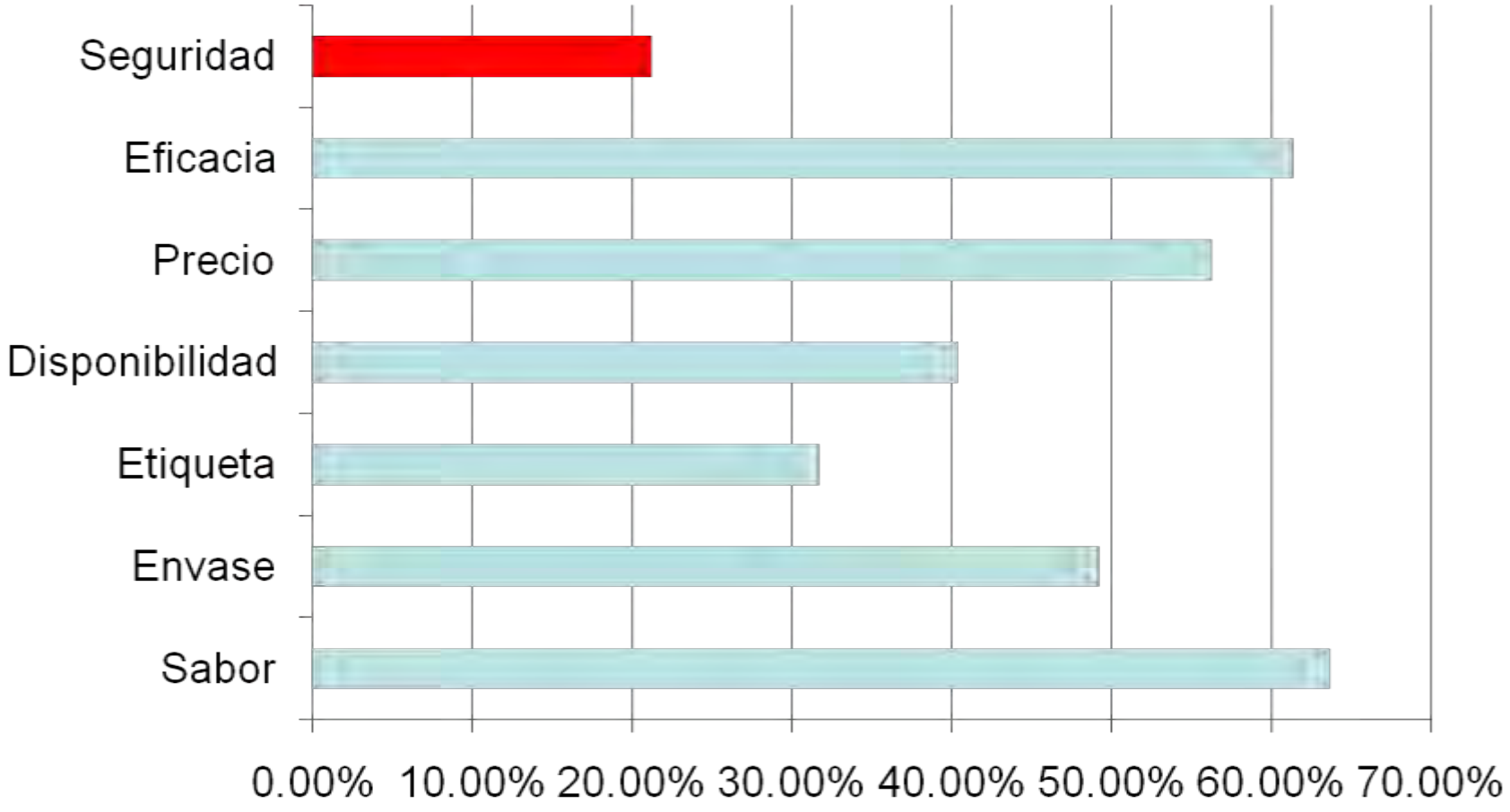
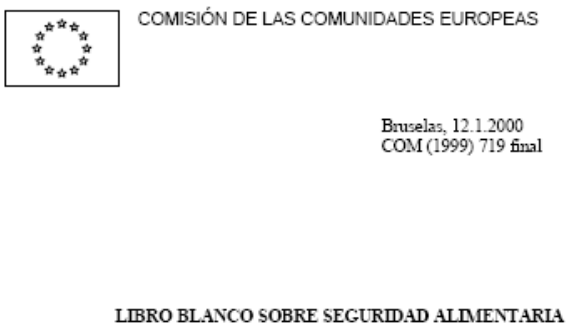


Figura 5. Diferencias en la masa grasa perdida en el grupo que consumió Tonalín® (a la izquierda de la Fig.) en función del tipo de medición. A la derecha vemos el grupo que consumió leche semidesnatada.

Valoración de características en los alimentos funcionales (y la seguridad?)



Libro Blanco sobre seguridad alimentaria
CCE. COM 1999,719



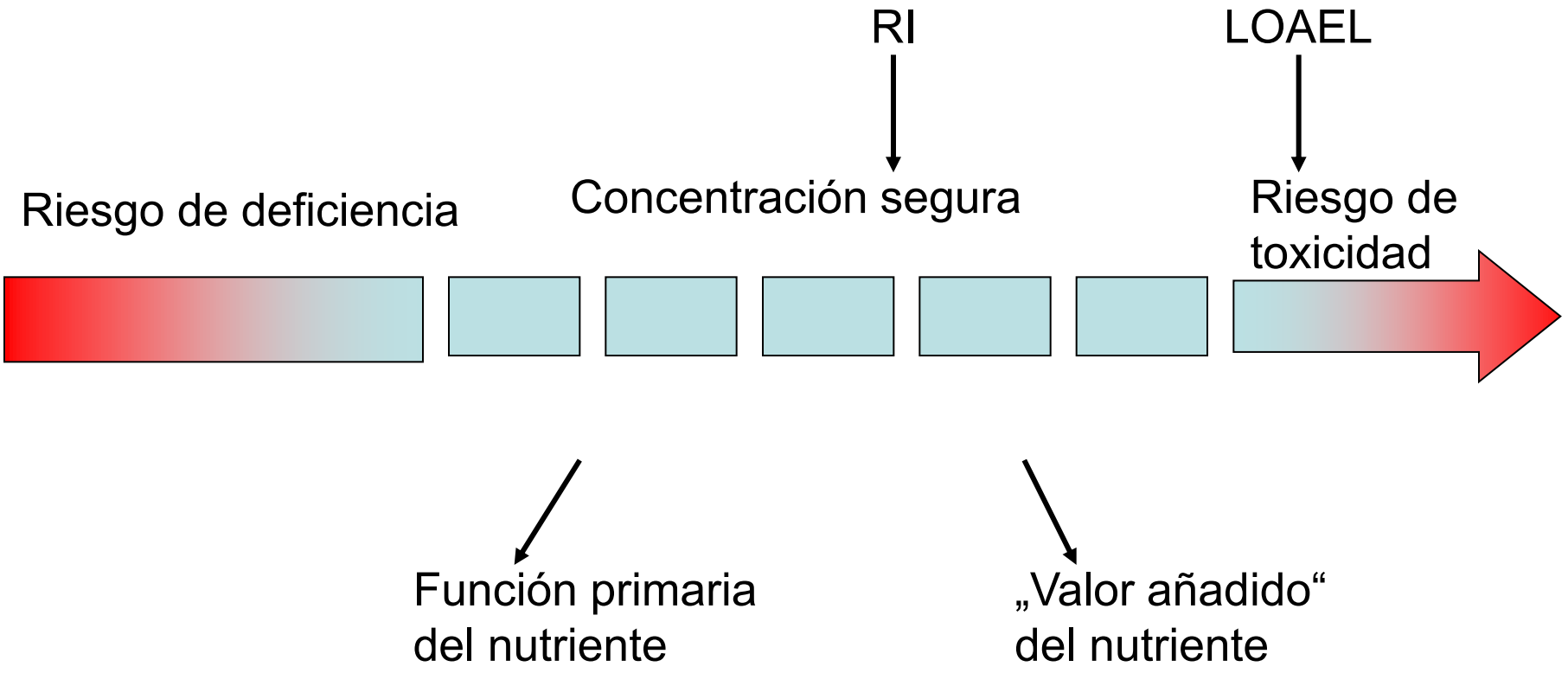
COMISIÓN DE LAS COMUNIDADES EUROPEAS

Bruselas, 12.1.2000
COM (1999) 719 final

LIBRO BLANCO SOBRE SEGURIDAD ALIMENTARIA

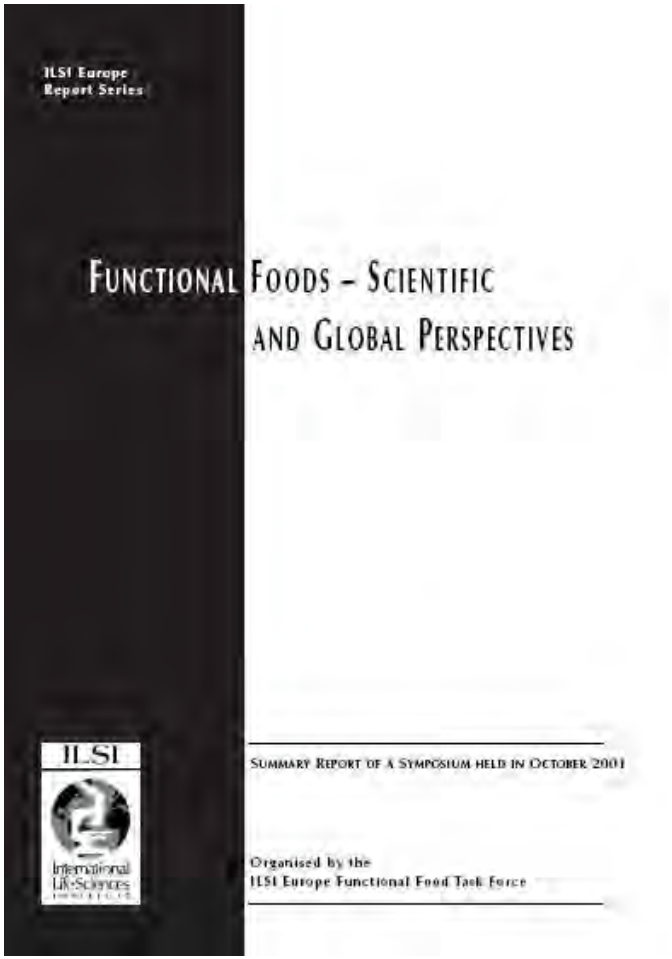
- **El análisis del riesgo debe ser la base de la política de seguridad alimentaria**. La UE ha de basar su política alimentaria en la aplicación de los tres componentes del análisis del riesgo:
  - determinación del riesgo (asesoramiento científico y análisis de datos),
  - gestión del riesgo (reglamentación y control) y
  - proceso de comunicación sobre el riesgo.
- Llegado el caso, el principio de precaución se aplicará en las decisiones de gestión del riesgo.

Seguridad de los alimentos funcionales



RI: Recommended Intake
LOAEL: Lowest Observed Adverse Effect Level

Symposium Report on Functional Foods – Scientific and Global Perspectives
ILSI, 2001



- El criterio tradicional de seguridad basado en el NOAEL (“No Observed Adverse Effect Level”) puede no ser apropiado para valorar la seguridad de los alimentos funcionales.
- Los alimentos funcionales son mezclas complejas siendo difícil generar efectos agudos como es esperado con la aproximación del NOAEL.
- La aproximación a los alimentos funcionales debe hacerse más sobre los efectos beneficiosos que sobre la seguridad.

Aspectos de seguridad a considerar

- El nivel esperado de exposición no debe superar el nivel de seguridad.
- Deberá hacerse un estudio de “exposición acumulativa” especialmente cuando el ingrediente pretenda ser incluido en varios tipos de alimentos.
- Debe estudiarse el impacto nutricional a los niveles aconsejados de consumo para objetivar que no existen cambios en los hábitos dietéticos.
- También se estudiará la influencia del Claim sobre los hábitos dietéticos.
- Debe considerarse la influencia entre los ingredientes bioactivos presentes en los alimentos.
- Debe identificarse el grupo target del alimento y aquellos colectivos que no deben usarlo.
- Debería estudiarse la posibilidad de identificar efectos adversos en población vulnerable (niños, embarazadas, ….).

¿Qué influencia puede tener la matriz sobre la eficacia y/o seguridad de un alimento funcional?

Health Council of the Netherlands. Foods and dietary supplements with health claims. The Hague: Health Council of the Netherlands, 2003; publication no. 2003/09E

- *A claim should always be based on scientific research involving human subjects and* ***use of the substance in the form it is found in the food or dietary supplement*** *for which the claim is made*.

Ejemplo: La dieta mediterránea reduce el riesgo de enfermedad cardiovascular

Effect of a Mediterranean-Style Diet on Endothelial Dysfunction and Markers o...
Katherine Esposito; Raffaele Marfella; Miryam Ciotola; Carmen Di Palo; et al
JAMA; Sep 22-Sep 29, 2004; 292, 12; AMA Titles
pg. 1440

ORIGINAL CONTRIBUTION

Effect of a Mediterranean-Style Diet on Endothelial Dysfunction and Markers of Vascular Inflammation in the Metabolic Syndrome

A Randomized Trial

See also pp 1433 and 1490.

Mediterranean Diet, Traditional Risk Factors, and the Rate of Cardiovascular Complications After Myocardial Infarction

Final Report of the Lyon Diet Heart Study

Michel de Lorgeril, MD; Patricia Salen, BSc; Jean-Louis Martin, PhD; Isabelle Monjaud, BSc; Jacques Delaye, MD; Nicole Mamelle, PhD

Background—The Lyon Diet Heart Study is a randomized secondary prevention trial aimed at testing whether a Mediterranean-type diet may reduce the rate of recurrence after a first myocardial infarction. An intermediate analysis showed a striking protective effect after 27 months of follow-up. This report presents results of an extended follow-up (with a mean of 46 months per patient) and deals with the relationships of dietary patterns and traditional risk factors with recurrence.

Methods and Results—Three composite outcomes (COs) combining either cardiac death and nonfatal myocardial infarction (CO 1), or the preceding plus major secondary end points (unstable angina, stroke, heart failure, pulmonary or peripheral embolism) (CO 2), or the preceding plus minor events requiring hospital admission (CO 3) were studied. In the Mediterranean diet group, CO 1 was reduced (14 events versus 44 in the prudent Western-type diet group, $P=0.0001$), as were CO 2 (27 events versus 90, $P=0.0001$) and CO 3 (95 events versus 180, $P=0.0002$). Adjusted risk ratios ranged from 0.28 to 0.53. Among the traditional risk factors, total cholesterol (1 mmol/L being associated with an increased risk of 18% to 28%), systolic blood pressure (1 mm Hg being associated with an increased risk of 1% to 2%), leukocyte count (adjusted risk ratios ranging from 1.64 to 2.86 with count $>9\times10^9$/L), female sex (adjusted risk ratios, 0.27 to 0.46), and aspirin use (adjusted risk ratios, 0.59 to 0.82) were each significantly and independently associated with recurrence.

Conclusions—The protective effect of the Mediterranean dietary pattern was maintained up to 4 years after the first infarction, confirming previous intermediate analyses. Major traditional risk factors, such as high blood cholesterol and blood pressure, were shown to be independent and joint predictors of recurrence, indicating that the Mediterranean dietary pattern did not alter, at least qualitatively, the usual relationships between major risk factors and recurrence. Thus, a comprehensive strategy to decrease cardiovascular morbidity and mortality should include primarily a cardioprotective diet. It should be associated with other (pharmacological?) means aimed at reducing modifiable risk factors. Further trials combining the 2 approaches are warranted. **(*Circulation*. 1999;99:779-785.)**

Key Words: diet ■ trials ■ coronary disease ■ myocardial infarction

Recent dietary trials in secondary prevention of coronary heart disease (CHD) reported impressive reduction of the recurrence rate by a range of 30% to 70%.[1-3] These were in contrast with previous dietary trials, which were aimed at reducing blood cholesterol by a low-cholesterol, low-saturated-fat, high-polyunsaturated-fat diet and failed to significantly improve the overall clinical prognosis of the dieters.[4] The successful trials tested dietary patterns characterized by a low intake of total and saturated fats[2,3] and/or increased intake of marine[1] or plant ω-3 fatty acids[2,3] and were not intended primarily to reduce blood cholesterol. Two of these trials[2,3] also included a high intake of fresh fruits and vegetables, legumes, and cereals containing large amounts of fibers, antioxidants, minerals, vegetable proteins, and vitamins of the B group. The credibility of these recent trials was considerably reinforced by a number of recent studies showing major cardioprotective effects of most of these foods and nutrients,[5-14] with a particular emphasis on ω-3 fatty acids[8,9] and on folates for their role in hyperhomocysteinemia and in the arginine-nitric oxide-tetrahydrobiopterin pathway,[11-14] 2 possible major mediators in the development of CHD.

See p 733

The Lyon Diet Heart Study is a randomized, single-blind secondary prevention trial aimed at testing whether a Mediterranean-type diet, compared with a prudent Western-

Received June 14, 1998; revision received October 14, 1998; accepted October 26, 1998.
From Explorations Fonctionnelles Cardiorespiratoires et Métaboliques, CHU de Saint-Etienne (M.d.L., P.S., I.M.), Saint-Etienne; and INRETS Epidemiology Unit (J.L.M.), Hôpital Cardiovasculaire (J.D.) and INSERM Unit 265 (N.M.), Lyon, France.
Correspondence to Dr M. de Lorgeril, Explorations Fonctionnelles Cardiorespiratoires et Métaboliques, Niveau 6, CHU Nord, 42055 Saint-Etienne Cedex 2, France. E-mail lorgeril@univ-st-etienne.fr

Circulation is available at http://www.circulationaha.org

Ejemplo: Productos lácteos y salud

British Journal of Nutrition (2006), 95, 1–8
DOI: 10.1079/BJN20061709

Dairy products and health: a review of the epidemiologic evidence

Eva-Elisa Álvarez-León[1], Blanca Román-Viñas[2] and Lluís Serra-Majem[1,2,3]*

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[2] *Community Nutrition Research Centre, Scientific Park of Barcelona, Spain*
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Evidence-based nutrition is essential to move forward in the science of community nutrition. The present study is a review of the epidemiological evidence of dairy products and health. There is an inverse association between the intake of dairy products and hypertension, stroke and colorectal cancer. There is no evidence of the association between the consumption of dairy products and breast cancer. There is some evidence linking high-fat dairy products and an incremental risk of prostate cancer and weak evidence of the protective capacity of dairy products on bone health. More prospective studies should be developed in order to establish better evidence of the relationship between dairy products and health. Due to the importance of dairy products on public health nutrition, quantitative recommendations should be established in the light of the scientific evidence.

Dairy products: Public health: Review literature

Public health nutrition should not be unaware of the importance of evidence-based medicine. Systematic review of the epidemiological evidence and the critical analysis of that evidence has resulted in a huge advance in the development of protocols and guides to clinical practice. Evidence-based medicine has resulted in more appropriate actions to solve everyday clinical problems, based on the critical evaluation of such evidence, instead of intuition or experience.

To develop public health nutrition policies based on scientific evidence, it is important to fight against misinformation of the general population about nutritional aspects of their daily food intake. Frequently, the benefits and risks were put down to dairy products on the basis of physiopathological theories, but with no epidemiological studies to support them.

The objective of the present work is to review papers covering dairy products in both health promotion and disease prevention. Focus was placed on the critical analysis of the scientific literature, pointing out future needs in the research of evidence between dairy products and health.

Methods

Relevant articles were obtained through searching the MEDLINE database (from 1966 to January 2005). Keywords used in this search were the MeSH term 'dairy products', defined as 'raw and processed or manufactured milk and milk-derived products' that included the following products: butter, cheese, ice cream, margarine, milk and cultured milk products (yoghurt) and some health conditions. The selection of health conditions was carried out on the basis of its public health importance (prevalence and/or severity) and included neoplasms, cardiovascular diseases (myocardial infarction, hypertension or cerebrovascular accident), and osteoporosis or bones. The MEDLINE search was complemented with the automatic PubMed clinical queries strategy, which combined 'dairy products' search with citations identified as systematic reviews, meta-analyses, reviews of clinical trials, evidence-based medicine, consensus development conferences and guidelines. Citations from journals specializing in clinical review studies are also included. To be edible, works must fulfil the following eligibility criteria: abstract must be available, be written in Spanish, English or French and cover human population. Priority was given to meta-analysis and systematic reviews.

Evidence from epidemiologic studies of dairy products and health was summarized. To evaluate the strength of the evidence, validity and accuracy were taken into account. Validity was assessed analysing the presence of possible systematic bias in the design or execution of the studies. Accuracy was assessed considering the size of the sample and the wideness of the confidence intervals.

Results

There were more than 85 000 articles on the consumption of dairy products. Once the inclusion criteria were applied, 14 meta-analyses or systematic reviews about dairy products and the selected health conditions were identified, six on cancer, six on cardiovascular diseases and two about bone health. The results were separated by health condition.

Dairy products and cancer

There were six meta-analyses and one systematic review that specifically analysed the consumption of dairy products and cancer risk (one for colorectal cancer, three for breast cancer and three for prostate cancer).

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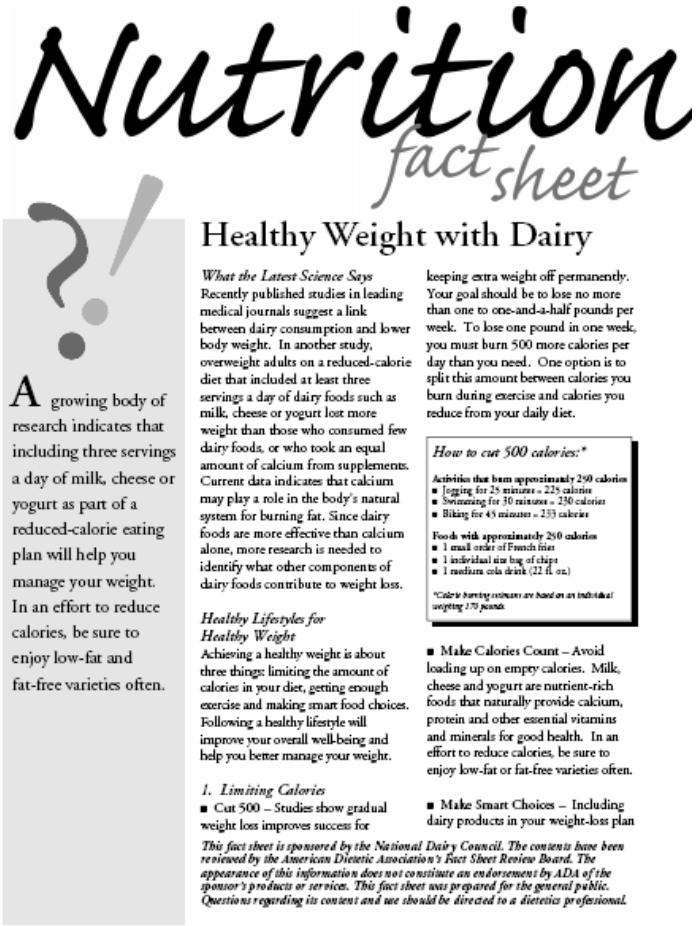
- *There is an inverse association between the intake of dairy products and hypertension, stroke and colorectal cancer.*
- *There is no evidence of the association between the consumption of dairy products and breast cancer.*
- *There is some evidence linking highfat dairy products and an incremental risk of prostate cancer and weak evidence of the protective capacity of dairy products on bone health.*

Los lácteos ayudan a reducir el peso corporal



Nutrition fact sheet

Healthy Weight with Dairy

A growing body of research indicates that including three servings a day of milk, cheese or yogurt as part of a reduced-calorie eating plan will help you manage your weight. In an effort to reduce calories, be sure to enjoy low-fat and fat-free varieties often.

What the Latest Science Says

Recently published studies in leading medical journals suggest a link between dairy consumption and lower body weight. In another study, overweight adults on a reduced-calorie diet that included at least three servings a day of dairy foods such as milk, cheese or yogurt lost more weight than those who consumed few dairy foods, or who took an equal amount of calcium from supplements. Current data indicates that calcium may play a role in the body's natural system for burning fat. Since dairy foods are more effective than calcium alone, more research is needed to identify what other components of dairy foods contribute to weight loss.

Healthy Lifestyles for Healthy Weight

Achieving a healthy weight is about three things: limiting the amount of calories in your diet, getting enough exercise and making smart food choices. Following a healthy lifestyle will improve your overall well-being and help you better manage your weight.

1. Limiting Calories

- Cut 500 – Studies show gradual weight loss improves success for keeping extra weight off permanently. Your goal should be to lose no more than one to one-and-a-half pounds per week. To lose one pound in one week, you must burn 500 more calories per day than you need. One option is to split this amount between calories you burn during exercise and calories you reduce from your daily diet.

*How to cut 500 calories:**

Activities that burn approximately 250 calories
- Jogging for 25 minutes = 225 calories
- Swimming for 30 minutes = 250 calories
- Biking for 45 minutes = 233 calories

Foods with approximately 250 calories
- 1 small order of French fries
- 1 individual size bag of chips
- 1 medium cola drink (22 fl. oz.)

*Calorie burning estimates are based on an individual weighing 170 pounds.

- Make Calories Count – Avoid loading up on empty calories. Milk, cheese and yogurt are nutrient-rich foods that naturally provide calcium, protein and other essential vitamins and minerals for good health. In an effort to reduce calories, be sure to enjoy low-fat or fat-free varieties often.
- Make Smart Choices – Including dairy products in your weight-loss plan

This fact sheet is sponsored by the National Dairy Council. The contents have been reviewed by the American Dietetic Association's Fact Sheet Review Board. The appearance of this information does not constitute an endorsement by ADA of the sponsor's products or services. This fact sheet was prepared for the general public. Questions regarding its content and use should be directed to a dietetics professional.

- *Recently published studies in leading medical journals suggest a link between dairy consumption and lower body weight.*

Ejemplo: Determinados péptidos lácteos pueden provocar alergia

ACTA VET. BRNO 2004, 73: 291-298

Antigenicity for Humans of Cow Milk Caseins, Casein Hydrolysate and Casein Hydrolysate Fractions

[1]I. NENTWICH, [1]ZS. SZÉPFALUSI, [2]C. KUNZ, [3]P. SPUERGIN, [1]R. URBANEK

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Abstract

Nentwich I., Szépfalusi Zs., Kunz C., Spuergin P., Urbanek R.: *Antigenicity for Humans of Cow Milk Caseins, Casein Hydrolysate and Casein Hydrolysate Fractions.* Acta Vet. Brno 2004, 73: 291-298.

Cow milk casein consists of several fractions each of which have different structure and differing antigenicity. The aim of the study was to investigate the capacity of cow milk casein, casein fractions, casein hydrolysate and its fractions to bind human IgG antibodies (antigenicity).

Whole cow milk, bovine casein, α-casein native and dephosphorylated, β- and κ-casein, further a casein hydrolysate and its fractions were incubated in a IgG-ELISA assay with sera from five patients with cow milk intolerance and a pooled control serum from milk drinking healthy individuals.

In healthy controls, predominantly β-caseins, both commercial and chromatographically separated, contained the strongest antigenic epitopes. In milk intolerant infants, however, κ-casein along with β-caseins was the strongest antigen. The antigenicity of the casein hydrolysate compared to nonhydrolysed casein was reduced down to 18.5 and 41.8% measured with patient and control sera, respectively. There were traces of intact protein in the hydrolysate. Antigenicity of the casein hydrolysate fractions reached only 24 to 44% of the antigenicity of the whole hydrolysate. Although their antigenicity roughly correlated with their molecular weight, only negligible differences among particular fractions were found.

Cow milk beta-casein is the strongest antigen in healthy controls while kappa-casein possesses the high antigenicity in the milk intolerant individuals. For milk intolerant individuals, the tested casein hydrolysate was approximately 5 times less antigenic compared to whole casein. Antigenicity of the hydrolysate fractions were lower than that of the whole hydrolysate. Identification of cow milk caseins and its fractions with the highest bindnig capacity for human IgG antibodies is important for manufacturing of antigen-reduced formulas based on casein hydrolysates.

Cow milk, caseins, infants, IgG, protein hydrolysates

Cow milk proteins belong to the strongest antigens in human diet. Caseins, representing about 80% of all cow milk proteins (Eigel et al. 1984), have a fibrilar structure consisting of mainly sequential epitopes able to bind to specific IgG antibodies. Antigenic reactivity of a protein refers to its capacity to bind specifically to the functional binding sites or paratopes of certain immunoglobulin molecules (van Regenmortel 1988). This is different among proteins due to the manifold quality and quantity of their specific epitopes. Using heat treatment and/or enzymatic hydrolysis, a reduction of the binding capacity of the proteins can be achieved. To study antigenicity of cow milk proteins and protein fragments sera from immunized animals on one hand and from sensitized human individuals on the other hand, can be used (Otani 1989; Otani et al. 1989). Comparing antigenicity of casein hydrolysate to that of raw casein gives information on the efficacy of hydrolysis performed. Assessment

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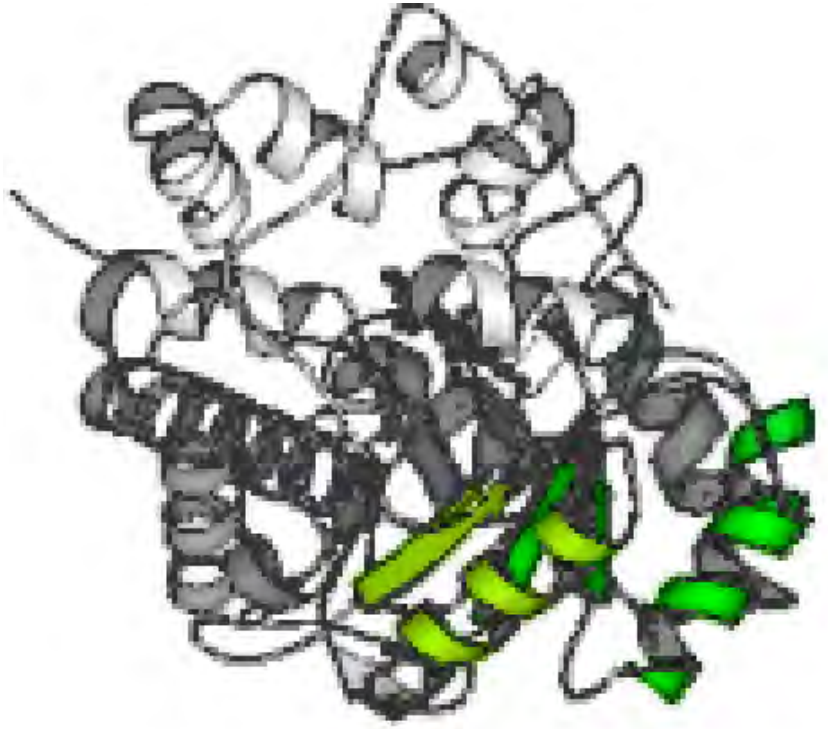

Ejemplo: Ingesta de Fitoesteroles y reducción de carotenoides en plasma

High dietary intake of phytosterol esters decreases carotenoids and increases plasma plant sterol levels with no additional cholesterol lowering

Peter M. Clifton,[1,*] Manny Noakes,[*] Donna Rose,[§] Andriana Fassoulakis,[§] Marja Gehm,[†] and Paul Nestel[†]

Goodman Fielder Pty Ltd.,* North Ryde 2113, Australia; and Baker Medical Research Institute,† Melbourne, Victoria, Australia; Commonwealth Scientific and Industrial Research Organisation,§ Human Nutrition, Adelaide, SA, Australia

Abstract The objective of this study was to measure the effects on serum lipids and plasma phytosterols of 6.6 g/day phytosterols from three foods (bread, breakfast cereal, and spread) consumed for 12 weeks compared with a diet that was not enriched with phytosterols. Thirty-five subjects in a dietitian-run metabolic unit, single-blind study consisting of a 2 week baseline period, 6 weeks on high-phytosterol intake, 6 weeks on high-phytosterol intake plus increased fruit and vegetable intake, and a final 2 week washout period. Serum total cholesterol decreased by 8.8% from 6.50 to 6.04 mmol/L and LDL cholesterol decreased by 12.6% from 4.44 to 3.88 mmol/L. Plasma phytosterol levels increased by 49% (sitosterol) and 109% (campesterol). Cholesterol-adjusted plasma α- and β-carotene levels decreased by 19–25%, lutein by 14%, and lycopene by 11%. Levels of α-carotene and lutein increased with extra fruit and vegetables. Only lycopene failed to increase during the washout phase. There were no significant changes in biochemical parameters. Serum LDL cholesterol lowering with 6.6 g/day ingested phytosterols was in the range seen with 1.6–3.2 g/day phytosterols. Lowering of plasma carotenoids was greater than that seen with lower phytosterol intake and was partially reversed by increased fruit and vegetable intake.—Clifton, P. M., M. Noakes, D. Rose, A. Fassoulakis, M. Gehm, and P. Nestel. High dietary intake of phytosterol esters decreases carotenoids and increases plasma plant sterol levels with no additional cholesterol lowering. *J. Lipid Res.* 2004. 45: 1405–1410.

Supplementary key words

There are extensive data confirming the effectiveness of esterified phytosterols in margarines, with LDL cholesterol lowering of 10–15 % with a dose of 1.6–2.4 g/day sterol (1–6). There are few published data (7, 8) on the short-term use of higher amounts of plant sterols (3.6–9 g/day) in margarines, and there is some evidence that cholesterol lowering is greater on a high dose of phytosterol without enhancement of cholesterol lowering (7). It is not known if increased fruit and vegetables can restore the plasma level of carotenoids after a higher intake of phytosterols, although they can achieve this with a more usual intake of phytosterols (4). The aim of this study was to examine the effect of 6.6 g/day phytosterols in breakfast cereal, bread, and margarine over a 12 week period, to examine the role of extra fruit and vegetables in ameliorating the decrease in carotenoid concentrations, and to examine the changes in carotenoid concentrations after cessation of phytosterol ingestion.

METHODS

Subjects

Thirty-five mildly hypercholesterolemic men and women were recruited and entered the study. The study was confirmed as a clinical research project by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Division of Human Nutrition in Adelaide and the Baker Medical Research Institute in Melbourne. Subjects were screened on the basis of the following inclusion criteria: age 20–70 years; body mass index (BMI) <28; total serum cholesterol >5.0 mmol/l and <7.5 mmol/l; and serum triglycerides <4.5 mmol/l. No lipid-lowering medications were permitted, and even medication likely to affect lipid metabolism. Subjects were not diabetic, had normal thyroid status, and had no metabolic disorder other than hyperlipidemia. Subjects with a strong aversion or known allergies (intolerance) to the foods involved were excluded. The study was approved by the CSIRO Committee for Human Experimentation and the Baker Medical Centre Ethics Committee, and all subjects gave informed consent.

Study design

All subjects, in both centers, underwent dietary interventions in a nonrandomized manner. The study was single blind, and

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- *Lowering of plasma carotenoids was greater than that seen with lower phytosterol intake and was partially reversed by increased fruit and vegetable intake.*

Ejemplo: El mercurio del pescado puede reducir los efectos cardioprotectores de los Omega 3

MERCURY, FISH OILS, AND THE RISK OF MYOCARDIAL INFARCTION

ELISEO GUALLAR, M.D., DR.P.H., M. INMACULADA SANZ-GALLARDO, M.D., M.P.H., PETER VAN'T VEER, PH.D., PETER BODE, PH.D., ANTTI ARO, M.D., PH.D., JORGE GÓMEZ-ARACENA, M.D., PH.D., JEREMY D. KARK, M.D., PH.D., RUDOLPH A. REMERSMA, PH.D., JOSÉ M. MARTÍN-MORENO, M.D., DR.P.H., AND FRANS J. KOK, PH.D., FOR THE HEAVY METALS AND MYOCARDIAL INFARCTION STUDY GROUP*

ABSTRACT

Background It has been suggested that mercury, a highly reactive heavy metal with no known physiologic activity, increases the risk of cardiovascular disease. Because fish intake is a major source of exposure to mercury, the mercury content of fish may counteract the beneficial effects of its n−3 fatty acids.

Methods In a case–control study conducted in eight European countries and Israel, we evaluated the joint association of mercury levels in toenail clippings and docosahexaenoic acid (C22:6n−3, or DHA) levels in adipose tissue with the risk of a first myocardial infarction among men. The patients were 684 men with a first diagnosis of myocardial infarction. The controls were 724 men selected to be representative of the same populations.

Results The average toenail mercury level in controls was 0.25 μg per gram. After adjustment for the DHA level and coronary risk factors, the mercury levels in the patients were 15 percent higher than those in controls (95 percent confidence interval, 5 to 25 percent). The risk-factor–adjusted odds ratio for myocardial infarction associated with the highest as compared with the lowest quintile of mercury was 2.16 (95 percent confidence interval, 1.09 to 4.29; P for trend=0.006). After adjustment for the mercury level, the DHA level was inversely associated with the risk of myocardial infarction (odds ratio for the highest vs. the lowest quintile, 0.59; 95 percent confidence interval, 0.30 to 1.19; P for trend=0.02).

Conclusions The toenail mercury level was directly associated with the risk of myocardial infarction, and the adipose-tissue DHA level was inversely associated with the risk. High mercury content may diminish the cardioprotective effect of fish intake. (N Engl J Med 2002;347:1747-54.)

MERCURY is a highly reactive heavy metal with no known physiologic activity.[1,2] Exposure to toxic levels of mercury results in neurologic and renal damage, but the consequences of long-term exposure to low levels of mercury are poorly understood.[1,2] Mercury may predispose people to atherosclerotic disease by promoting the production of free radicals or by inactivating several antioxidant mechanisms through binding to thiol-containing molecules or to selenium.[3-5] In 1995, Salonen et al. reported an increased risk of coronary heart disease among residents of the Kuopio area in Finland whose hair samples had increased levels of mercury.[6,7] The participants in that study, however, had relatively high levels of mercury, which were derived largely from locally contaminated freshwater fish.

Fish intake is a major source of exposure to mercury, mainly in the form of methylmercury.[2] Intake of fish or fish oils (long-chain n−3 polyunsaturated fatty acids) has long been hypothesized to prevent cardiovascular events.[8] Two large, randomized clinical trials have shown reduced mortality after myocardial infarction among patients assigned to a diet rich in fatty fish[9] or to fish-oil supplements,[10] but the generalizability of these findings to subjects without coronary heart disease is uncertain. The results of epidemiologic studies relating fish intake or fish-oil levels to coronary events have been contradictory,[11] and it has been suggested that mercury may counteract the beneficial cardiovascular effects of n−3 fatty acids in fish.[2,6,7]

To evaluate the association of mercury with the risk of myocardial infarction, and to test the hypothesis that high mercury levels may offset the inverse association between fish oil consumption and myocardial infarction, we assessed the joint association of mercury levels in toenail clippings and docosahexaenoic acid (C22:6n−3, or DHA) levels in adipose tissue with the risk of a first myocardial infarction among men who were participants in the European Multicenter Case–

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*Other investigators are listed in the Appendix.

- *High mercury content may diminish the cardioprotective effect of fish intake.*

Ejemplo: El consumo habitual de Te se relaciona con una menor masa grasa corporal

Relationship among Habitual Tea Consumption, Percent Body Fat, and Body Fat Distribution

Chih-Hsing Wu, Feng-Hwa Lu, Chin-Song Chang, Tsui-Chen Chang, Ru-Hsueh Wang, and Chih-Jen Chang

Abstract

WU, CHIH-HSING, FENG-HWA LU, CHIN-SONG CHANG, TSUI-CHEN CHANG, RU-HSUEH WANG, AND CHIH-JEN CHANG. Relationship among habitual tea consumption, percent body fat, and body fat distribution. *Obes Res.* 2003;11:1088–1095.

Objective: To disclose the possible relationship between habitual tea consumption and changes in total body fat and fat distribution in humans.

Research Methods and Procedures: A cross-sectional survey of 1210 epidemiologically sampled adults (569 men and 641 women) were enrolled in our study. Tea consumption and other lifestyle characteristics were obtained by structured questionnaires. Percent body fat (BF%) was measured using bioelectrical impedance analysis. Body fat distribution was assessed using waist-to-hip ratio (WHR).

Results: Among the 1103 analyzed subjects, 473 adults (42.9%) consumed tea once or more per week for at least 6 months. The habitual tea drinkers were male-dominant, more frequently current smokers, and alcohol or coffee drinkers than the nonhabitual tea drinkers. Habitual tea drinkers for more than 10 years showed a 19.6% reduction in BF% and a 2.1% reduction in WHR compared with nonhabitual tea drinkers. The multiple stepwise regression models revealed that men, older age, higher BMI, and current smokers were positive factors for BF% and WHR. In contrast, longer duration of habitual tea consumption and higher total physical activity were negative factors for BF%. Longer duration of habitual tea consumption, higher socioeconomic status, and premenopausal status were negative factors for WHR.

Discussion: An inverse relationship may exist among habitual tea consumption, BF%, and body fat distribution, especially for subjects who have maintained the habit of tea consumption for more than 10 years.

Key words: tea, percent body fat, bioelectrical impedance analysis, body fat distribution, waist-to-hip ratio

Introduction

Recently, Dulloo et al. have demonstrated the positive effect of tea on thermogenesis in rats (1). Increasing fat oxidation and 24-hour energy expenditure in humans were observed in healthy young men who consumed green tea extract experimentally (2). Furthermore, the fact that oolong tea extract may enhance noradrenaline-induced lipolysis in adipose tissue and inhibit pancreatic lipase activity (3) seemed to suggest the possible antiobesity action of tea consumption (4). Interestingly, whether these experimental findings could be extrapolated to the change of percent body fat (BF%)[1] in humans is still questionable. To the best of our knowledge, no human study has been reported. On the other hand, tea has also been proven to express a cardiovascular-protective and lipid-lowering effect (5,6). Several studies have shown a close relationship among general obesity, central (abdominal) obesity, and cardiovascular morbidity and mortality (7,8). Supposing there is a relationship between tea consumption and BF%, it would be valuable to know the possible effect of tea consumption on body fat distribution. However, this is also an unexplored issue.

There are numerous methods of measuring BF% and body fat distribution (9,10). According to a recent consensus report (11), bioelectrical impedance analysis (BIA) is a feasible, reliable, and comparable method for measuring BF% by well-trained professionals. On the other hand, the World Health Organization recommended that both waist

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[1] Nonstandard abbreviations: BF%, percent body fat; BIA, bioelectrical impedance analysis; WHR, waist-to-hip ratio; ANCOVA, analysis of covariance.

- *An inverse relationship may exist among habitual tea consumption, BF%, and body fat distribution, especially for subjects who have maintained the habit of tea consumption for more than 10 years.*

Ejemplo: El consumo habitual de cafeína reduce el balance de calcio

Supplement

Caffeine, Urinary Calcium, Calcium Metabolism and Bone[1,2]

LINDA K. MASSEY[3] AND SUSAN J. WHITING*

*Food Science and Human Nutrition, Washington State University, Spokane, WA 99204-0399 and *Division of Nutrition and Dietetics, College of Pharmacy, University of Saskatchewan, Saskatoon, SA S7N 0W0, Canada*

ABSTRACT Oral doses of caffeine increase the urinary excretion of calcium, magnesium, sodium and chloride for at least 3 h after consumption. The hypercalciuric effect can be blocked by adenosine receptor agonists. The effect is proportional to dose per lean body mass and no adaptation to the urinary losses occurs with continuing consumption of caffeine. Uncompensated losses of calcium would be a risk factor for development of osteoporosis. Risks of osteoporosis due to caffeine consumption are reviewed. Comparison of data from epidemiological surveys and animal and human studies suggests that for younger adult women consuming adequate calcium, moderate caffeine intakes may have little or no deleterious effects. Increased urinary and intestinal losses may be compensated for by increased intestinal calcium absorption. However older women do not seem to compensate adequately to maintain their former calcium balance, especially when calcium intakes are below recommendations. J. Nutr. 123: 1611–1614, 1993.

INDEXING KEY WORDS:

• caffeine • methylxanthine
• calcium • bone • urine

Caffeine is consumed daily by the majority of individuals in the form of beverages, foods and medications. Caffeine, 1,3,7-methylxanthine, is widely consumed because of its stimulant effects. Caffeine is a weak diuretic (Massey and Wise 1992) and increases sodium and water excretion. In 1982 Heaney and Recker reported that urinary calcium excretion and intestinal calcium secretion were correlated with caffeine consumption in metabolic studies on premenopausal women. The direct action of caffeine to increase urinary calcium excretion has been demonstrated (Massey and Wise 1984). Caffeine also increases urinary excretion of magnesium, sodium, chloride and water, but not potassium, phosphate or creatinine (Massey and Wise 1992). Caffeine-induced urinary loss of calcium is largely attributable to a reduction in renal reabsorption, because creatinine clearance and filtered load did not change significantly (Bergman et al. 1990). Caffeine's effects are proportional to dose per lean body mass (Massey and Wise 1992). Theophylline, 1,3-methylxanthine, also increases urinary calcium excretion in both rats (Whiting and Whitney 1987) and humans (Colin et al. 1984). Theobromine, a 3,7- methylxanthine found in cocoa products, did not elicit diuresis in rats (Whiting and Whitney 1987) and was considerably less hypercalciuric. Whiting and Hughes (unpublished) found that 1.7 mmol (300 mg) of theobromine in a cocoa-based fudge did not increase human 3-h total urinary calcium volume or sodium excretion compared with consumption of a non-cocoa fudge.

It is now recognized that many of the effects of caffeine are due to adenosine antagonism rather than inhibition of phosphodiesterase as previously hypothesized. Caffeine is structurally similar to adenosine, an extracellular messenger that acts at specific cell surface receptors. Adenosine is produced from adenosine monophosphate when levels of that compound rise due to high cellular energy needs. The most widely recognized role of adenosine in the kidney is as a mediator in the tubuloglomerular feedback response (Osswald et al. 1991). Research in rats suggests antagonism of adenosine receptors is

[1]Presented as part of the third Annual Workshop of Nutrition and Bone Health Group given at the Annual Meeting of the American Society for Bone and Mineral Research, October 3, 1992, Minneapolis, MN. Financial support for the workshop was provided by a grant from the National Dairy Council, Rosemont, IL. Guest editor for this supplement was L. K. Massey, Department of Food Science and Human Nutrition, Washington State University, Spokane, WA.

[2]The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked "advertisement" in accordance with 18 USC section 1734 solely to indicate this fact.

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THE JOURNAL OF NUTRITION

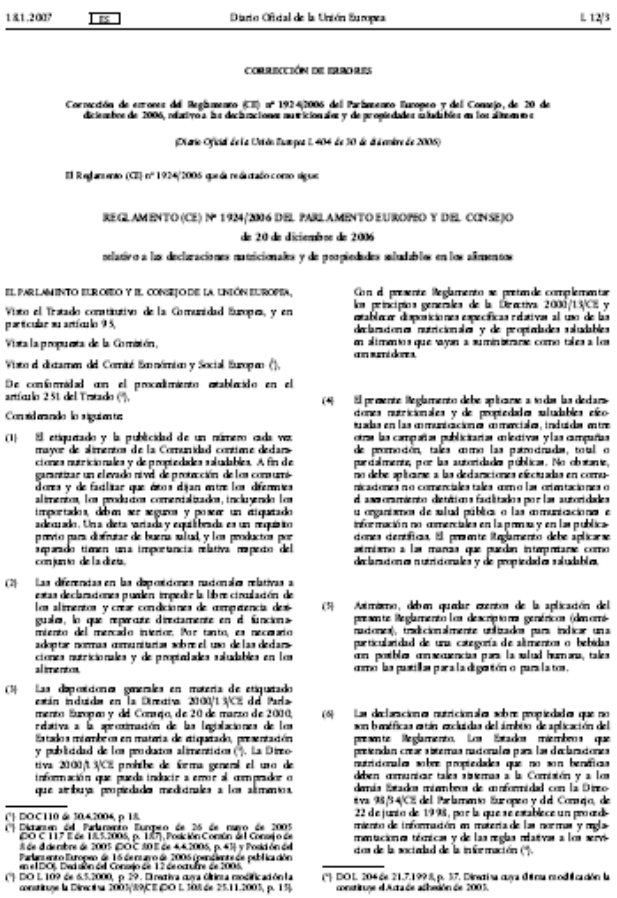
- *However older women do not seem to compensate adequately to maintain their former calcium balance, especially when calcium intakes are below recommendations.*

Declaraciones de salud generalmente aceptadas y declaraciones de salud prohibidas

LOS “CLAIMS” RELACIONADOS CON LA SALUD DEBEN ...

- Ser científicamente sostenibles.
- Válidos para el alimento tal y como es consumido.
- Comunicados clara, inteligible y verazmente al consumidor.
- No ser engañosos.

Reglamento (CE) no 1924/2006 del Parlamento Europeo y del Consejo, de 20 de diciembre de 2006, relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos



18.1.2007 ES Diario Oficial de la Unión Europea L 12/3

CORRECCIÓN DE ERRORES

Corrección de errores del Reglamento (CE) nº 1924/2006 del Parlamento Europeo y del Consejo, de 20 de diciembre de 2006, relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos

(*Diario Oficial de la Unión Europea L 404 de 30 de diciembre de 2006*)

El Reglamento (CE) nº 1924/2006 queda redactado como sigue:

REGLAMENTO (CE) Nº 1924/2006 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 20 de diciembre de 2006

relativo a las declaraciones nutricionales y de propiedades saludables en los alimentos

EL PARLAMENTO EUROPEO Y EL CONSEJO DE LA UNIÓN EUROPEA,

Visto el Tratado constitutivo de la Comunidad Europea, y en particular su artículo 95,

Vista la propuesta de la Comisión,

Visto el dictamen del Comité Económico y Social Europeo (1),

De conformidad con el procedimiento establecido en el artículo 251 del Tratado (2),

Considerando lo siguiente:

(1) El etiquetado y la publicidad de un número cada vez mayor de alimentos de la Comunidad contiene declaraciones nutricionales y de propiedades saludables. A fin de garantizar un elevado nivel de protección de los consumidores y de facilitar que éstos dijan entre los diferentes alimentos, los productos comercializados, incluyendo los importados, deben ser seguros y poseer un etiquetado adecuado. Una dieta variada y equilibrada es un requisito previo para disfrutar de buena salud, y los productos por separado tienen una importancia relativa respecto del conjunto de la dieta.

(2) Las diferencias en las disposiciones nacionales relativas a estas declaraciones pueden impedir la libre circulación de los alimentos y crear condiciones de competencia desiguales, lo que repercute directamente en el funcionamiento del mercado interior. Por tanto, es necesario adoptar normas comunitarias sobre el uso de las declaraciones nutricionales y de propiedades saludables en los alimentos.

(3) Las disposiciones generales en materia de etiquetado están incluidas en la Directiva 2000/13/CE del Parlamento Europeo y del Consejo, de 20 de marzo de 2000, relativa a la aproximación de las legislaciones de los Estados miembros en materia de etiquetado, presentación y publicidad de los productos alimenticios (3). La Directiva 2000/13/CE prohíbe de forma general el uso de información que pueda inducir a error al comprador o que atribuya propiedades medicinales a los alimentos.

Con el presente Reglamento se pretende complementar los principios generales de la Directiva 2000/13/CE y establecer disposiciones específicas relativas al uso de las declaraciones nutricionales y de propiedades saludables en alimentos que vayan a suministrarse como tales a los consumidores.

(4) El presente Reglamento debe aplicarse a todas las declaraciones nutricionales y de propiedades saludables efectuadas en las comunicaciones comerciales, incluidas entre otras las campañas publicitarias colectivas y las campañas de promoción, tales como las patrocinadas, total o parcialmente, por las autoridades públicas. No obstante, no debe aplicarse a las declaraciones efectuadas en comunicaciones no comerciales tales como las orientaciones o el asesoramiento dietético facilitados por las autoridades u organismos de salud pública o las comunicaciones e información no comerciales en la prensa y en las publicaciones científicas. El presente Reglamento debe aplicarse asimismo a las marcas que puedan interpretarse como declaraciones nutricionales y de propiedades saludables.

(5) Asimismo, deben quedar exentos de la aplicación del presente Reglamento los descriptores genéricos (denominaciones), tradicionalmente utilizados para indicar una particularidad de una categoría de alimentos o bebidas con posibles consecuencias para la salud humana, tales como las pastillas para la digestión o para la tos.

(6) Las declaraciones nutricionales sobre propiedades que no son beneficiosas están excluidas del ámbito de aplicación del presente Reglamento. Los Estados miembros que pretendan crear sistemas nacionales para las declaraciones nutricionales sobre propiedades que no son beneficiosas deben comunicar tales sistemas a la Comisión y a los demás Estados miembros de conformidad con la Directiva 98/34/CE del Parlamento Europeo y del Consejo, de 22 de junio de 1998, por la que se establece un procedimiento de información en materia de las normas y reglamentaciones técnicas y de las reglas relativas a los servicios de la sociedad de la información (4).

(1) DO C 110 de 30.4.2004, p. 18.
(2) Dictamen del Parlamento Europeo de 26 de mayo de 2005 (DO C 117 E de 18.5.2006, p. 187), Posición Común del Consejo de 8 de diciembre de 2005 (DO C 30 E de 8.6.2006, p. 43) y Posición del Parlamento Europeo de 15 de marzo de 2006 (pendiente de publicación en el DO). Decisión del Consejo de 12 de octubre de 2006.
(3) DO L 109 de 6.5.2000, p. 29. Directiva cuya última modificación la constituye la Directiva 2003/89/CE (DO L 308 de 25.11.2003, p. 15).
(4) DO L 204 de 21.7.1998, p. 37. Directiva cuya última modificación la constituye el Acta de adhesión de 2003.

Artículo 12. Restricciones en el uso de determinadas propiedades saludables

- *No se autorizarán las siguientes declaraciones de propiedades saludables:*
  - *a) las declaraciones que sugieran que la salud podría verse afectada si no se consume el alimento de que se trate;*
  - *b) las declaraciones que hagan referencia al ritmo o la magnitud de la pérdida de peso;*
  - *c) las declaraciones que hagan referencia a recomendaciones de médicos individuales u otros profesionales de la salud y otras asociaciones no mencionadas en el artículo 11.*

QUE SON LOS ALIMENTOS FUNCIONALES?

D*ocumento de consenso de la Comisión Europea y el International life Science Institute (ILSI Europe) (FUFOSE, 1999)*

"Un alimento puede ser considerado funcional si se ha demostrado de forma satisfactoria que posee un efecto beneficioso sobre una o varias funciones específicas en el organismo, más allá de los efectos nutricionales habituales, siendo esto relevante para la mejora de la salud y el bienestar y/o la reducción del riesgo de enfermar".

Además incorpora dos premisas: Debe seguir siendo un alimento y debe ejercer el efecto con las cantidades que normalmente se consumen en la dieta.

¿Qué Claims están aprobados en Europa (JHCI, SNF, AFSSA) que pueden ayudarnos a proponer o preparar Claims de salud?

Claims usados antes de la publicación del Reglamento 1924/2006

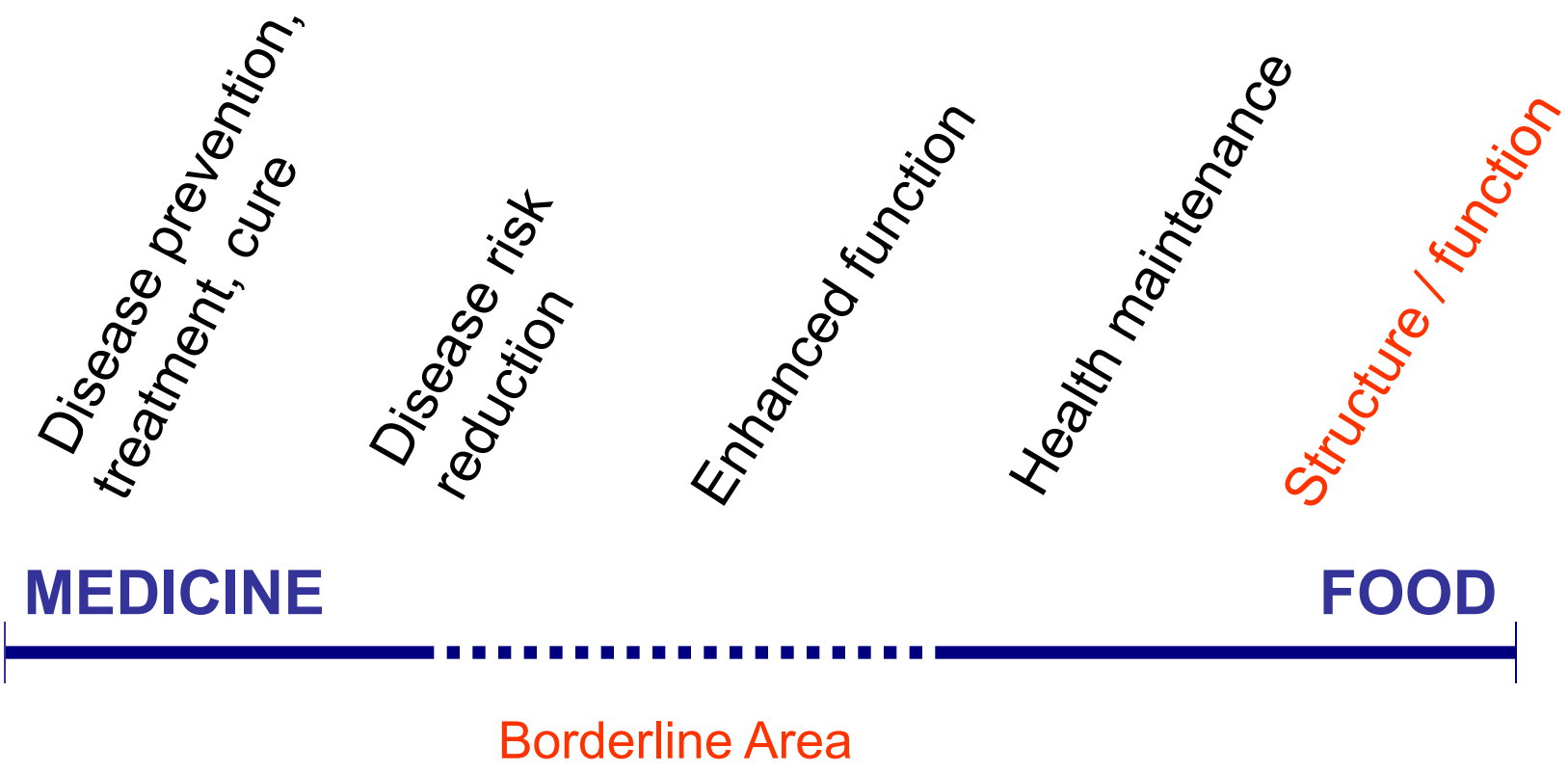
CIAA ERNA ehpm

Brussels, 31 October 2007

Compiled Version of the Final List (incl. Corrigendum and Addendum)
CIAA section only

No	Food or Food component	Health Relationship	Conditions of use (if any)	Nature of evidence	References	Example of wording
		MICRONUTRIENTS				
		VITAMINS				
	VITAMINS		MUST AT LEAST BE A SOURCE OF VITAMINS AS PER ANNEX TO REGULATION 1924/2006		Regulation on Nutrition and Health Claims made on Foods 1924/2006 Directive on Nutrition Labelling for Foodstuffs 90/496/EEC	
1	Vitamins, in general	Development, growth, body maintenance, body metabolism and equilibrium		Authoritative Body Textbook	JHCI, NHPD, CH	-vitamin(s) help the development of all body structures; -vitamin(s) help to maintain a strong body; -vitamin(s) are essential for your body; -vitamin(s) are needed for body metabolism.
	Vitamin A		15% RDA of vitamin A is equivalent to 720 micrograms beta-carotene	Scientific Body Textbook	Garrow et al 2000; IOM 2001	
2		Bone growth and development of teeth		Authoritative Body Textbook	NHPD	-vitamin A is essential for healthy bone and teeth growth.
3		Cell differentiation including immune system		Authoritative Body Scientific Body Textbook	CH, JHCI, WHO See: Vitamin A and immune function	-vitamin A is essential for the proper functioning of the immune system; -vitamin A is essential for the proper functioning of the cells.
4		Structure and function of the skin and mucous membranes (such as in the lung, intestines, nose, eyes and female reproductive tract)		Authoritative Body Textbook	CH, CEDAP, NHPD, JHCI	-vitamin A helps keep the skin and mucous membranes healthy.
5		Vision		Authoritative Body Textbook	JHCI, CH, CEDAP, FNFC, NHPD	-vitamin A is essential for normal vision.
6	Vitamin B1 (Thiamin)	Energy and Carbohydrate metabolism		Authoritative Body Textbook	CH, CEDAP, NHPD, JHCI, FNFC	-vitamin B1 (Thiamin) is needed to release the energy from foods; -vitamin B1 (Thiamin) is needed to release the energy from carbohydrates.
7		Cardiac function		Authoritative Body Scientific Body Textbook	JHCI, IOM 1998 See: Vitamin B1 and cardiac function	-vitamin B1 (Thiamin) is needed to keep the heart working properly.
8		Neurological function		Authoritative Body Textbook	CH, JHCI	-vitamin B1(Thiamin) helps keeping the nervous system working properly.

Nutrient Function Claims



Nutrient function claims currently on the market in the UK, e.g.

EYES

Vitamin A helps keep eyes healthy and maintain good eyesight.

CONCENTRATION

Iron plays an important role in maintaining healthy blood, which is needed for work performance and concentration.

BLOOD

Sufficient intake of vitamin B_{12}, folic acid and iron are essential to help maintain healthy blood cells. Calcium also has a role in blood pressure.

LOOKING HEALTHY

Vitamins A,C,E and the B vitamins (riboflavin, niacin and B_6) for maintenance of healthy-looking hair, skin and nails.

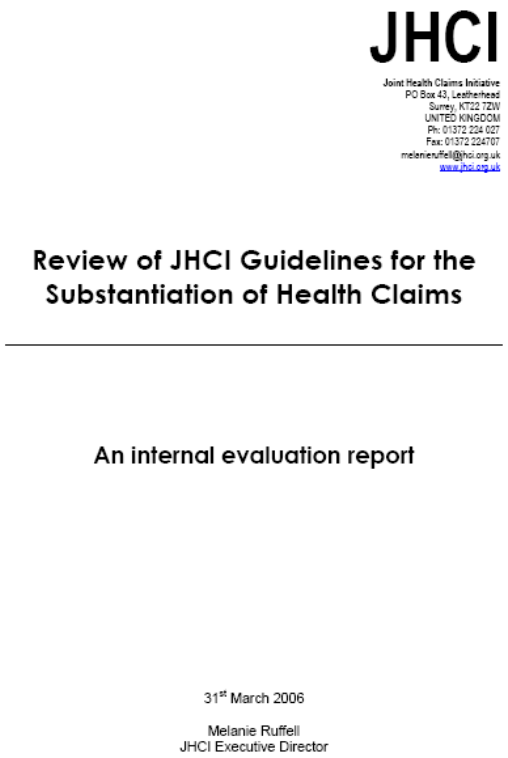
ENERGY

Vitamins B_1, B_2, Pantothenic acid, B_6 and the minerals phosphorus and magnesium are needed for release of energy from foods.

HEART

Folic acid, combined with other B vitamins, helps to reduce high levels of the amino acid homocysteine - helping to maintain a healthy heart.

Joint Health Claim Initiative (JHCI)



JHCI

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UNITED KINGDOM
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Review of JHCI Guidelines for the Substantiation of Health Claims

An internal evaluation report

31st March 2006

Melanie Ruffell
JHCI Executive Director

Approved claims

- 12/10/01 Generic health claim for reduced saturated fat and blood cholesterol
- 04/02/02 Generic health claim for wholegrain foods and heart health
- 27/07/02 Generic health claim for soya protein and blood cholesterol
- 06/05/04 Generic health claim for oats and blood cholesterol
- 11/02/05 Generic health claim for omega-3 PUFA and heart health

Joint Health Claim Initiative (JHCI)

Project Start Date	01/01/03
Project End Date	30/06/03
Project Code	ZQ0203

JHCI

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Fax: 01372 822 388
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JHCI Ref: JHCI/76/03

FINAL TECHNICAL REPORT

PART 1:
A Process to Define and Identify Well-Established Health Statements

PART 2:
A list of Well-Established Nutrient Function Statements

A report by the Joint Health Claims Initiative to the Food Standards Agency

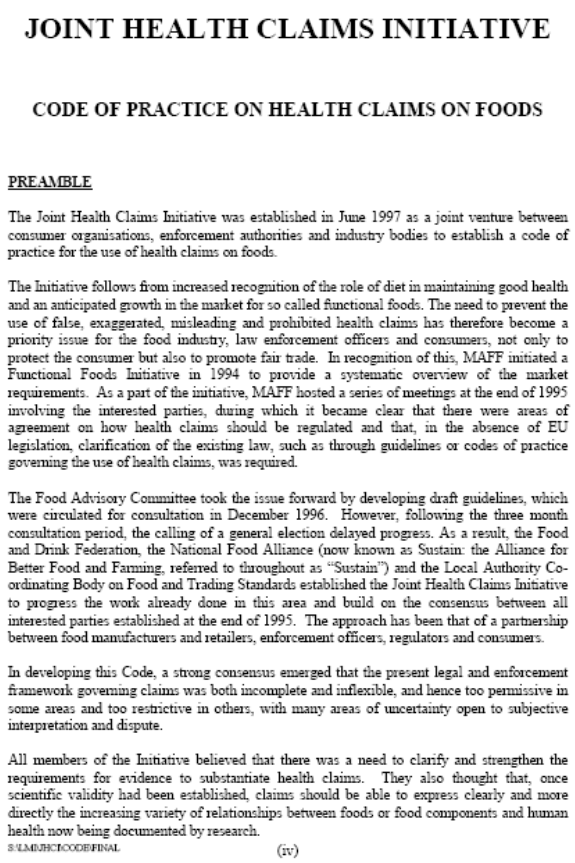
Prepared by
JHCI Executive Director

17th Dec 2003

Approved claims

- Decreasing dietary saturates (saturated fat) can help lower blood cholesterol
- People with a healthy heart tend to eat more wholegrain foods as part of a healthy lifestyle
- The inclusion of at least 25g soya protein per day as part of a diet low in saturated fat can help reduce blood cholesterol
- The inclusion of oats as part of a diet low in saturated fat and a healthy lifestyle can help reduce blood cholesterol
- Eating 3g weekly, or 0.45g daily, long chain omega-3 polyunsaturated fatty acids, as part of a healthy lifestyle, helps maintain heart health

Joint Health Claim Initiative (JHCI)



JOINT HEALTH CLAIMS INITIATIVE

CODE OF PRACTICE ON HEALTH CLAIMS ON FOODS

PREAMBLE

The Joint Health Claims Initiative was established in June 1997 as a joint venture between consumer organisations, enforcement authorities and industry bodies to establish a code of practice for the use of health claims on foods.

The Initiative follows from increased recognition of the role of diet in maintaining good health and an anticipated growth in the market for so called functional foods. The need to prevent the use of false, exaggerated, misleading and prohibited health claims has therefore become a priority issue for the food industry, law enforcement officers and consumers, not only to protect the consumer but also to promote fair trade. In recognition of this, MAFF initiated a Functional Foods Initiative in 1994 to provide a systematic overview of the market requirements. As a part of the initiative, MAFF hosted a series of meetings at the end of 1995 involving the interested parties, during which it became clear that there were areas of agreement on how health claims should be regulated and that, in the absence of EU legislation, clarification of the existing law, such as through guidelines or codes of practice governing the use of health claims, was required.

The Food Advisory Committee took the issue forward by developing draft guidelines, which were circulated for consultation in December 1996. However, following the three month consultation period, the calling of a general election delayed progress. As a result, the Food and Drink Federation, the National Food Alliance (now known as Sustain: the Alliance for Better Food and Farming, referred to throughout as "Sustain") and the Local Authority Co-ordinating Body on Food and Trading Standards established the Joint Health Claims Initiative to progress the work already done in this area and build on the consensus between all interested parties established at the end of 1995. The approach has been that of a partnership between food manufacturers and retailers, enforcement officers, regulators and consumers.

In developing this Code, a strong consensus emerged that the present legal and enforcement framework governing claims was both incomplete and inflexible, and hence too permissive in some areas and too restrictive in others, with many areas of uncertainty open to subjective interpretation and dispute.

All members of the Initiative believed that there was a need to clarify and strengthen the requirements for evidence to substantiate health claims. They also thought that, once scientific validity had been established, claims should be able to express clearly and more directly the increasing variety of relationships between foods or food components and human health now being documented by research.

S:\LM\JHCI\CODE\FINAL (iv)

Generic Claims Considered

The following claims are not available for use under current EU food law.

- 15/02/02 Generic health claim for fruit and vegetables and stomach cancer
- 15/02/02 Generic health claim for fruit and lung cancer
- 15/02/02 Generic health claim for vegetables and bowel cancer

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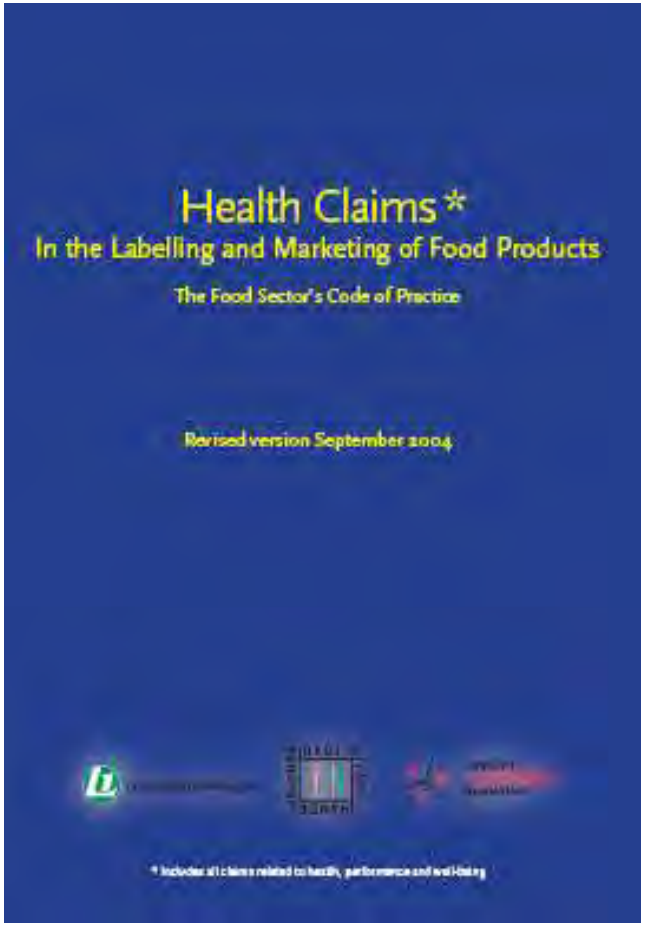


Reduction of disease risk claims - nine allowed connections

1) Overweight/obesity - energy
2) Cardiovascular disease – blood cholesterol levels -
   a) hard fat
   b) certain types of dietary fibre
3) Cardiovascular disease – blood pressure - salt
4) Cardiovascular disease – omega-3-fatty acids from fish
5) Constipation – dietary fibre
6) Osteporosis – calcium and/or vitamin D
7) Caries – sugar / fermentable carbohydrates
8) Iron deficiency – iron
9) (Coronary) heart disease – whole grain

SNF Swedish Nutrition Foundation

Scandinavian Journal of Nutrition/Näringsforskning Vol 45: 189, 2001

The Swedish code on health-related claims in action – extended to product-specific physiological claims

By Nils-Georg Asp and Mari Trossing

ABSTRACT

● THE SWEDISH VOLUNTARY CODE on health-related claims in the labelling and marketing of food products was recently extend to "product-specific physiological claims" (abbreviated PFP in Swedish). The first expert panels have been set up by the SNF Swedish Nutrition Foundation for the required pre-marketing evaluation of the scientific documentation. The Assessment Board for Diet-Health Information (abbreviated BKH in Swedish) was established on 23 November 2001 and is now available for post-marketing assessment of particular marketing and labelling actions that have been questioned in relation to the Code.

Extension of the Swedish Code

After several consultations at the Department of Agriculture, the Swedish voluntary Code "Health Claims in the Labelling and Marketing of Food Products" could be extended to "product-specific physiological claims", abbreviated PFP in Swedish. The responsible organisations behind the Code – the Swedish Cooperative Union, the Federation of Swedish Farmers, the Swedish Food Federation, the Swedish Federation of Trade, and the Swedish Food Retail Association – formed a steering group. The extended Code has two main parts: *1)* The pre-marketing evaluation of the scientific documentation of claims, planned to be used; and *2)* The Assessment Board for Diet-Health Information to deal with complaints on marketing actions in relation to the Code.

Evaluation of scientific documentation

The required pre-marketing evaluation of the scientific documentation behind a product-specific physiological claim is handled by SNF Swedish Nutrition Foundation and described in detail in this issue of *Scand J Nutr* (pages 190-191). At least three independent experts are appointed case by case by the research board of SNF. Their report is to become publicly available, together with the human effect studies, when the product is put on the market with the claim.

The Board (BKH)

The Assessment Board for Diet-Health Information, hence referred to as the The Board (BKH), was established on November 23, 2001. The Board (BKH) will deal with complaints as to whether a particular marketing and labelling action complies with the Code. After giving the marketer an opportunity to explain and to justify the marketing, the Board (BKH) will decide whether the complaint is to be upheld or not. The Board (BKH) consists of a chairman, a vice-chairman and a secretary, all lawyers with a good knowledge of marketing laws. The President of the Skåne County Administrative Court, Gunilla Hedesten Nordin, who participated in the establishment of the original Code in 1990, was elected chair of the Board. Five Board members represent the responsible organisations, two represent medical and nutritional expertise and two members represent public interest, especially consumer interest. Besides this, eight deputy members have the right to attend the meetings. The charter of the Board (BKH) is published in this issue (p 192).

Different health-related claims

The original Swedish Code from 1990, revised in 1997, was limited to *generic claims* in two steps, related to well-established diet-health connections. These eight connections are: 1) *Obesity* – energy content, 2) *Cholesterol level in the blood* – fat quality or some soluble dietary fibre, 3) *Blood pressure* – salt (sodium chloride), 4) *Atherosclerosis* – blood cholesterol level/blood pressure, n-3 (omega-3) fatty acids in fat fish and fish products, 5) *Constipation* – dietary fibre, 6) *Osteoporosis* – calcium, 7) *Caries* – absence of sugars and other easily fermented carbohydrates, 8) *Iron deficiency* – iron content. Provided that the claims are made strictly in two steps and in the context of a healthy balanced diet, the original Code allows *generic reduction of disease risk claims*.

Product-specific physiological claims according to the extension of the programme means claims related to a specific physiological effect of the product itself, according to a 1998 report from SNF Swedish Nutrition Foundation and the organisations behind the programme (1,2). It corresponds to product-specific *enhanced function claims* as defined in reports from Codex Alimentarius (3) and Council of Europe (4), and would be classified as *innovative claims* according to the UK Joint Health Claims Initiative (5).

Nutrient function claims are defined by Codex and now also regarded as a kind of (generic) health claims (3).

The original Swedish Code is subject to evaluation, including reconsideration of the diet-health connections approved for generic claims. The process of such a revision has started. Rules for the use of nutrient function claims should then also be elaborated. Such claims are commented only in brief in the present Code.

INFORMATION

Information about the Swedish Code can be found on the website of the SNF Swedish Nutrition Foundation *www.snf.ideon.se*

REFERENCES

1. Asp N-G, Lauer Reutersward A, Ljungberg H. Produktspecifika fysiologiska påståenden (PFP) Förslag till utvidgning av egenåtgärdsprogrammet. Juni 1998. SNF Swedish Nutrition Foundation (*In Swedish*).
2. Asp N-G, Lauer Reutersward A. Proposal for extension of the Swedish code on health claims – to functional food products. Scand J Nutr/Näringsforskning 1998;42:119.
3. Codex Alimentarius Committee on Food Labelling. Aliacom 01/22A (appendix VIII), currently at step 3 of the Procedure (2001). *www.codexalimentarius.net*
4. Council of Europe's policy statements concerning nutrition, food safety and consumer health. Technical document. Guidelines concerning scientific substantiation of health-related claims for functional foods, 2 July 2001. http://www.coe.fr/soc-sp
5. UK Joint Health Claims Initiative. http://www.jhci.co.uk

Nils-Georg Asp, MD, PhD, Professor Applied Nutrition, Lund University, Director of SNF, Mari Trossing, M.Sc., in Food Science, is in charge of handling matters related to the Code, SNF Swedish Nutrition Foundation, Research Park Ideon, SE-223 70 Lund, Sweden. E-mail: asp@ideon.se

Health Claims in the Labelling and Marketing of Food Products
The Food Industry's Rules
(Self-Regulating Programme)

c/o SNF Swedish Nutrition Foundation
Ideon Research Park • SE-223 70 Lund • Sweden
Phone + 46 46 286 22 82 • Fax + 46 46 286 22 81
mari.trossing@snf.ideon.se • www.snf.ideon.se

Application Form for Evaluation of Scientific Documentation behind a Product-Specific Physiological Claim

The food products referred to in the programme should be part of a normal diet and not dietary supplements or other substances in the form of capsules, tablets, dragées, powders or the like. All parties concerned should treat the application confidentially.

The following shall be included in the application:

- Nutrition declaration, containing at least energy and seven nutrients (group 2 according to Nutrition Declaration Ordinance, SLVFS 1993:21, i.e. protein, carbohydrates, sugars, fat, saturated fat, dietary fibre and sodium)
- Information on consumption needed to attain the desired physiological effect and potential risk in the event of overconsumption.
- The human intervention study/studies on which the claim is primarily based, if desired in summary with reference to researchers and institutes/departments that have performed the study.
- Additional documentation to be submitted after consultation with, and directly to, the appointed experts.

The undersigned/applicant: _____

_____

_____

hereby request(s) the SNF Swedish Nutrition Foundation to initiate evaluation of the documentation behind the following health benefit of the product in accordance with the extended Swedish Code Practice: "Health Claims in the Labelling and Marketing of Food Products: The Food Industry's Rules (Self-Regulating Programme)" of 2001.

Product: _____

_____

_____

Health benefit/ type of physiological effect to be claimed in the marketing (both in Swedish and in English):

_____

_____

_____

Target group(s): _____

Signed:

Place/Date: _____

Applicant: _____

Mailing address: _____

Phone /Fax: _____

e-mail: _____

Logotipo

”Documentation supporting the health benefits of this product has been evaluated in accordance with the Food Sector’s Code of Practice. hp-info.nu”

Examples of appropriate wordings for generic reduction of disease risk claims

swedish nutrition foundation

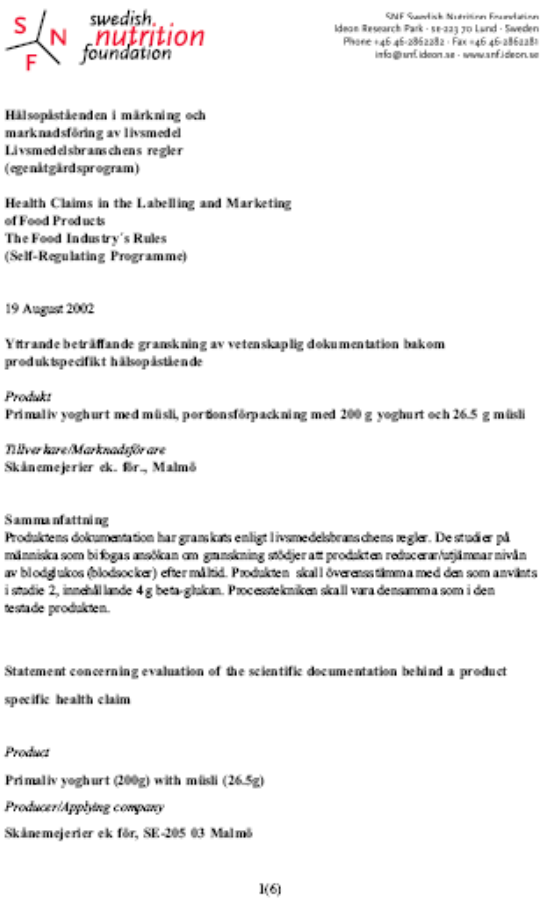
1	A nutritionally balanced diet with a well-adapted energy content is a key factor in maintaining one's weight. Product X has a lower energy content than corresponding normal products.
2[A]	*(a)* A nutritionally balanced diet with a low saturated fat content contributes to lower cholesterol levels in the blood and can thereby reduce the risk of cardiovascular disease/atherosclerosis. Product Y has a low saturated fat content. *(b)* A nutritionally balanced diet high in soluble fibres from oats (beta-glucans) can contribute to lower cholesterol levels in the blood and thereby to a reduced risk of cardiovascular disease/atherosclerosis/hardening of the arteries. Product Z is high in soluble oat fibres (beta-glucans).
3[B]	A nutritionally balanced diet with a low sodium/salt content can contribute to lower blood pressure and thereby to a reduced risk of cardiovascular disease/atherosclerosis. Product XX has a lower sodium/salt content than corresponding normal products.
4	A nutritionally balanced diet high in long omega 3 fatty acids from fish and fish products reduces the risk of cardiovascular disease/atherosclerosis. Product YY is high in long omega 3 fatty acids.
5	A nutritionally balanced diet high in dietary fibre is important for maintaining bowel regularity and reduces the risk of constipation. Product ZZ is high in dietary fibre.
6	A nutritionally balanced diet high in (a) Calcium, (b) Vitamin D, (c) Calcium and Vitamin D reduces the risk of osteoporosis. Product XXX is high in (a) Calcium, (b) Vitamin D (c) Calcium and Vitamin D.
7	Frequent consumption of products containing regular sugar (or other carbohydrates that are easily broken down by bacteria in the mouth) increases the risk for caries. Product YYY contains no sugar.
8	A nutritionally balanced diet high in iron reduces the risk for iron deficiency. Product ZZZ is high in iron.
9[C]	A healthy lifestyle and well-balanced diet high in whole grain products (a) reduces the risk of coronary heart disease, (b) reduces the risk of heart disease. Product XXXX has a high whole grain content (Y% whole grain).

[A] Claims regarding this connection can be worded to state (1) the connection between hard fats or certain types of dietary fibre and reduction of the risk of cardiovascular disease/atherosclerosis, or (2) only the connection between hard fats or certain types of dietary fibre and blood cholesterol levels. When using the first alternative, the claim should clearly state that it is the risk factor "cholesterol level in the blood" that affects the risk of disease.

[B] A claim must be worded to clearly state that it is the risk factor "high blood pressure" that affects the risk of disease.

[C] A new claim introduced in this version of the Code. A claim must be formulated according to one of the alternatives given here.

Product-specific physiological claims PRIMALIV



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Hälsopåståenden i märkning och marknadsföring av livsmedel
Livsmedelsbranschens regler
(egenåtgärdsprogram)

Health Claims in the Labelling and Marketing of Food Products
The Food Industry's Rules
(Self-Regulating Programme)

19 August 2002

Yttrande beträffande granskning av vetenskaplig dokumentation bakom produktspecifikt hälsopåstående

Produkt
Primaliv yoghurt med müsli, portionsförpackning med 200 g yoghurt och 26.5 g müsli

Tillverkare/Marknadsförare
Skånemejerier ek. för., Malmö

Sammanfattning
Produktens dokumentation har granskats enligt livsmedelsbranschens regler. De studier på människa som bifogas ansökan om granskning stödjer att produkten reducerar/utjämnar nivån av blodglukos (blodsocker) efter måltid. Produkten skall överensstämma med den som använts i studie 2, innehållande 4 g beta-glukan. Processtekniken skall vara densamma som i den testade produkten.

Statement concerning evaluation of the scientific documentation behind a product specific health claim

Product
Primaliv yoghurt (200g) with müsli (26.5g)
Producer/Applying company
Skånemejerier ek för, SE-205 03 Malmö

1(6)

- 200 g flavoured or ”natural” yoghurt with 26,5 g müsli based on oat bran enriched in beta-glucans.
- Claim accepted: ”Reduces glucose levels after the meal”.

Product-specific physiological claims
BECEL PRO-ACTIV

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1(5)

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FINAL REPORT

Health Claims in the Labelling and Marketing
of Food Products
The Food Sector's Code of Practice

January 13, 2006

STATEMENT CONCERNING EVALUATION OF THE SCIENTIFIC DOCUMENTATION BEHIND A PRODUCT SPECIFIC HEALTH CLAIM

YTTRANDE BETRÄFFANDE GRANSKNING AV VETENSKAPLIG DOKUMENTATION BAKOM PRODUKTSPECIFIKT HÄLSOPÅSTÅENDE

Product
Becel pro.activ yoghurt drink (single shot minidrink)
2.9% fat, 2 g esterified plant sterols/shot (100 g)

Applying company
Unilever Bestfoods AB

Suggested claim/Föreslaget påstående
Becel pro.activ yoghurt drink lowers total and LDL-cholesterol. Intake of one drink/shot per day has a cholesterol lowering effect.

Becel pro.activ yoghurtdryck sänker total- och LDL-kolesterol. Konsumtion av en shot per dag har en kolesterolsänkande effekt.

Target group
The product is intended exclusively for people who want to lower their blood cholesterol level. The product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years.

Summary/Sammanfattning
Cholesterol lowering effects of plant sterols/stanols in, e.g. Becel pro.activ spread and milk drink, have previously been shown. Important issues has been how the effect is influenced by the fat content and texture of the product, the need to coordinate the intake with a meal and to administer several times each day. Based on one well-designed study and supported by other studies there is scientific evidence that intake of 100 g low fat Becel pro.activ yoghurt drink containing 2 g plant sterols esterified with long chain fatty acids, given alone or with a meal, lowers total and LDL cholesterol. The effect is more pronounced if the yoghurt is given with a meal.

Den kolesterolsänkande effekten av växtsteroler/stanoler i t.ex. Becel pro.activ matfett och mjölkdrink har visats tidigare. Viktiga frågor har varit hur effekten påverkas av produktens fettinnehåll och struktur, betydelsen av intag med måltid och antal doseringstillfällen per dag. Baserat på en välupplagd studie med stöd av andra studier finns vetenskapliga bevis för att intag av 100 g Becel pro.activ yoghurtdrink med lågt fettinnehåll och 2 g växtsteroler förestrade med långkedjiga fettsyror, i samband med måltid eller ensamt, sänker totalkolesterol och LDL kolesterol. Effekten är störst vid intag i samband med måltid.

- Becel pro.activ yoghurt drink (single shot minidrink): 2.9% fat, 2 g esterified plant sterols/shot (100 g)
- "Becel pro.activ yoghurt drink lowers total and LDL-cholesterol. Intake of one drink/shot per day has a cholesterol lowering effect".

Product-specific physiological claims
PROVIVA FRUITDRINK

swedish nutrition foundation

Hälsopåståenden i märkning och marknadsföring av livsmedel

Livsmedelsbranschens regler (egenåtgärdsprogram)

Health Claims in the Labelling and Marketing of Food Products
The Food Industry's Rules (Self-Regulating Programme)

12 september 2003

Yttrande beträffande granskning av vetenskaplig dokumentation bakom produktspecifikt hälsopåstående

Produkt
Proviva fruktdryck med *Lactobacillus plantarum* 299v

Tillverkare/Marknadsförare
Skånemejerier ek. för., Malmö

12 September 2003

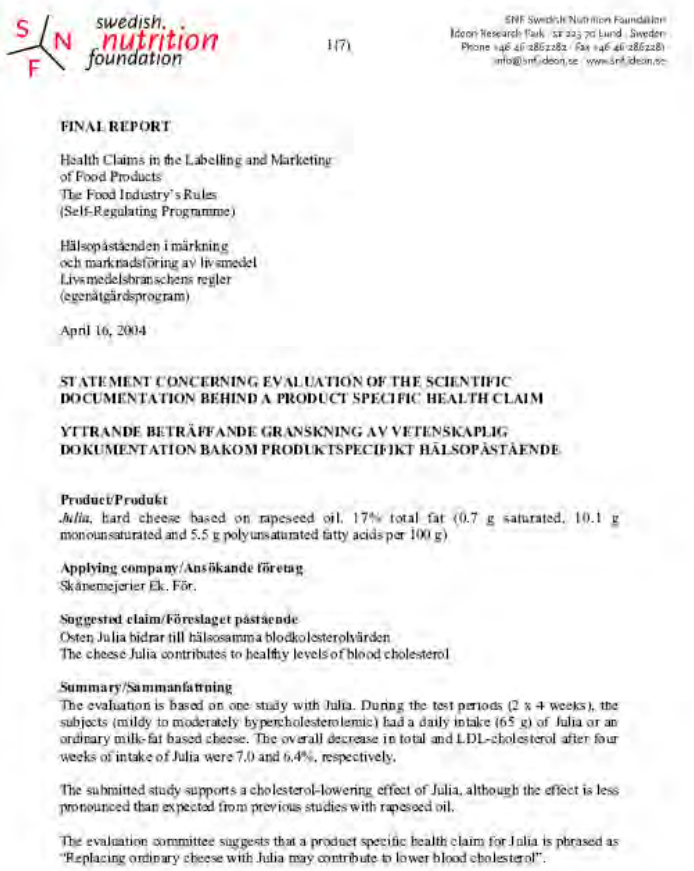
Statement concerning evaluation of the scientific documentation behind a product specific health claim

Product
Proviva Fruit Drink with *Lactobacillus plantarum* 299v

Producer/Applying company
Skånemejerier ek för, SE-205 03 Malmö

- Fruit Drink with Lactobacillus plantarum 299v
- The reviewers came to the conclusion that the product is interesting and that an effect to decrease flatulence is reasonably well documented. But the scientific base is not yet solid enough for a wider product-specific claim regarding IBS-like complaints.

Product-specific physiological claims JULIA



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1(7)

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FINAL REPORT

Health Claims in the Labelling and Marketing of Food Products
The Food Industry's Rules
(Self-Regulating Programme)

Hälsopåståenden i märkning och marknadsföring av livsmedel
Livsmedelsbranschens regler
(egenåtgärdsprogram)

April 16, 2004

STATEMENT CONCERNING EVALUATION OF THE SCIENTIFIC DOCUMENTATION BEHIND A PRODUCT SPECIFIC HEALTH CLAIM

YTTRANDE BETRÄFFANDE GRANSKNING AV VETENSKAPLIG DOKUMENTATION BAKOM PRODUKTSPECIFIKT HÄLSOPÅSTÅENDE

Product/Produkt
Julia, hard cheese based on rapeseed oil. 17% total fat (0.7 g saturated, 10.1 g monounsaturated and 5.5 g polyunsaturated fatty acids per 100 g)

Applying company/Ansökande företag
Skånemejerier Ek. För.

Suggested claim/Föreslaget påstående
Osten Julia bidrar till hälsosamma blodkolesterolvärden
The cheese Julia contributes to healthy levels of blood cholesterol

Summary/Sammanfattning
The evaluation is based on one study with Julia. During the test periods (2 x 4 weeks), the subjects (mildly to moderately hypercholesterolemic) had a daily intake (65 g) of Julia or an ordinary milk-fat based cheese. The overall decrease in total and LDL-cholesterol after four weeks of intake of Julia were 7.0 and 6.4%, respectively.

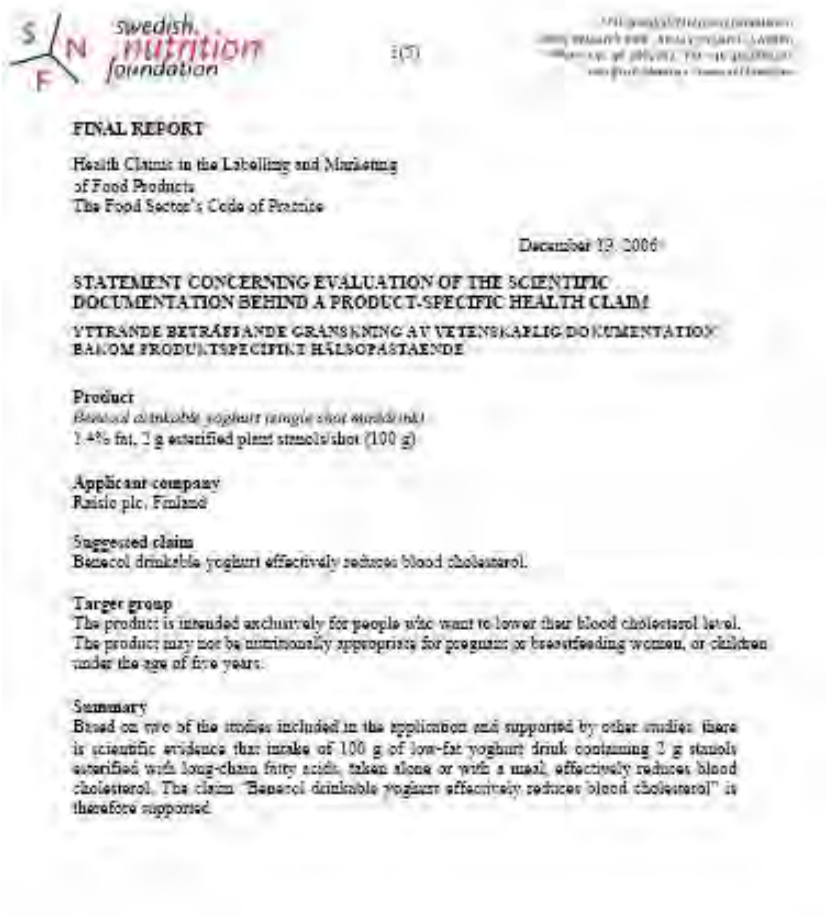
The submitted study supports a cholesterol-lowering effect of Julia, although the effect is less pronounced than expected from previous studies with rapeseed oil.

The evaluation committee suggests that a product specific health claim for Julia is phrased as "Replacing ordinary cheese with Julia may contribute to lower blood cholesterol".

- Hard cheese based on rapeseed oil, 17% total fat.
- "Replacing ordinary cheese with Julia may contribute to lowering blood cholesterol".

Skåne mejerier

Product-specific physiological claims BENECOL



swedish nutrition foundation

FINAL REPORT

Health Claims in the Labelling and Marketing of Food Products
The Food Sector's Code of Practice

December 19, 2006

STATEMENT CONCERNING EVALUATION OF THE SCIENTIFIC DOCUMENTATION BEHIND A PRODUCT-SPECIFIC HEALTH CLAIM

YTTRANDE BETRÄFFANDE GRANSKNING AV VETENSKAPLIG DOKUMENTATION BAKOM PRODUKTSPECIFIKT HÄLSOPÅSTÅENDE

Product
Benecol drinkable yoghurt (single shot minidrink)
1.4% fat, 2 g esterified plant stanols/shot (100 g)

Applicant company
Raisio plc, Finland

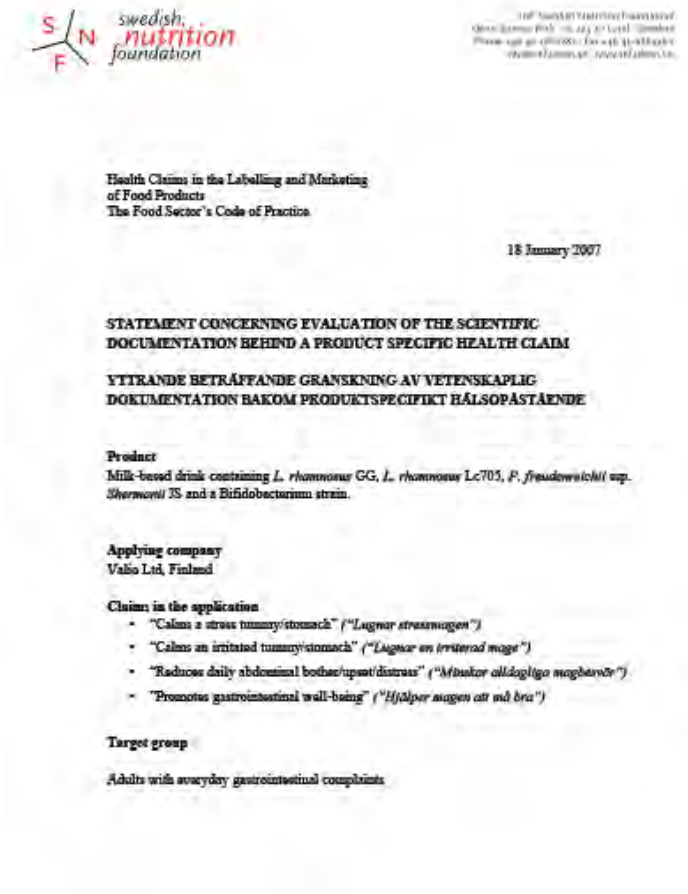
Suggested claim
Benecol drinkable yoghurt effectively reduces blood cholesterol.

Target group
The product is intended exclusively for people who want to lower their blood cholesterol level. The product may not be nutritionally appropriate for pregnant or breastfeeding women, or children under the age of five years.

Summary
Based on two of the studies included in the application and supported by other studies there is scientific evidence that intake of 100 g of low-fat yoghurt drink containing 2 g stanols esterified with long-chain fatty acids, taken alone or with a meal, effectively reduces blood cholesterol. The claim "Benecol drinkable yoghurt effectively reduces blood cholesterol" is therefore supported.

- Benecol drinkable yoghurt (single shot minidrink), 1.4% fat, 2 g esterified plant stanols/shot (100 g).
- "Benecol drinkable yoghurt effectively reduces blood cholesterol".

Product-specific physiological claims VALIO MBD



swedish nutrition foundation

Health Claims in the Labelling and Marketing
of Food Products
The Food Sector's Code of Practice

18 January 2007

STATEMENT CONCERNING EVALUATION OF THE SCIENTIFIC DOCUMENTATION BEHIND A PRODUCT SPECIFIC HEALTH CLAIM

YTTRANDE BETRÄFFANDE GRANSKNING AV VETENSKAPLIG DOKUMENTATION BAKOM PRODUKTSPECIFICT HÄLSOPÅSTÅENDE

Product
Milk-based drink containing *L. rhamnosus* GG, *L. rhamnosus* Lc705, *P. freudenreichii* ssp. *Shermanii* JS and a Bifidobacterium strain.

Applying company
Valio Ltd, Finland

Claim in the application
- "Calms a stress tummy/stomach" *("Lugnar stressmagen")*
- "Calms an irritated tummy/stomach" *("Lugnar en irriterad mage")*
- "Reduces daily abdominal bother/upset/distress" *("Minskar alldagliga magbesvär")*
- "Promotes gastrointestinal well-being" *("Hjälper magen att må bra")*

Target group

Adults with everyday gastrointestinal complaints

- Milk-based drink containing L. rhamnosus GG, L. rhamnosus Lc705, P. freudenreichii ssp. Shermanii JS and a Bifidobacterium strain.
- "Helps to reduce IBS-symptoms/helps to relieve lower gastrointestinal discomfort".

VALIO

Products with a documented low glycaemic index (GI)

- Weight Watchers Pasta Bolognese, Heinz AB
- Weight Watchers Kyckling Verona, Heinz AB
- Axa Balance GI-ruta, Lantmännen Axa
- Axa f-müsli russin/banan/kanel osötad, Lantmännen Axa
- Risifrutti Fiber, Procordia Foods AB
- AXA GIndex/Havre, Lantmännen Axa
- ReGI , Nord Mills AB
- AXA Balance osötad müsli kanel & frukt, Lantmännen Axa
- GoGreen GoAfrica, Lantmännen Axa
- GoGreen GoCarribea, Lantmännen Axa
- GoGreen GoIndia, Lantmännen Axa
- GoGreen GoItaly, Lantmännen Axa
- GoGreen GoMalaysia, Lantmännen Axa
- GoGreen GoThai, Lantmännen Axa
- AXA Balansbröd Yoghurt, Lantmännen Axa

swedish nutrition foundation

Agence Française de Sécurité Sanitaire des Aliments (AFSSA)

Afssa – Saisine n° 2006-SA-0182

Maisons-Alfort, le 10 janvier 2007

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif aux lignes directrices pour la constitution et l'évaluation de dossiers portant sur les allégations nutritionnelles et de santé revendiquées pour les denrées alimentaires

Dans l'attente du vote définitif du règlement européen sur les allégations nutritionnelles et de sa mise en application, l'Agence française de sécurité sanitaire des aliments (Afssa) s'est auto-saisie le 18 novembre 2004 d'une demande d'élaboration de lignes directrices pour la constitution et l'évaluation de dossiers portant sur les allégations nutritionnelles et de santé revendiquées pour les denrées alimentaires.

Après consultation du Comité d'experts spécialisé (CES) « Nutrition humaine » réuni les 26 janvier et 23 mars 2006, l'Afssa rend l'avis suivant :

L'objectif de ce document est double :
contribuer à l'homogénéisation et la cohérence de l'évaluation des allégations nutritionnelles et de santé par les experts du CES « Nutrition humaine » ;
proposer un guide aux industriels pour la constitution de dossiers en vue de l'évaluation des allégations nutritionnelles et de santé.

Les présentes lignes directrices répertorient un ensemble des critères jugés pertinents par les experts du CES « Nutrition humaine » pour l'évaluation des allégations. Ils sont regroupés en 4 grands thèmes :

- les critères d'exclusion définitive de l'allégation,
- l'évaluation du produit portant l'allégation,
- l'évaluation de l'allégation
  - données établissant un lien entre le nutriment et l'effet revendiqué
  - pertinence en termes de santé publique
- la formulation de l'allégation et sa compréhension par le consommateur.

De l'intégration de l'ensemble de ces critères dépend l'avis définitif rendu quant à la justification scientifique de l'allégation.

Ces lignes directrices sont en phase avec des documents antérieurs émis au niveau européen (Howlett & Shortt 2004 ; Conseil de l'Europe 2001).
Elles viennent compléter celles relatives à la constitution de dossiers industriels soumis au Comité d'experts « Nutrition humaine » (Avis Afssa du 19 avril 2001) et doivent être uniquement considérées comme un outil d'aide à la démonstration et à l'expertise scientifiques. En effet, elles présentent les principales questions que soulève la justification scientifique d'une allégation et constituent le support de l'évaluation des allégations par les experts.
Ce guide constitue donc un repère auquel l'industriel pourra se référer, chaque fois que nécessaire, de manière à s'assurer que le dossier soumis intègre les éléments jugés indispensables à l'évaluation. Il est amené à s'enrichir compte tenu des discussions nationales et européennes actuelles dans le cadre de la mise en place de la future réglementation communautaire en matière d'allégations.

Enfin, ces lignes directrices générales ne remettent pas en cause les recommandations spécifiques de l'Afssa en matière d'évaluation de certaines catégories de produits ; notamment, les produits portant des allégations et destinés aux enfants de moins de 3 ans (Avis Afssa du 26 avril 2006), produits contenant des pro- ou pré-biotiques et portant des allégations relative à la flore et l'immunité chez le sujet adulte (Rapport Afssa, février 2005), produits à base de plantes (Rapport Afssa, février 2003), produits contenant des acides gras oméga 3 et portant des allégations relatives au système cardiovasculaire (Rapport Afssa, juillet 2003).

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Après consultation du Comité d'experts spécialisé (CES) «Nutrition humaine» réuni les 26 janvier et 23 mars 2006, l'Afssa rend l'avis suivant :

L'objectif de ce document est double :

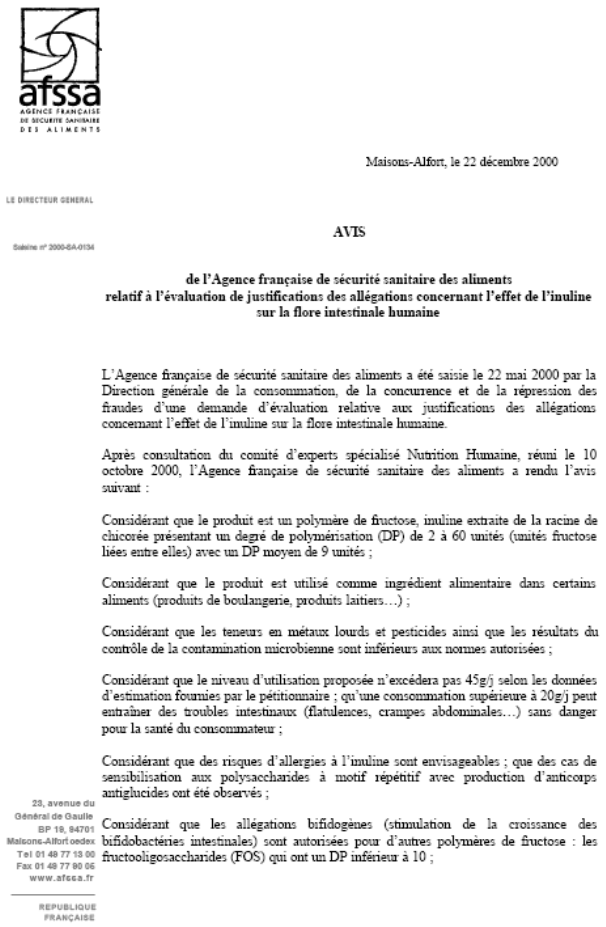
1. contribuer à l'homogénéisation et la cohérence de l'évaluation des allégations nutritionnelles et de santé par les experts du CES «Nutrition humaine»;
2. proposer un guide aux industriels pour la constitution de dossiers en vue de l'évaluation des allégations nutritionnelles et de santé.

Les présentes lignes directrices répertorient un ensemble des critères jugés pertinents par les experts du CES « Nutrition humaine » pour l'évaluation des allégations. Ils sont regroupés en 4 grands thèmes:

- les critères d'exclusion définitive de l'allégation,
- l'évaluation du produit portant l'allégation,
- l'évaluation de l'allégation o données établissant un lien entre le nutriment et l'effet revendiqué o pertinence en termes de santé publique
- la formulation de l'allégation et sa compréhension par le consommateur,

De l'intégration de l'ensemble de ces critères dépend l'avis définitif rendu quant à la justification scientifique de l'allégation.

Évaluation de justifications des allégations concernant l'effet de l'inuline sur la flore intestinale humaine



afssa
AGENCE FRANÇAISE DE SECURITE SANITAIRE DES ALIMENTS

Maisons-Alfort, le 22 décembre 2000

LE DIRECTEUR GENERAL

Saisine n° 2000-SA-0134

AVIS

de l'Agence française de sécurité sanitaire des aliments
relatif à l'évaluation de justifications des allégations concernant l'effet de l'inuline sur la flore intestinale humaine

L'Agence française de sécurité sanitaire des aliments a été saisie le 22 mai 2000 par la Direction générale de la consommation, de la concurrence et de la répression des fraudes d'une demande d'évaluation relative aux justifications des allégations concernant l'effet de l'inuline sur la flore intestinale humaine.

Après consultation du comité d'experts spécialisé Nutrition Humaine, réuni le 10 octobre 2000, l'Agence française de sécurité sanitaire des aliments a rendu l'avis suivant :

Considérant que le produit est un polymère de fructose, inuline extraite de la racine de chicorée présentant un degré de polymérisation (DP) de 2 à 60 unités (unités fructose liées entre elles) avec un DP moyen de 9 unités ;

Considérant que le produit est utilisé comme ingrédient alimentaire dans certains aliments (produits de boulangerie, produits laitiers…) ;

Considérant que les teneurs en métaux lourds et pesticides ainsi que les résultats du contrôle de la contamination microbienne sont inférieurs aux normes autorisées ;

Considérant que le niveau d'utilisation proposée n'excédera pas 45g/j selon les données d'estimation fournies par le pétitionnaire ; qu'une consommation supérieure à 20g/j peut entraîner des troubles intestinaux (flatulences, crampes abdominales…) sans danger pour la santé du consommateur ;

Considérant que des risques d'allergies à l'inuline sont envisageables ; que des cas de sensibilisation aux polysaccharides à motif répétitif avec production d'anticorps antiglucides ont été observés ;

Considérant que les allégations bifidogènes (stimulation de la croissance des bifidobactéries intestinales) sont autorisées pour d'autres polymères de fructose : les fructooligosaccharides (FOS) qui ont un DP inférieur à 10 ;

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BP 19, 94701
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Tel 01 49 77 13 00
Fax 01 49 77 90 06
www.afssa.fr

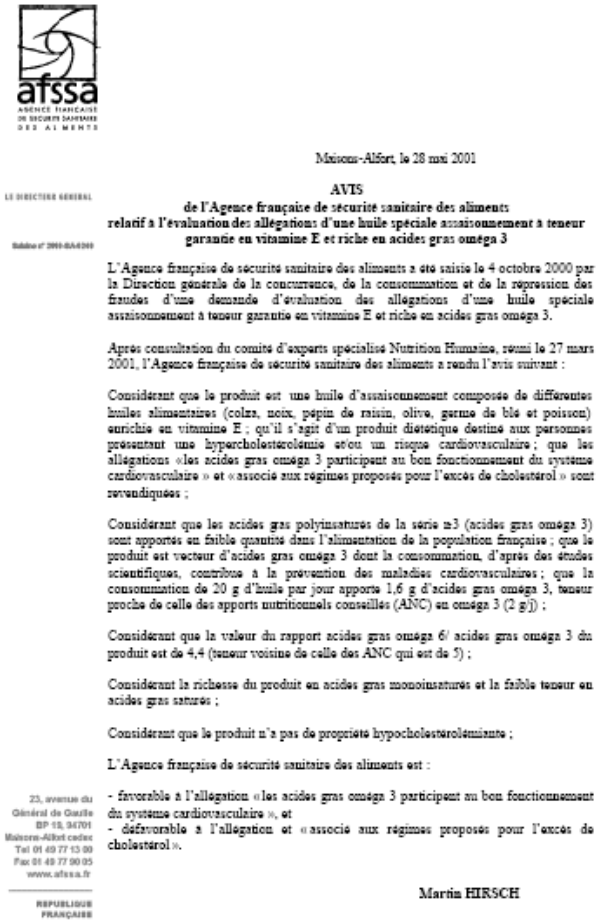
REPUBLIQUE FRANÇAISE

L'Agence française de sécurité sanitaire des aliments estime que:

- L'allégation «la prise orale d'inuline DP9 augmente significativement la population de Bifidobacterium dans l'intestin humain» est acceptable, cette allégation devant toutefois être accompagnée des précisions suivantes, sans que puisse être revendiqué un effet bénéfique préventif ni curatif sur la santé : «consommation minimale de 9 g/j pour obtenir l'effet allégué - apparition possible de troubles intestinaux en cas de consommation supérieure à 20g/j»

BENEO

Évaluation des allégations d'une huile spéciale assaisonnement à teneur garantie en vitamine E et riche en acides gras oméga 3



afssa
AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES ALIMENTS

LE DIRECTEUR GÉNÉRAL

Saisine n° 2000-SA-0260

Maisons-Alfort, le 28 mai 2001

AVIS
de l'Agence française de sécurité sanitaire des aliments
relatif à l'évaluation des allégations d'une huile spéciale assaisonnement à teneur garantie en vitamine E et riche en acides gras oméga 3

L'Agence française de sécurité sanitaire des aliments a été saisie le 4 octobre 2000 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation des allégations d'une huile spéciale assaisonnement à teneur garantie en vitamine E et riche en acides gras oméga 3.

Après consultation du comité d'experts spécialisé Nutrition Humaine, réuni le 27 mars 2001, l'Agence française de sécurité sanitaire des aliments a rendu l'avis suivant :

Considérant que le produit est une huile d'assaisonnement composée de différentes huiles alimentaires (colza, noix, pépin de raisin, olive, germe de blé et poisson) enrichie en vitamine E ; qu'il s'agit d'un produit diététique destiné aux personnes présentant une hypercholestérolémie et/ou un risque cardiovasculaire ; que les allégations «les acides gras oméga 3 participent au bon fonctionnement du système cardiovasculaire » et «associé aux régimes proposés pour l'excès de cholestérol » sont revendiquées ;

Considérant que les acides gras polyinsaturés de la série n3 (acides gras oméga 3) sont apportés en faible quantité dans l'alimentation de la population française ; que le produit est vecteur d'acides gras oméga 3 dont la consommation, d'après des études scientifiques, contribue à la prévention des maladies cardiovasculaires ; que la consommation de 20 g d'huile par jour apporte 1,6 g d'acides gras oméga 3, teneur proche de celle des apports nutritionnels conseillés (ANC) en oméga 3 (2 g/j) ;

Considérant que la valeur du rapport acides gras oméga 6/ acides gras oméga 3 du produit est de 4,4 (teneur voisine de celle des ANC qui est de 5) ;

Considérant la richesse du produit en acides gras monoinsaturés et la faible teneur en acides gras saturés ;

Considérant que le produit n'a pas de propriété hypocholestérolémiante ;

L'Agence française de sécurité sanitaire des aliments est :

- favorable à l'allégation «les acides gras oméga 3 participent au bon fonctionnement du système cardiovasculaire », et
- défavorable à l'allégation et «associé aux régimes proposés pour l'excès de cholestérol ».

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RÉPUBLIQUE FRANÇAISE

L'Agence française de sécurité sanitaire des aliments est favorable à l'allégation « les acides gras oméga 3 participent au bon fonctionnement du système cardiovasculaire»

Évaluation des justificatifs concernant les allégations revendiquées pour un jus de raisin

Afssa – Saisine n° 2002-SA-0046

Maisons-Alfort, le 16 juillet 2002

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif à l'évaluation des justificatifs concernant les allégations revendiquées pour un jus de raisin

L'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 15 février 2002 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation des allégations revendiquées pour un jus de raisin.

Après consultation du Comité d'experts spécialisé « Nutrition humaine » le 30 avril 2002, l'Afssa rend l'avis suivant :

Considérant que la demande concerne l'évaluation des allégations : « naturellement riche en antioxydants » et « une alimentation riche en antioxydants comme l'alimentation méditerranéenne, contribue à une bonne circulation sanguine, à la protection de l'organisme entier » revendiquées pour un jus de raisin dont 5 % de muscat, élaboré à partir de cépages sélectionnés, que les antioxydants sont présents sous forme de polyphénols ;

Considérant que l'essentiel des propriétés antioxydantes revendiquées par le produit repose sur la présence de certains composés phénoliques (majoritairement anthocyanes et flavanols) alors que, selon la littérature scientifique, d'autres substances peuvent concourir à ces effets ; que les études épidémiologiques présentées dans le dossier ne sont pas pertinentes ; que les études expérimentales chez l'homme évoquent la possibilité d'une activité antithrombogénique des polyphénols, mais qui n'est pas forcément liée à leur pouvoir antioxydant ;

Considérant que bien que les effets du régime méditerranéen ne soient pas contestables, certains mécanismes d'action des facteurs impliqués restent controversés ; que la richesse en antioxydants du régime méditerranéen est confirmée par de nombreuses études ; que cependant la relation causale entre les antioxydants et les effets protecteurs du régime méditerranéen n'est pas exclusive ;

Considérant toutefois que le produit présente un intérêt nutritionnel et permet une consommation accrue et facilement accessible de ces substances ; qu'il peut être consommé plus volontiers par les jeunes adultes en lieu et place d'autres boissons sucrées ; que cet argument est en accord avec les recommandations du Programme National Nutrition Santé (PNNS) en matière de consommation de fruits,

L'Afssa estime qu'avant de statuer définitivement sur le dossier, les éléments suivants doivent être considérés par le pétitionnaire :

- L'allégation « naturellement riche en antioxydants » peut être acceptable à condition de spécifier la nature des antioxydants pour ne pas induire le consommateur en erreur, une nouvelle formulation de l'allégation tenant compte de cet élément pourra être proposée par le pétitionnaire ;
- L'allégation « une alimentation riche en antioxydants comme l'alimentation méditerranéenne, contribue à une bonne circulation sanguine, à la protection de l'organisme entier » n'est pas acceptable car elle peut induire une image réductrice

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L'allégation «naturellement riche en antioxydants» peut être acceptable à condition de spécifier la nature des antioxydants pour ne pas induire le consommateur en erreur, une nouvelle formulation de l'allégation tenant compte de cet élément pourra être proposée par le pétitionnaire.

Évaluation de «yaourts» enrichis en esters de stanols végétaux, accompagnés d'une allégation faisant état de l'effet sur la réduction de la cholestérolémie

Afssa – Saisine n° 2002-SA-0322

Maisons-Alfort, le 5 mai 2003

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif à l'évaluation de « yaourts » enrichis en esters de stanols végétaux, accompagnés d'une allégation faisant état de l'effet sur la réduction de la cholestérolémie

Par courrier reçu le 9 décembre 2002, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 5 décembre 2002 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation de « yaourts » enrichis en esters de stanols végétaux, accompagnés d'une allégation faisant état de l'effet sur la réduction de la cholestérolémie.

Après consultation du Comité d'experts spécialisé « Nutrition humaine » le 20 février 2003, l'Afssa rend l'avis suivant :

Considérant que la demande concerne d'une part l'évaluation de l'emploi de « yaourts » enrichis en esters de stanols végétaux et d'autre part, l'évaluation des justificatifs de l'allégation envisagée : « enrichi en stanols végétaux qui aident à réduire le cholestérol dans le cadre d'un régime adapté » ;

Considérant que le pétitionnaire commercialise déjà une margarine allégée enrichie en phytostanols portant la même allégation ; que l'utilisation de cette allégation pour la margarine avait fait l'objet d'un avis favorable du Conseil supérieur d'hygiène publique de France le 10 octobre 2000 ; que compte tenu des données scientifiques actuelles, le niveau d'apport en phytostérols et/ou phytostanols considéré comme optimal pour obtenir l'effet recherché de réduction de la concentration plasmatique de LDL-cholestérol est de 2 à 3 g/j ; qu'il existe peu d'études à long terme relatives aux effets d'un apport élevé en phytostanols ;

Considérant que le pétitionnaire propose d'enrichir en esters de phytostanols des « yaourts » allégés en matière grasse (environ 0,7 g de lipides pour 100 g de yaourts) ; que ces « yaourts » seraient conditionnés en pots de 125 g à raison de 1,4 g d'ester de phytostanols (soit 0,8 g de stanols libres par unité de consommation) ; que ces produits enrichis devraient se conformer aux règlements des Etat membres pour leur appellation et ne seraient donc pas dénommés "yaourts" ;

Considérant que l'Afssa avait estimé, dans son avis en date du 1 août 2002, qu'un éventuel élargissement de la gamme de produits enrichis en phytostérols devrait être justifié sur la base d'une part, d'un travail de simulation de consommation et, d'autre part, de données de suivi de consommation des produits enrichis en phytostérols déjà sur le marché ; que ces recommandations peuvent également s'appliquer aux produits enrichis en phytostanols ; que les données de consommation, fournies par le pétitionnaire et issues d'Etats membres où d'autres vecteurs que la margarine (dont des « yaourts ») sont disponibles, montrent que :

- l'apport en phytostanols par les margarines et les yaourts équivaudrait en moyenne à une consommation par jour inférieure ou égale à 2 g chez les consommateurs les plus réguliers des produits commercialisés par le pétitionnaire ;
- l'utilisation d'un second produit enrichi en phytostanols par des individus qui consomment déjà des produits enrichis en ces substances n'aurait pas pour effet d'augmenter leur consommation moyenne totale de phytostanols, ce qui laisse supposer un effet de substitution entre produits ;
- le recouvrement entre consommateurs de margarines enrichies et consommateurs de « yaourts » enrichis est faible (inférieur à 15 % des consommateurs dans l'étude) ;

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L'Afssa considère :

Concernant l'allégation :

L'utilisation de l'allégation «enrichi en stanols végétaux qui aident à réduire le cholestérol dans le cadre d'un régime adapté » est justifiée pour des «yaourts» dont la composition est proche de celle des yaourts allégés en matière grasse (environ 0,7 g de lipides pour 100 g de yaourts)

Évaluation des justifications scientifiques des allégations «la lutéine contribue à protéger la rétine et le cristallin de l'oxydation», «la lutéine renforce la protection de la rétine et du cristallin contre l'oxydation», «la lutéine est l'un des constituants majeurs de la rétine et du cristallin», «la lutéine, constituant majeur de la rétine et du cristallin, contribue à protéger la rétine et le cristallin de l'oxydation» relatives à un complément alimentaire contenant de la lutéine sous forme libre

Afssa – Saisine n° 2003-SA-0295
Saisine liée 2002-SA-0195

Maisons-Alfort, le 23 janvier 2004

AVIS

de l'Agence française de sécurité sanitaire des aliments
relatif à l'évaluation des justifications scientifiques des allégations « la lutéine contribue à protéger la rétine et le cristallin de l'oxydation », « la lutéine renforce la protection de la rétine et du cristallin contre l'oxydation », « la lutéine est l'un des constituants majeurs de la rétine et du cristallin », « la lutéine, constituant majeur de la rétine et du cristallin, contribue à protéger la rétine et le cristallin de l'oxydation » relatives à un complément alimentaire contenant de la lutéine sous forme libre

Par courriel reçu le 20 juin 2003, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 17 juin 2003 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation des justifications scientifiques des allégations « la lutéine contribue à protéger la rétine et le cristallin de l'oxydation », « la lutéine renforce la protection de la rétine et du cristallin contre l'oxydation », « la lutéine est l'un des constituants majeurs de la rétine et du cristallin », « la lutéine, constituant majeur de la rétine et du cristallin, contribue à protéger la rétine et le cristallin de l'oxydation » relatives à un complément alimentaire contenant de la lutéine sous forme libre.

L'Afssa, dans son avis du 19 décembre 2002, considère que les deux allégations « contribue à la santé de l'œil » et « contribue au bon fonctionnement oculaire » ne sont pas scientifiquement étayées par le pétitionnaire. Cet avis est motivé par un niveau de preuves insuffisant pour justifier les allégations proposées ainsi que par l'absence d'une étude d'intervention relative aux effets de la consommation du produit, à la dose proposée, pour la population visée. Sur la base du même dossier scientifique, le pétitionnaire soumet quatre nouvelles allégations.

Après consultation du Comité d'experts spécialisé « Nutrition humaine » le 20 novembre 2003, l'Afssa rend l'avis suivant :

Considérant que la lutéine est un pigment de la famille des caroténoïdes retrouvé dans la rétine, qui est particulièrement concentré dans sa partie centrale appelée macula où il joue le rôle de filtre de la lumière bleue et probablement celui d'antioxydant ; que cette hypothèse est fortement renforcée par la présence dans la rétine de métabolites issus de l'oxydation de la lutéine ; qu'en outre, ces pigments ne sont pas synthétisés par l'organisme humain ; qu'il a été montré que leur apport alimentaire est indispensable à la constitution du pigment maculaire ;

Considérant que le cristallin est une lentille transparente positionnée dans la partie antérieure de l'œil ; que le cristallin a une structure essentiellement protéique ; que la cataracte est une maladie liée à l'opacification du cristallin ; que cette opacification résulte de modifications oxydatives des protéines de structure du cristallin ; que les principaux antioxydants retrouvés dans le cristallin sont l'ascorbate, le glutathion, les tocophérols et les caroténoïdes ; que parmi ces derniers, on retrouve essentiellement la lutéine et la zéaxanthine ; que ces substances agissent par lyse des protéines dénaturées, responsables de la diminution de la transparence du cristallin ;

Considérant les arguments scientifiques en faveur d'un rôle antioxydant de la lutéine au sein de la rétine et du cristallin ; qu'en outre, une étude a montré l'existence d'« une relation inverse entre la densité du pigment maculaire et la densité du cristallin », l'allégation « la lutéine contribue à protéger la rétine et le cristallin de l'oxydation » est scientifiquement justifiée ;

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L'Afssa estime que :

les allégations

- « la lutéine contribue à protéger la rétine et le cristallin de l'oxydation »
- « la lutéine est un (des) constituant(s) de la rétine et du cristallin » sont scientifiquement justifiées

Évaluation des justificatifs scientifiques concernant les allégations présentes sur l'étiquetage d'un lait fermenté contenant notamment du Lactobacillus casei DN-114 001

Afssa – Saisine n° 2003-SA-0200

Maisons-Alfort, le 23 janvier 2004

AVIS

de l'Agence française de sécurité sanitaire des aliments
relatif à l'évaluation des justificatifs scientifiques concernant les allégations présentes sur l'étiquetage d'un lait fermenté contenant notamment du *Lactobacillus casei DN-114 001*

Par courrier reçu le 12 juin 2003, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 5 juin 2003 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation des justificatifs scientifiques concernant les allégations présentes sur l'étiquetage d'un lait fermenté contenant notamment du *Lactobacillus casei DN-114 001*.

Après consultation du Comité d'experts spécialisé «Nutrition humaine» le 20 novembre 2003, l'Afssa rend l'avis suivant :

Considérant que la demande concerne l'évaluation des justifications scientifiques de 10 allégations relatives à un lait fermenté contenant du *Lactobacillus casei DN-114 001*, regroupées ci-dessous en 4 ensembles :

1. aide à renforcer les défenses naturelles
   aide votre barrière intestinale à se renforcer
2. aide à la régulation du système immunitaire
   contribue au bon fonctionnement du système immunitaire
   aide à renforcer le système immunitaire intestinal
3. aide le corps à bien se défendre
   contribue à rendre le corps plus résistant
   aide à protéger votre corps
4. aide votre intestin à repousser certaines bactéries indésirables
   aide votre corps à lutter contre certaines agressions du quotidien

Considérant les données générales et sanitaires du produit

Considérant que le produit est obtenu par fermentation du lait par les deux souches bactériennes utilisées dans la fabrication des yaourts : *Streptococcus thermophilus* et *Lactobacillus bulgaricus*, auxquelles est ajoutée une autre souche bactérienne originale : *Lactobacillus casei DN-114 001* ; que les souches utilisées ont toutes le statut de GRAS (Generally Recognised As Safe) ; que le produit est présenté dans des bouteilles de 93,7 mL, soit un poids de 100 g, sous les formes allégée (aux édulcorants), sucrée ou aromatisée à l'orange ; que ce produit présente les exigences réglementaires de sécurité sanitaire ;

Considérant le devenir de *Lactobacillus casei DN-114 001* dans l'intestin

Considérant que dans une première étude menée chez 4 sujets sains, consistant en une consommation journalière de 300 mL d'un lait fermenté identique contenant un variant de *Lactobacillus casei DN-114 001* résistant à la rifampicine, un taux de survie de 6,5 ± 3,5 % a été observé au niveau fécal ; que dans une deuxième étude réalisée sur 12 volontaires adultes ayant consommé pendant 10 jours 3 bouteilles du produit, *Lactobacillus casei DN-114 001* est retrouvé dans les fèces des volontaires à des taux stables après 4 jours de consommation jusqu'à la fin de

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L'Afssa estime que :

L'allégation «participe à renforcer les défenses naturelles de l'organisme», remplaçant l'allégation «aide à renforcer les défenses naturelles», est justifiée.

Évaluation des justificatifs concernant l'allégation «contribue à diminuer la fixation de certaines bactéries E.coli sur les parois des voies urinaires» et sur l'emploi de la «cranberry/canneberge» ou «Vaccinium macrocarpon» dans des jus concentrés, des compléments alimentaires et un cocktail/nectar de jus

Afssa – Saisine n° 2003-SA-0352

Saisine liée n°2003-SA-0056

Maisons-Alfort, le 6 avril 2004

AVIS

de l'Agence française de sécurité sanitaire des aliments
relatif à l'évaluation des justificatifs concernant l'allégation « contribue à diminuer la fixation de certaines bactéries *E.coli* sur les parois des voies urinaires » et sur l'emploi de la « cranberry/canneberge » ou « *Vaccinium macrocarpon* » dans des jus concentrés, des compléments alimentaires et un cocktail/nectar de jus

L'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 17 novembre 2003 par la Direction générale de la consommation, de la concurrence et de la répression des fraudes d'une demande d'évaluation des justificatifs concernant l'allégation « contribue à diminuer la fixation de certaines bactéries *E.coli* sur les parois des voies urinaires » et sur l'emploi de la « cranberry/canneberge » ou « *Vaccinium macrocarpon* » dans des jus concentrés, des compléments alimentaires et un cocktail/nectar de jus.

Après consultation du Comité d'experts spécialisé « Nutrition humaine » le 28 janvier 2004, l'Afssa rend l'avis suivant.

Considérant que la demande concerne d'une part l'emploi de trois produits issus de la canneberge : (i) un jus concentré, (ii) un cocktail/nectar à 25 % de jus et 13 % de sucres ajoutés, et (iii) une poudre de jus concentré atomisé (80 % de matière sèche), et d'autre part la justification de l'allégation « contribue à diminuer la fixation de certaines bactéries *E.coli* sur les parois des voies urinaires » ; considérant l'avis du 29 août 2003 relatif à ce produit ; considérant les nouveaux éléments soumis à l'évaluation ;

Considérant les précisions apportées sur les procédés de fabrication des trois produits et sur la procédure de contrôle des risques mise en œuvre (procédure HACCP), sur les spécifications chimiques (pesticides) et microbiologiques, sur la méthode de dosage des proanthocyanidines, et sur le transport, le stockage, et la période de conservation des produits ;

Considérant la démonstration de l'effet du jus de fruit et de la poudre de jus de fruit au regard des données issues de la tradition et des données expérimentales établies dans l'avis du 29 août 2003 et rappelées ci-dessous ;

Depuis plusieurs dizaines d'années, le jus de fruits de *Vaccinium macrocarpon* est consommé en Amérique du Nord comme remède traditionnel des infections urinaires.
Des études cliniques randomisées démontrent une diminution de la fréquence des infections urinaires chez des femmes âgées de 30 à 78 ans selon les études) liée à la consommation de jus de fruits de *Vaccinium macrocarpon*. Dans l'une de ces études, 36 mg de proanthocyanidines mesurées étaient apportés chaque jour.

Dans une autre étude, une diminution non significative de la fréquence des infections urinaires est également observée sur un faible effectif (n=10) de femmes âgées de 28 à 44 ans, souffrant d'infections urinaires chroniques, et consommant *Vaccinium macrocarpon* sous forme de poudre encapsulée.

Les études mécanistiques disponibles permettent de penser que ces effets bénéfiques sont liés à l'inhibition de l'adhérence de certains *E. coli* à la muqueuse urinaire, notamment pour les souches uropathogènes qui présentent certaines adhésines (P-fimbriae). Ce mécanisme semble lié à la présence de proanthocyanidines.

Les données présentées suggèrent donc que la consommation de jus de *Vaccinium macrocarpon* (contenant 36 mg de proanthocyanidines mesurées) conduit à une diminution de la

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L'Afssa estime :

que l'allégation «contribue à diminuer la fixation de certaines bactéries E.coli sur les parois des voies urinaires» est acceptable uniquement pour le jus du fruit de la plante Vaccinum macrocorpon et la poudre de jus du fruit de cette plante; les données sont insuffisantes pour attribuer cette allégation au cocktail/nectar.

Évaluation des justificatifs concernant l'allégation «contribue à diminuer la fixation de certaines bactéries E. coli sur les parois urinaires» pour un nectar/cocktail de jus de cranberry / canneberge

Afssa – Saisine n° 2004-SA-214
Saisine liée n°2003-SA-0066 et 2003-SA-0362

Maisons-Alfort, le 8 décembre 2004

AVIS

de l'Agence française de sécurité sanitaire des aliments
d'évaluation des justificatifs concernant l'allégation « contribue à diminuer la fixation de certaines bactéries *E. coli* sur les parois urinaires » pour un nectar/cocktail de jus de cranberry / canneberge

Par courrier reçu le 03 juin 2004, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 28 mai 2004 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes d'une demande d'évaluation des justificatifs concernant l'allégation « contribue à diminuer la fixation de certaines bactéries *E. coli* sur les parois urinaires » pour un nectar/cocktail de jus de cranberry / canneberge.

Après consultation du comité d'experts spécialisé « Nutrition Humaine » le 23 septembre 2004, l'Afssa rend l'avis suivant.

Considérant que la saisine consistait en un complément d'information à 2 saisines précédemment instruites, les saisines 2003-SA-0066 et 2003-SA-362, concernant un jus concentré, une poudre, et le cocktail/nectar de jus, que les avis précédemment émis ont permis de conclure favorablement quant à (i) la sécurité des produits, (ii) la justification de l'allégation pour le jus concentré et pour la poudre ;

Considérant les compléments d'information envoyés par le pétitionnaire ;

L'Afssa estime que l'allégation « contribue à diminuer la fixation de certaines bactéries *E. coli* sur les parois urinaires » peut être étendue au cocktail/nectar de jus.

Martin HIRSCH

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L'Afssa estime que l'allégation «contribue à diminuer la fixation de certaines bactéries E. coli sur les parois urinaires» peut être étendue au cocktail/nectar de jus.

Évaluation des allégations nutritionnelles concernant l'effet bifidogène de l'inuline sur la flore intestinale humaine : «L'inuline native de chicorée est bifidogène (stimulation de la croissance des bifidobactéries intestinales) à un dosage quotidien de 5 g/j.», «L'inuline native de chicorée stimule la croissance des bifidobactéries intestinales à un dosage quotidien de 5 g/j», «L'inuline native de chicorée est prébiotique à un dosage quotidien de 5 g/j» et «L'inuline native de chicorée à un dosage quotidien de 5 g/j aide à maintenir une flore intestinale saine dans le côlon»

Afssa – Saisine n° 2004-SA-0365

Maisons-Alfort, le 20 avril 2005

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif à l'évaluation des allégations nutritionnelles concernant l'effet bifidogène de l'inuline sur la flore intestinale humaine : « L'inuline native de chicorée est bifidogène (stimulation de la croissance des bifidobactéries intestinales) à un dosage quotidien de 5 g/j. », « L'inuline native de chicorée stimule la croissance des bifidobactéries intestinales à un dosage quotidien de 5 g/j », « L'inuline native de chicorée est prébiotique à un dosage quotidien de 5 g/j » et « L'inuline native de chicorée à un dosage quotidien de 5 g/j aide à maintenir une flore intestinale saine dans le côlon »

Par courrier reçu le 26 octobre 2004, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 20 octobre 2004 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes, d'une demande d'évaluation des allégations nutritionnelles concernant l'effet bifidogène de l'inuline sur la flore intestinale humaine : « L'inuline native de chicorée est bifidogène (stimulation de la croissance des bifidobactéries intestinales), à un dosage quotidien de 5 g/j. », « L'inuline native de chicorée stimule la croissance des bifidobactéries intestinales à un dosage quotidien de 5 g/j », « L'inuline native de chicorée est prébiotique à un dosage quotidien de 5 g/j » et « L'inuline native de chicorée à un dosage quotidien de 5 g/j aide à maintenir une flore intestinale saine dans le côlon ».

Après consultation du Comité d'experts spécialisé « Nutrition humaine » réuni le 27 janvier 2005, l'Afssa rend l'avis suivant :

Considérant que l'inuline est un polymère constitué de molécules de fructose de degré de polymérisation compris entre 10 et 60 ; que l'inuline proposée par le pétitionnaire est extraite de la chicorée ; que l'effet bifidogène est défini par l'augmentation du niveau de population et/ou de l'activité des bifidobactéries totales[1] ; que l'Afssa a reconnu dans son avis du 22 décembre 2000 (saisine 2000-SA-0134) que la consommation de 9 g d'inuline par jour a un effet bifidogène ; que la demande concerne l'évaluation de l'effet bifidogène de l'inuline pour une consommation quotidienne de 5 g ainsi que 4 allégations ; que pour argumenter sa demande, le pétitionnaire se base sur deux études originales menées *in vitro* et *in vivo* ;

Considérant que l'étude *in vitro* a été réalisée avec un système qui permet de simuler la digestion et la fermentation colique chez l'humain, après inoculation avec un mélange d'échantillons fécaux de 3 volontaires sains ; que la fermentation *in vitro* a été réalisée pendant 5 semaines, d'une part en présence de l'inuline, d'autre part avec un témoin (amidon) ; qu'un accroissement de la population de bifidobactéries est observé ; que toutefois la méthodologie suivie quant au mode d'évaluation de l'effet de l'inuline sur la flore lactique est critiquable, et ne permet pas de conclure à un effet : l'inuline est introduite dans le réacteur au niveau « colique » en substitution à de l'amidon dont la nature n'est pas indiquée et il n'est pas possible de savoir si cet amidon est fermenté ou non dans le réacteur ;

Considérant que l'étude *in vivo* a été réalisée sur 39 volontaires sains répartis en deux groupes : 20 sujets dans le groupe ayant consommé 2 fois/j un sachet de 2,5 g d'inuline dilué dans un verre d'eau et 19 dans le groupe ayant pris un placebo ; que l'étude est contrôlée, randomisée, parallèle en double aveugle contre placebo ; que les concentrations initiales de bifidobactéries ne

[1] Rapport Afssa relatif aux « Effets des prébiotiques et probiotiques sur la flore et l'immunité de l'homme adulte » - Février 2003

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L'Afssa considère que :

- La consommation quotidienne de 5 g d'inuline native de chicorée est bifidogène ;
- Les allégations «L'inuline native de chicorée est bifidogène (stimulation de la croissance des bifidobactéries intestinales) à un dosage quotidien de 5 g/j.», «L'inuline native de chicorée stimule la croissance des bifidobactéries intestinales à un dosage quotidien de 5 g/j.», «L'inuline native de chicorée est prébiotique à un dosage quotidien de 5 g/j» sont scientifiquement validées.

Évaluation des justificatifs concernant les allégations : «8g/ j d'oligofructose enrichi en inuline augmentent l'absorption de calcium» et «8g/ j d'oligofructose enrichi en inuline augmentent la densité en calcium de l'os».

Afssa – Saisine n° 2006-SA-0438

Maisons-Alfort, le 23 novembre 2006

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif à l'évaluation des justificatifs concernant les allégations : « 8g/ j d'oligofructose enrichi en inuline augmentent l'absorption de calcium » et « 8g/ j d'oligofructose enrichi en inuline augmentent la densité en calcium de l'os ».

Par courrier reçu le 28 décembre 2006, l'Agence française de sécurité sanitaire des aliments (Afssa) a été saisie le 27 décembre 2006 par la Direction générale de la concurrence, de la consommation et de la répression des fraudes (Dgccrf) d'une demande d'évaluation des justificatifs concernant les allégations : « 8 g/j d'oligofructose enrichi en inuline augmentent l'absorption de calcium » et « 8 g/j d'oligofructose enrichi en inuline augmentent la densité en calcium de l'os ».

Après consultation du Comité d'experts spécialisé « Nutrition humaine » le 7 juillet 2006, l'Afssa rend l'avis suivant :

Considérant que la demande porte sur l'évaluation des allégations revendiquées pour un ingrédient alimentaire constitué de fructo-oligosaccharides à courte chaîne et d'inuline ; que l'inuline est un polysaccharide présent dans de nombreux végétaux (tels que la racine de chicorée, l'oignon, le poireau, l'ail, la banane) ; qu'il s'agit d'un polymère linéaire d'unités fructose (Fn, n compris entre 2 et 60) liées en (2-1) et terminé par une unité glucose ; que l'inuline peut être également hydrolysée par voie enzymatique en oligofructose (n compris entre 2 et 9) ; que l'inuline et les oligofructoses ont été qualifiés de fibres alimentaires par de nombreux pays, dont la France ;

Considérant selon le pétitionnaire que compte tenu, d'une part, de l'incidence croissante de l'ostéoporose et des fractures osseuses et d'autre part, de l'insuffisance des apports calciques et vitaminique D qui ne permettent pas de couvrir les besoins d'une proportion importante de la population, l'accent est mis sur la biodisponibilité du calcium alimentaire ; que cette biodisponibilité pourrait être augmentée par un apport de fructanes agissant particulièrement sur la voie passive de l'absorption dans le gros intestin, indépendante de la vitamine D ; que la littérature montre qu'un effet particulier pourrait être attribué à une combinaison d'oligo-fructosaccharides à courte chaîne et d'inuline à plus longue chaîne ; que cet effet a été particulièrement démontré chez le rat ;

Considérant que l'ingrédient est destiné à être incorporé dans une large gamme d'aliments courants (produits laitiers, desserts glacés, pains, plats cuisinés, céréales pour petit-déjeuner, préparations de fruits, produits diététiques, substituts de repas, produits carnés) ; qu'il est destiné à la population générale ; que la dose journalière recommandée par le pétitionnaire est de 8 à 12 g par jour ; que les allégations revendiquées sont : « 8 g/j d'oligofructose enrichi en inuline augmentent l'absorption de calcium » et « 8 g/j d'oligofructose enrichi en inuline augmentent la densité en calcium de l'os » ;

Considérant que le mécanisme proposé par le pétitionnaire pour expliquer l'influence de la consommation des différents polymères de fructose est l'augmentation de la

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L'Afssa estime donc que :

- l'allégation relative à l'augmentation de l'absorption du calcium peut être acceptable sous plusieurs conditions :
  - (i) la restreindre à la seule population des adolescents car elle n'est pas démontrée pour d'autres populations
  - (ii) qu'elle ne soit pas aussi affirmative car les données de la littérature ne permettent pas d'affirmer que la dose efficace journalière est de 8 g/ j
- (iii) que si l'absorption du calcium peut être favorisée, la littérature ne permet pas d'affirmer de façon certaine qu'elle est augmentée.

Netherlands Code of Practice

Foods and dietary supplements
with health claims

Voluntary code for assessing the scientific evidence for health benefits stated in health claims on food and drink products

Keuringsraad

Approved Health Benefits

1. Phytosterol-enriched margarine (Becel pro-active) and LDL-cholesterol lowering (1999)
2. Bread with added n-3 LC-PUFA and lower risk of fatal coronary heart disease (2000)
3. Phytostanol ester-enriched margarine and yoghurt (Benecol) and LDL-cholesterol lowering (2001)
4. Bread with added prebiotic (Frutafit® inulin) and bowel function (2003)
5. Yoghurt with probiotic (Bifidus Essensis) and bowel function (2004)
6. Bread with added OatWell® fibre and LDL-cholesterol lowering (2005)
7. Yoghurt with probiotic (LGG) and intestinal barrier function (2006)

Keuringsraad

Margarine (and yoghurt) with added plant sterols (Becel pro.active)

Assessment Report, Becel pro activ dairy products

The undersigned:
1. Prof dr M.B. Katan (chairman), Wageningen University
2. Prof dr A.F.H. Stalenhoef, University Hospital Nijmegen St. Radboud
3. Mevrouw W.M.M. Verschuren, National Institute of Public Health and the Environment (RIVM), Bilthoven
4. Prof dr R.J. Vonk, University Hospital Groningen

have been appointed by: Unilever Bestfood Netherlands (the Applicant) and the Netherlands Nutrition Centre to assess the scientific evidence for the following health benefit:

Product
Becel pro activ milk type product en pro activ yoghurt type product, each containing 0.75 g of plant sterols per portion.

Proposed Health Benefit
Daily consumption of 3 portions Becel pro activ products (equivalent to 2.25 g of plant sterols) lowers the serum concentration of Low-density lipoprotein (LDL) cholesterol on average by 10%

Target Group:
The products are specially suitable for non pregnant adults, over 45 years of age concerned about their serum cholesterol level.

The undersigned have reached their decision in accordance with the Code of Practice for Assessing the scientific evidence for health benefits stated in health claims on food and drink products 1999. The Applicant submitted a dossier, has co-operated fully in the assessment and has provided the undersigned with all the information requested.

Note
This assessment concerns the health benefit of a new application of plant sterol in a low fat milk and a yoghurt, whereas the health benefit of the application of this plant sterol in spread, is already accepted for the Code of Practice, in an earlier procedure (Voedingscentrum, 1999).
The accepted health benefit in this preceding procedure stated:

"Extra cholesterolverlagend effect ten opzichte van gebruikelijke margarines en vergelijkbare producten".
(Extra cholesterol-lowering effect in comparison to usual spreads and comparable products.)

This procedure not only has to deal with the effect the plant sterol in a new product, but also with a newly brought forward quantitative aspect.

The decision of the undersigned reads:

With respect to Becel pro activ yoghurt and milk drink, there is sufficient scientific evidence, if the proposed health benefit is stated as: daily consumption of 2 - 3 g plant sterol in dairy products results in a reduction up to 10% of the LDL level.

Extra cholesterol lowering effect of using Becel pro.active margarine as compared with usual margarines

Bread with added β-glucan (OatWell® oat bran)

Assessment Report 19-04-05

1. **Prof A.F.H. Stalenhoef (chairman)**, Department of Internal Medicine, University Medical Centre Nijmegen
2. **Prof G. Hornstra**, Universiteit Maastricht/ Nutrisearch, Gronsveld
3. **Prof G.J. Schaafsma**, Wageningen University/ TNO Voeding, Food and Health, Zeist
4. **Dr. W.M.M. Verschuren**, National Institute of Public Health and the Environment (RIVM), Bilthoven

have been appointed by the Netherlands Nutrition Centre and the Applicant **CS Food Innovations, Krimpen aan den IJssel**, to assess the scientific evidence for the following health benefit:

Product: Pró-FIT® bread, containing 2.2 g β-glucan from OatWell® oat bran per 100 g bread

Health Benefit:
Daily consumption of 140 g of Pró-FIT® bread (4 slices, providing 3 g β-glucan from OatWell® oat bran per day), has been shown to reduce the serum concentration of low-density lipoprotein (LDL) by 3% within three weeks, in persons with elevated cholesterol levels.

The undersigned have reached their decision in accordance with the Code of Practice for assessing the scientific evidence for health benefits stated in health claims on food and drink products 1998. The Applicant has co-operated fully in this assessment and has provided the undersigned with all the information requested.

The decision of the undersigned reads:

There is **sufficient scientific evidence**, as referred to in the Code of Practice, for the Health Benefit described above.

This assessment is based on the available data from the scientific literature and confidential data provided by the Applicant. The panel's decision is based in part on the following publications:

1. Truswell AS. Cereal grains and coronary heart disease. Review. Eur J Clin Nutr 2002;56:1-14.
2. Brown L, Rosner B, Willett WW, Sacks FM. Cholesterol-lowering effects of dietary fiber: a meta-analysis. Am J Clin Nutr 1999;69(1):30-42. Comment in: 69(1):1; 70(5):942-3. Amundsen AL, Haugum B, Andersson H. Changes in serum cholesterol and sterol metabolites after intake of products enriched with an oat bran concentrate within a controlled diet. Scandinavian Journal of Nutrition 2003:47(2);68-74.
3. Ripsin CM, Keenan JM, Jacobs DR, Elmer PJ et al. Oat procucts and lipid lowering. A meta-analysis. JAMA 1992; 267(24): 3317-3325.
4. Braaten JT, Wood PJ, Scott FW, Wolynetz MS, Lowe MK, Bradley-White P, Collins MW. Oat β-glucanreduces blood cholesterol concentration in hypercholesterolaemic subjects. Eur J Clin Nutr 1994;48(7):465-74.
5. Davy BM, Davy KP, Ho RC, Beske SD, Davrath LR, Melby CL. High-fiber oat cereal compared with wheat cereal consumption favorably alters LDL-cholesterol subclass and particle numbers in middle-aged and older men. Am J Clin Nutr 2002; 76(2): 351-8.
6. Gerhardt AL, Gallo NB. Full-fat rice bran and oat bran similarly reduce hypercholesterolemia in humans. J Nutr 1998; 128(5): 865-9.

Daily consumption of 140 g of Pró-FIT® bread (4 slices, providing 3 g β-glucan from oat bran per day), has been shown to reduce the serum concentration of lowdensity lipoprotein (LDL) by 3% within three weeks, in persons with elevated cholesterol levels.

Danone Activia with Bifidus Essensis®

Assessment Report 13-4-2004

The undersigned:
1. F.M. Nagengast PhD (chairman), Department of Gastroenterology, University Medical Centre Nijmegen
2. Mrs. E. Kampman PhD, Division of Human Nutrition, Wageningen University
3. R. Hartsmink PhD, Division of Food Science, Wageningen University
4. Prof R.J. Vonk, Laboratory of Nutrition and Metabolism, University of Groningen

have been appointed by the Netherlands Nutrition Centre and the Applicant Danone Nederland, Tiel to assess the scientific evidence for the following health benefit:

Product:
Danone Activia yoghurt containing Bifidus Essensis® (*Bifidobacterium animalis* DN-173 010).

Health Benefit:
1. Consumption of at least one portion (125 g) Danone Activia per day stimulates the intestinal transit in subjects with slow transit times.
2. Consumption of at least one portion (125 g) Danone Activia per day increases the number of bifidobacteria in the large intestine. This increase of bifidobacteria may support a well-balanced gut flora.

In Dutch:
1. Consumptie van tenminste één portie (125 g) Danone Activia per dag bevordert de darmpassage bij personen met een trage stoelgang.
2. Tevens verhoogt de consumptie van tenminste één portie (125 g) Danone Activia de hoeveelheid bifidobacteriën in de dikke darm. Deze toename van bifidobacteriën kan een bijdrage leveren aan een evenwichtige darmflora.

The undersigned have reached their decision in accordance with the Code of Practice for Assessing the scientific evidence for health benefits stated in health claims on food and drink products 1998. The Applicant has co-operated fully in this assessment and has provided the undersigned with all the information requested.

The decision of the undersigned reads:

There is sufficient scientific evidence, as referred to in the Code of Practice, for the Health Benefits 1 and 2, as described above.

Consumption of at least one portion (125 g) Danone Activia per day stimulates the intestinal transit in subjects with slow transit times

Vifit® yoghurt (drink) with LGG® (Lactobacillus rhamnosus Goldin & Gorbach)

ASSESSMENT REPORT VIFIT **14-6-2006**

The undersigned,
Prof. G.J. Schaafsma (chairman), Wageningen University
Prof. F.M. Rombouts, Wageningen University
Dr. G.T. Rijkers, Wilhelmina Children's Hospital, University Medical Center, Utrecht,

have been appointed by the Netherlands Nutrition Centre and the Applicant **Campina, Consumer Products Europe** to assess the scientific evidence for the following health benefit:

Product: **Vifit® with LGG®** (*Lactobacillus rhamnosus* Goldin & Gorbach)

Health Benefit:
Consumption of at least one portion of Vifit® per day supports the barrier function of the intestine.
A suggested serving of either Vifit® yoghurt drink (200 ml) or Vifit® yoghurt (150 ml) or one 100 g bottle of Vifit® Plus provides 10^{10} live LGG®.

In Dutch:
Gezondheidseffect:
Consumptie van ten minste één portie Vifit® per dag ondersteunt de barrièrefunctie van de darm.
Een portie Vifit® yoghurt drink (200 ml), Vifit® yoghurt (150 ml) of een 100 g fleje Vifit® Plus bevat 10^{10} levende LGG®.

The undersigned have reached their decision in accordance with the Code of Practice for Assessing the scientific evidence for health benefits stated in health claims on food and drink products 1998. The Applicant has co-operated fully in this assessment and has provided the undersigned with all the information requested.

The decision of the undersigned reads:
There is **sufficient scientific evidence,** as referred to in the Code of Practice, for the Health Benefit, as described above.

This assessment is based on the available data from the scientific literature and confidential data provided by the Applicant. The panel's decision is based in part on the following publications:

- Appelt PI, Antoine J-M, Asp N-G et al. Functions: Process for the Assessment of Scientific Support for Claims on Foods; Consensus on Criteria. Eur J Nutr 2005;44 Suppl 1:I1-30.
- Arvola A, Cremonini F, Bartolozzi F et al. The effect of oral administration of Lactobacillus GG on antibiotic-associated gastrointestinal side-effects during Helicobacter pylori eradication therapy. Aliment Pharmacol Ther 2005;15(2):163-9.
- Arvola A, Cremonini F, Ojetti V et al. Effect of Lactobacillus GG supplementation on antibiotic-associated gastrointestinal side effects during Helicobacter pylori eradication therapy: a pilot study. Digestion. 2004;69(1):1-7.
- Arvola T, Laiho K, Torkkeli S et al. Prophylactic Lactobacillus GG reduces antibiotic-associated diarrhea in children with respiratory infections: a randomized study. Pediatrics 1999;104(3):e64.
- Ibeno Y et al. Effects of Lactobacillus GG yoghurt on human intestinal microecology in Japanese subjects. Nutrition Today Supplement 1998;31:9S-11S.
- Bonnello SP, Hammes WP, Holzapfel W et al. Safety of probiotics that contain lactobacilli or bifidobacteria. Clin Infect Dis 2003;36(6):775-80.
- Cremonini F, Di Caro S, Covino M et al. Effect of different probiotic preparations on anti-helicobacter pylori therapy-related side effects: a parallel group, triple blind, placebo-controlled study. Am J Gastroenterol 2002;97(11):2744-9.
- Cummings JH, Antoine JM, Azpiroz F et al. PASSCLAIM--gut health and immunity. Eur J Nutr 2004;43 Suppl 2:II118-II173.

Consumption of at least one portion of Vifit® per day supports the barrier function of the intestine.

Bread with added prebiotic (Frutafit® inulin)

Assessment Report

The undersigned:
Prof dr ir F.M. Rombouts (chairman), Wageningen University
Prof dr ir P.A. van den Brandt, Maastricht University
Dr F.M. Nagengast, University Hospital Nijmegen St. Radboud
Prof dr ir G.J. Schaafsma, Wageningen University/ TNO Voeding, Food and Health, Zeist

have been appointed by the Netherlands Nutrition Centre and the Applicant **Bakkerij Veenhuis BV, subsidiary of Borgesius Holding, Stadskanaal (supported by Sensus, a subsidiary of Royal Cosun, Breda)** to assess the scientific evidence for the following health benefit:

Product: **Vitaalbrood® flora**

Health Benefit: **Consumption of three slices of Vitaalbrood® flora per day supports a well-balanced gut flora composition and colonic function by selectively stimulating the growth of *Bifidobacterium*. Vitaalbrood® flora contains at least 5 g Frutafit®-inulin per 100 gram.**

In Dutch:
Consumptie van drie sneden Vitaalbrood® flora per dag ondersteunt een evenwichtige samenstelling van de darmflora en een goede dikke darmfunctie door selectieve groeistimulatie van *Bifidobacterium*. Vitaalbrood® flora bevat ten minste 5 g Frutafit®-inuline per 100 gram.

The undersigned have reached their decision in accordance with the Code of Practice for Assessing the scientific evidence for health benefits stated in health claims on food and drink products 1998. The Applicant submitted a high quality dossier, has co-operated fully in this assessment and has provided the undersigned with all the information requested.

The decision of the undersigned reads:

There is **sufficient scientific evidence**, as referred to in the Code of Practice, for the Health Benefit described above.

Consumption of three slices of Vitaalbrood® flora per day supports a well-balanced gut flora composition and colonic function by selectively stimulating the growth of Bifidobacterium. Vitaalbrood® flora contains at least 5 g Frutafit®-inulin per 100 gram.

Frutafit®

Benecol® Line

Assessment Report

The undersigned:
1. Prof dr A.F.H. Stalenhoef (chairman), University Hospital Nijmegen St. Radboud
2. Prof dr ir G.J. Schaafsma, Wageningen University/ TNO Voeding, Food and Health, Zeist
3. Mw dr ir W.M.M. Verschuren, National Institute of Public Health and the Environment (RIVM), Bilthoven
4. Prof dr F. Kuipers, Institute for Liver, Digestive, and Metabolic Diseases, Department of Pediatrics, University Hospital Groningen

have been appointed by: McNeil Consumer Nutritionals Benelux, a division of Janssen-Cilag (the Applicant) and the Netherlands Nutrition Centre to assess the scientific evidence for the following health benefit:

Product:
1. Benecol ¾ margarine (product with 62 % fat)
2. Benecol light (product with 32 % fat)
3. Benecol preparation with yoghurt

Health Benefit:
Two to three servings of Benecol margarine, Benecol Light margarine or Benecol yoghurt daily lower serum total and low-density lipoprotein cholesterol concentrations and may consequently reduce the risk for coronary heart disease.

The undersigned have reached their decision in accordance with the Code of Practice for Assessing the scientific evidence for health benefits stated in health claims on food and drink products 1998. The Applicant submitted a high quality dossier, has co-operated fully in this assessment and has provided the undersigned with all the information requested.

The decision of the undersigned reads:

1. With respect to Benecol ¾ margarine
   There is sufficient scientific evidence, as referred to in the Code of Practice, for the Health Benefit described above.

2. With respect to Benecol light margarine:
   There is sufficient scientific evidence, as referred to in the Code of Practice, for the Health Benefit described above.

3. With respect to Benecol preparation with yoghurt:
   There is sufficient scientific evidence, as referred to in the Code of Practice, for the Health Benefit described above.

Two to three servings of Benecol margarine, Benecol Light margarine or Benecol yoghurt daily lower serum

total and low-density lipoprotein cholesterol concentrations and may consequently reduce the risk for coronary heart disease.

Yakult® fermented milk product

ASSESSMENT REPORT YAKULT® **10-11-2006**

The undersigned:
1. **Prof R.J. Vonk (chairman)**, Laboratory of Nutrition and Metabolism, University of Groningen
2. **Mrs. E. Kampman PhD**, Division of H uman Nutrition, Wageningen University
3. **F.M. Nagengast PhD**, Department of Gastroenterology, University Medical Centre Nijmegen
4. **Prof. L. de Vuyst**, Research Group of Industrial Microbiology, Vrije Universiteit, Brussel

have been appointed by the Netherlands Nutrition Centre and the Applicant **Yakult Europe BV**, to assess the scientific evidence for the following health benefit:

Product:
Yakult® fermented milk product, containing *Lactobacillus casei* strain Shirota (LcS).

Health Benefit:
Drinking at least one bottle (65 ml) of Yakult® per day
1. **may improve bowel habit in subjects who are susceptible to constipation**
2. **may support a well-balanced gut microbiota through an increased number of lactobacilli.**

In Dutch:
Consumptie van ten minste één portie (65 ml) Yakult® gefermenteerde melk per dag
1. kan de stoelgang verbeteren bij personen die gevoelig zijn voor constipatie
2. kan bijdragen aan een evenwichtige darmflora door een toename van het aantal lactobacillen.

The decision of the panel reads:
There is **sufficient scientific evidence**, as referred to in the Code of Practice, **for the Health Benefits 1 and 2**, as described above.

References:

- Aggett PJ, Antoine J-M, Asp N-G et al. Passclaim: Process for the Assessment of Scientific Support for Claims on Foods; Consensus on Criteria. Eur J Nutr 2005;44 Suppl 1:25-30.
- Asahara T, Takahashi M, Nomoto K et al. Assessment of safety of lactobacillus strains based on resistance to host innate defense mechanisms. Clin Diagn Lab Immunol 2003;10:169-73.
- Borriello SP, Hammes WP, Holzapfel W et al. Safety of probiotics that contain lactobacilli or bifidobacteria. Clin Infect Dis 2003;36(6):775-80.
- Cummings JH, Antoine JM, Azpiroz F et al. PASSCLAIM--gut health and immunity. Eur J Nutr 2004;43 Suppl 2:II118-II173.
- De Preter V, Geboes K, Verbrugghe K et al. The in vivo use of the stable isotope-labelled biomarkers lactose-[15N]ureide and [2H4]tyrosine to assess the effects of pro- and pre-biotics on the intestinal flora of healthy human volunteers. Br J Nutr 2004;92:439-446.
- De Roos NM, Katan MB. Effects of probiotic bacteria on diarrhea, lipid metabolism, and carcinogenesis: a review of papers published between 1988 and 1998. Am J Clin Nutr 2000;71(2):405-11.
- FAO/WHO expert consultation. Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria, 2001.
  http://www.who.int/foodsafety/publications/fs_management/en/probiotics.pdf 34 pp
- Gibson GR, Wang X. Regulatory effects of bifidobacteria on the growth of other colonic bacteria. J Appl Bacteriol 1994; 77:412-20.

Drinking at least one bottle (65 ml) of Yakult® per day may improve bowel habit in subjects who are susceptible to constipation AND/OR may support a well-balanced gut microbiota through an increased number of lactobacilli.

¿Qué Claims están aprobados a nivel internacional (FSANZ, FOSHU, FDA) y que pueden ayudarnos a proponer o preparar Claims de salud?

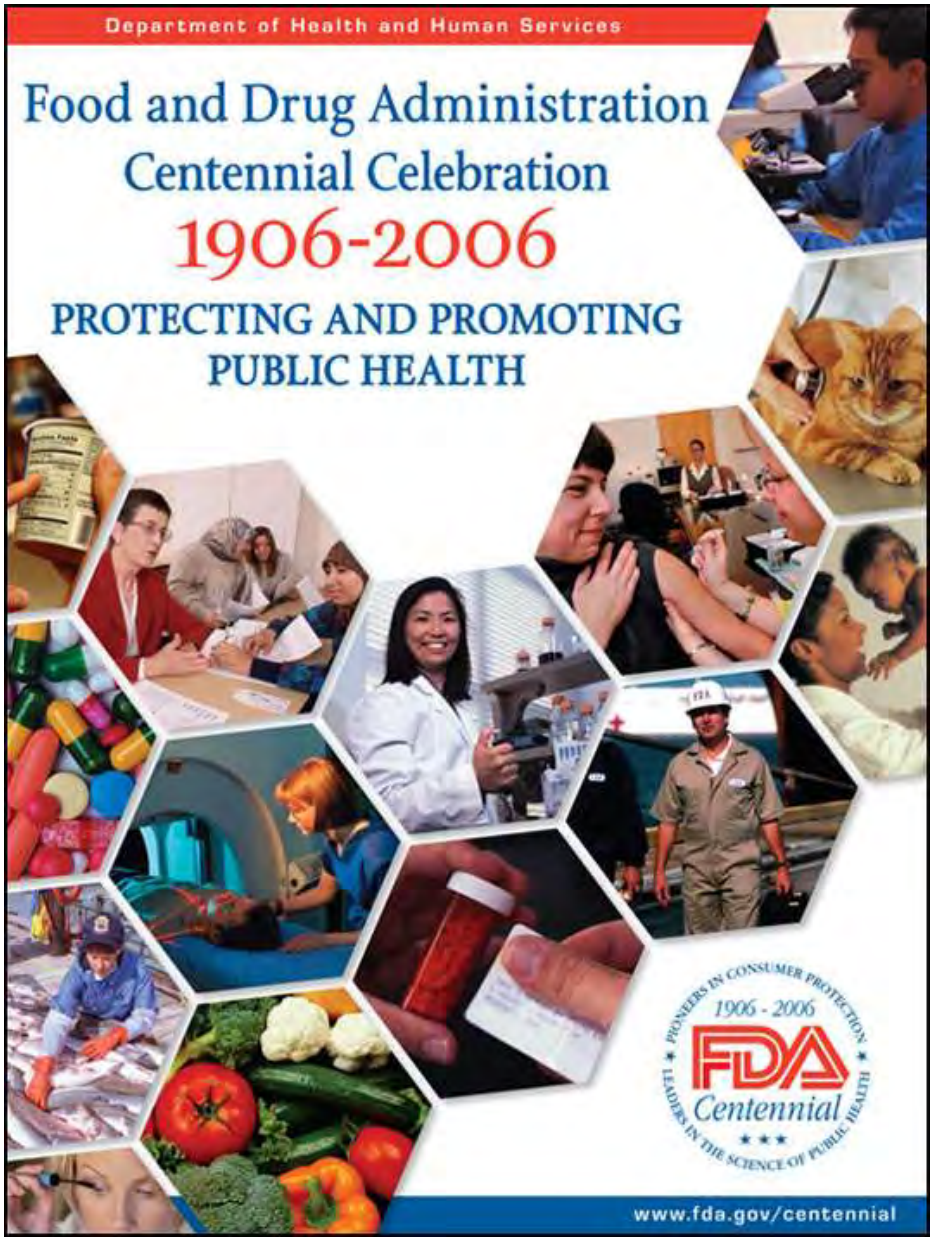
Regulatory Framework

A Comparative Analysis of the Regulatory Framework Affecting Functional Food Development and Commercialization in Canada, Japan, the European Union and the United States of America

Barry L. Smith
Michelle Marcotte
Gordon Harrison

March 31, 1996

Celebrating 100 Years of Public Service



The name and address of the manufacturer, packer, or distributor

The common or usual product name

Approved nutrient claims if the product meets specified criteria

The net contents in weight, measure, or count

Approved health claims stated in terms of the total diet

© Wadsworth – Thomson Learning

Nutrition Facts

Serving size	3/4 cup (28 g)
Servings per container	14
Amount per serving	
Calories 110	Calories from fat 9
	% Daily Value*
Total Fat 1 g	2%
Saturated fat 0 g	0%
Trans fat 0 g	
Cholesterol 0 mg	0%
Sodium 250 mg	10%
Total Carbohydrate 23 g	8%
Dietary fiber 1.5 g	6%
Sugars 10 g	
Protein 3 g	

Vitamin A 25% • Vitamin C 25% • Calcium 2% • Iron 25%

*Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2000	2500
Total fat	Less than	65 g	80 g
Sat fat	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2400 mg	2400 mg
Total Carbohydrate		300 g	375 g
Fiber		25 g	30 g

Calories per gram
Fat 9 • Carbohydrate 4 • Protein 4

INGREDIENTS, listed in descending order of predominance: Corn, Sugar, Salt, Malt flavoring, freshness preserved by BHT. **VITAMINS and MINERALS:** Vitamin C (Sodium ascorbate), Niacinamide, Iron, Vitamin B_6 (Pyridoxine hydrochloride), Vitamin B_2 (Riboflavin), Vitamin A (Palmitate), Vitamin B_1 (Thiamin hydrochloride), Folic acid, and Vitamin D

The serving size and number of servings per container

kCalorie information and quantities of nutrients per serving, in actual amounts

Quantities of nutrients as "% Daily Values" based on a 2000-kcalorie energy intake

Daily Values reminder for selected nutrients for a 2000- and a 2500-kcalorie diet

kCalorie per gram reminder

The ingredients in descending order of predominance by weight

FF regulations in USA

Three types of claims allowed in USA

Type of claims for food and supplements	Law
Health Claims	Nutrition Labeling & Education Act (NLEA)
	Food and Drug Administration Modernization Act (FDAMA)
Structural & Functional Claims	Dietary Supplements Health Education Act (DSHEA)
Nutritional Claims	(NLEA) (FDAMA)

12 Health Claims allowed under NLEA in USA

Compound	Hillness	Requirements
Calcium	Osteoporosis	• the product must have a high content in Ca • the content in P cannot be higher than that of Ca
Sodium	Hypertension	• the product must have a low content in Na
Fat	Cancer	• the product must have a low content in fat
Saturated fat & cholesterol	Cardiovascular diseases	• the product must have a low content in fat • the product must have a low content in cholesterol
Cereals containing fibers, Fruits & vegetables	Cancer	• the product must have a low content in fat • the product must represent a good source of fibers
Fruits & vegetables	Cardiovascular diseases	• the product must contain 0.6 g fibers / serving

12 Health Claims allowed under NLEA in USA

Compound	Hillness	Requirements
Folate	Neural tube anomalies	• 40 µg /400 µg servings
Fruits & vegetables	Cancer	• Should represent a good source of Vit-A and C, low fat and high fibers
Polyalcools sugars	Tooth decay	• Should contain no sugar • Should not decrease saliva Ph under 5.7
Fibers in Oats and Psyllium	Cancer	• Should contain a least 0,75 g soluble fibres / serving
Soya protein	Cardiovascular diseases	• The products should have low content in Fat and have low cholesterol
Phytostanols & phytosterols	Cardiovascular diseases	• the product must contain 0.6 g phytosterol / serv. or 1.7 g phytostanols / serv.

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Calcium and Osteoporosis**
  - "regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life."
  - reduced fat milk, fortified orange juice

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Sodium and hypertension**
  - "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors"
  - unsalted tuna, salmon, low-fat milks, cereal, pastas, sherbets

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Dietary fat and cancer**
  - "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers"
  - fruits, vegetables, reduced-fat milk, cereals, pastas, flours

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Saturated fat & cholesterol and coronary heart disease**
  - "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease"
  - fruits and vegetables, skim milk, cereals, whole grain products, pastas

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Fiber and cancer**
  - "Low-fat diets rich in fiber may reduce the risk of some types of cancer, a disease associated with many factors"
  - whole grain breads and cereals, fruits, vegetables

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Fiber and coronary heart disease**
  - "Diets low in saturated fat and cholesterol that include 3 g of soluble fiber from whole oats per day may reduce the risk of heart disease"
  - oatmeal cookies, muffins, oat bran

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Folate and neural tube birth defects**
  - "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect"
  - enriched cereal grain products, dried beans, peas, oranges, grapefruit, berries, fortified breakfast cereals

Health Claims: Characterize the Relationship of a Nutrient to a Disease

- **Dietary sugar alcohol and dental cavities**
  - "Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in this food do not promote tooth decay"
  - sugarless candy and gum

Health Claims Study

Advertising
Nutrition & Health
Evidence from Food Advertising
1977 - 1997

Pauline M. Ippolito
Janis K. Pappalardo

BUREAU OF ECONOMICS STAFF REPORT
FEDERAL TRADE COMMISSION
Washington, D. C. 20580
September 2002

PURPOSE

- Test effect of regulatory environment on health claims in advertising
- Review of magazine advertising from 1977 to 1997
- 11.647 ads analyzed

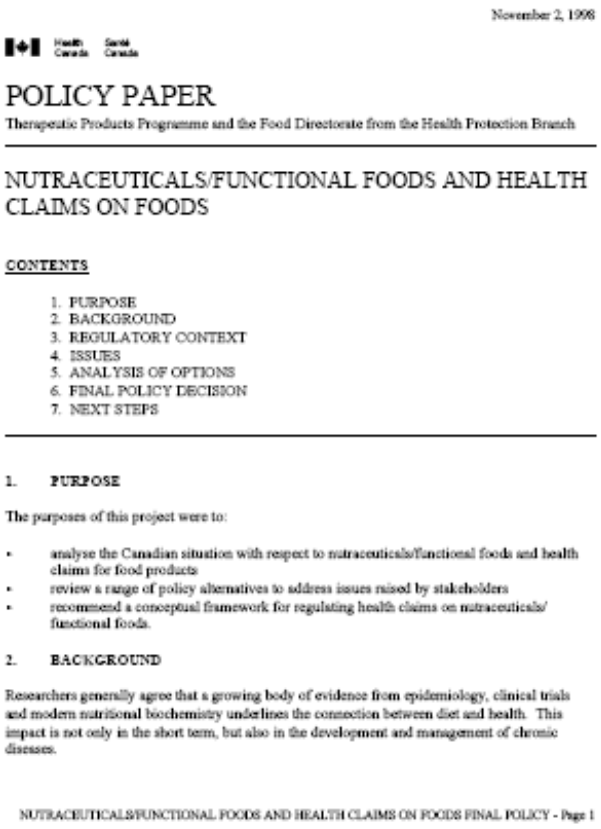
Qualified Health Claims Subject to Enforcement Discretion

1. **Qualified Claims About Cancer Risk**
   - Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers
   - Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps
   - Green Tea & Cancer
   - Selenium & Cancer
   - Antioxidant Vitamins & Cancer
2. **Qualified Claims About Cardiovascular Disease Risk**
   - Nuts & Heart Disease
   - Walnuts & Heart Disease
   - Omega-3 Fatty Acids & Coronary Heart Disease
   - B Vitamins & Vascular Disease
   - Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease
   - Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
   - Corn Oil & Heart Disease
3. **Qualified Claims About Cognitive Function**
   - Phosphatidylserine & Cognitive Dysfunction and Dementia
4. **Qualified Claims About Diabetes**
   - Chromium Picolinate & Diabetes
5. **Qualified Claims About Hypertension**
   - Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia
6. **Qualified Claims About Neural Tube Birth Defects**
   - 0.8 mg Folic Acid & Neural Tube Birth Defects

Health Canada Santé Canada

Canada

Health Canada



November 2, 1998

Health Canada Santé Canada

POLICY PAPER

Therapeutic Products Programme and the Food Directorate from the Health Protection Branch

NUTRACEUTICALS/FUNCTIONAL FOODS AND HEALTH CLAIMS ON FOODS

CONTENTS

1. PURPOSE
2. BACKGROUND
3. REGULATORY CONTEXT
4. ISSUES
5. ANALYSIS OF OPTIONS
6. FINAL POLICY DECISION
7. NEXT STEPS

1. PURPOSE

The purposes of this project were to:

- analyse the Canadian situation with respect to nutraceuticals/functional foods and health claims for food products
- review a range of policy alternatives to address issues raised by stakeholders
- recommend a conceptual framework for regulating health claims on nutraceuticals/ functional foods.

2. BACKGROUND

Researchers generally agree that a growing body of evidence from epidemiology, clinical trials and modern nutritional biochemistry underlines the connection between diet and health. This impact is not only in the short term, but also in the development and management of chronic diseases.

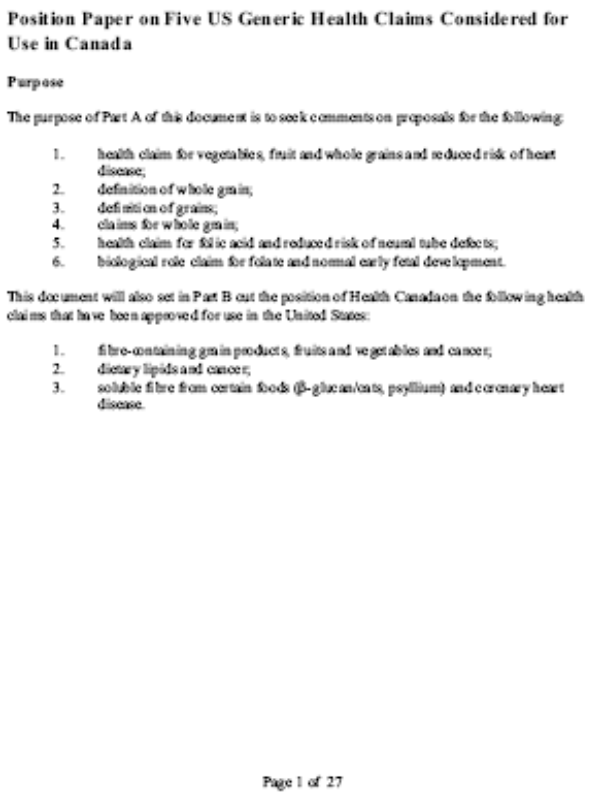
NUTRACEUTICALS/FUNCTIONAL FOODS AND HEALTH CLAIMS ON FOODS FINAL POLICY - Page 1

POLICY PAPER

Therapeutic Products Programme and the Food Directorate from the Health Protection Branch

NUTRACEUTICALS/ FUNCTIONAL FOODS AND HEALTH CLAIMS ON FOODS

Health Canada



Position Paper on Five US Generic Health Claims Considered for Use in Canada

Purpose

The purpose of Part A of this document is to seek comments on proposals for the following:

1. health claim for vegetables, fruit and whole grains and reduced risk of heart disease;
2. definition of whole grain;
3. definition of grains;
4. claims for whole grain;
5. health claim for folic acid and reduced risk of neural tube defects;
6. biological role claim for folate and normal early fetal development.

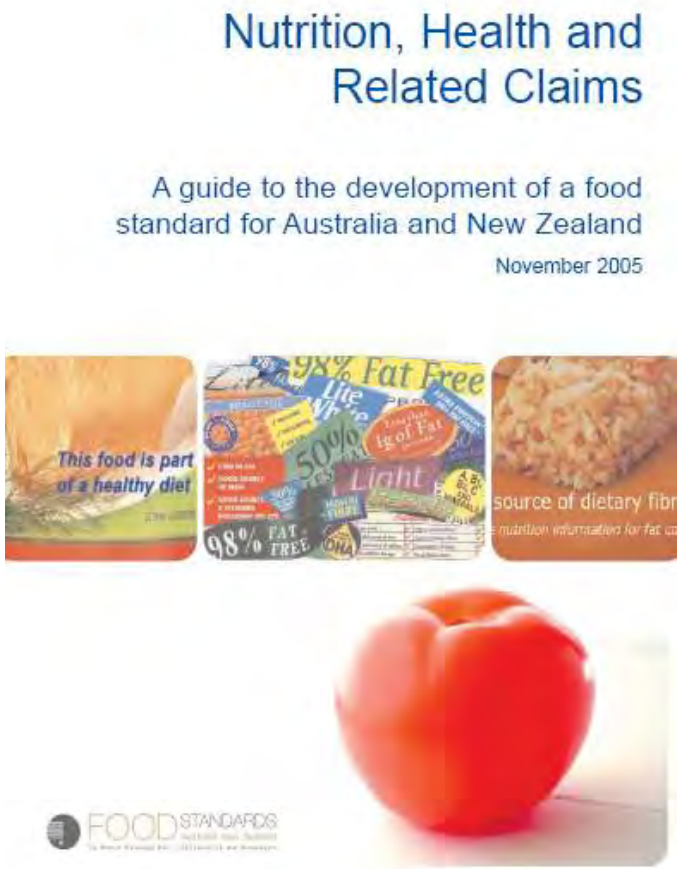
This document will also set in Part B out the position of Health Canada on the following health claims that have been approved for use in the United States:

1. fibre-containing grain products, fruits and vegetables and cancer;
2. dietary lipids and cancer;
3. soluble fibre from certain foods (β-glucan/oats, psyllium) and coronary heart disease.

Page 1 of 27

- Health Canada recently reviewed the scientific support for four health claims that address the relationship between the following:
  - fruits, vegetables and grain products that contain fibre, particularly soluble fibre and coronary heart disease;
  - fibre-containing grain products, fruits and vegetables and cancer;
  - dietary lipids and cancer;
  - folate and neural tube defects.

Food Standards Australia New Zealand (FSANZ)



ATTACHMENT 7

SUMMARY OF SUBMISSIONS

Introduction

In total, FSANZ received 147 submissions to the Initial Assessment Report of Proposal P293 – Nutrition, Health and Related Claims. Table 7.1 in Appendix 1 to this attachment illustrates the spread of submissions across stakeholder groups and between Australia and New Zealand. Table 7.2 in Appendix 2 to this Attachment provides a list of these submitters' names.

The following provides a brief summary of the main responses that were received in answer to each question that was asked in the Initial Assessment Report. Further detail on submitters' comments will be available on the FSANZ website at a later date.

Note: The following answers and percentage calculations relate to the number of submitters who directly responded to the particular question.

Issue: Advantages and disadvantages of Regulatory Option 1 (*Status quo*)
Question
What do you think are the advantages and disadvantages of Option 1?

About 25% of submitters (20) believed Option 1 was invalid. Reasons related to its inconsistency with the Policy Guidelines. Another 25% stated that there were no advantages for this option. However, others noted advantages relating to protection of public health and safety and the prevention of false or misleading health claims to consumers. Others stated there would be no costs associated with substantiation, enforcement, monitoring, evaluation of health claims, or changes in domestic product labelling. Some noted Option 1 would bring the least disruption to all businesses. With regard to disadvantages, 25% stated that CoPoNC was not readily enforceable or legally binding. Some noted non-compliance issues. Other submitters noted disadvantages relating to consumer/public safety, imports or international trends.

Issue: Advantages and disadvantages of Regulatory Option 2 (Standard & Guideline)
Question
What do you think are the advantages and disadvantages of Option 2?

Nearly 30% of submitters (21) stated that Option 2 was either consistent with the Policy Guideline or allowed for development of a framework for health claims. Advantages related to consumer/public health and safety (e.g. more information made available to consumers leading to more informed food choices), enforcement and compliance (e.g. high level claims being included in a standard that is legally enforceable). Other advantages included less costs to government, a level playing field for claims, an impetus for product innovation, and greater flexibility (e.g. guidelines easier and faster to amend than a standard). However, 25% of submitters stated a disadvantage was that guidelines are not enforceable or as easy to enforce. Other disadvantages were about non-compliance, consumer protection and confusion among manufacturers.

Dietary fruit and vegetable intake and risk of coronary heart disease

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa


Food Standards Australia New Zealand
Diet-Disease Relationship Review
Dietary fruit and vegetable intake and risk of coronary heart disease

Report Prepared by
Ms Elisabeth Winkler (Research Officer)
Associate Professor Carla Patterson
Professor Beth Newman
School of Public Health
Queensland University of Technology

July 2006

Overall, the available research points to a convincing level of evidence for a relationship between a diet rich in vegetables and/or fruits and reduced risk of CHD, which is sufficiently consistent and substantial to underpin policy recommendations.

The relationship between dietary calcium intake, alone or in association with Vitamin D status, and risk of developing osteoporosis

Food Standards Australia New Zealand

Diet-Disease Relationship Review

The Relationship Between Dietary Calcium Intake, Alone or in Association With Vitamin D Status, and Risk of Developing Osteoporosis

Prof Ian R Reid MD, FRSNZ

Department of Medicine, University of Auckland, New Zealand

Correspondence to:
Prof IR Reid
Department of Medicine
University of Auckland
Private Bag 92019
Auckland
New Zealand

Tel: (+64 9) 3737 599 extn 86259
Fax: (+64 9) 3677 146
email: i.reid@auckland.ac.nz

The available data are convincing with respect to the anti-fracture efficacy of calcium/vitamin D combinations in the frail elderly, particularly in women.

The available data are convincing with respect to the positive effects of calcium supplementation on bone density across a broad age range, particularly in women.

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

The relationship between dietary sodium intake, alone or in combination with potassium intake, and risk of hypertension in adults

"Moderation in intake of sodium may reduce the risk of high blood pressure, a condition associated with many factors including overweight, excessive alcohol consumption, inadequate intake of dietary potassium, and inactivity".

The relationship between saturated and trans unsaturated fatty acids and LDL-cholesterol and coronary heart disease

The relationship between saturated and *trans* unsaturated fatty acids and LDL-cholesterol and coronary heart disease

A review undertaken for Food Standards Australia New Zealand

Chris Booker, BSc(Hons)

Jim Mann, CNZM, FRSNZ

Edgar National Centre for Diabetes Research,
Departments of Medicine and Human Nutrition,
University of Otago, New Zealand

This issue may not have direct bearing on health claims suggesting the cardiovascular benefits of reducing saturated and trans fatty acids, but is of considerable relevance when considering the implementation of such advice.

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

The relationship between dietary folate intake of women of childbearing age and risk of neural tube defects

The relationship between dietary folate intake of women of child-bearing age and risk of neural tube defects in the foetus.

Diet-disease relationship review

Tim Green

Elias Green

18 Montague Street

Dunedin, NZ

A report prepared for:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610

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The strength of evidence indicating that natural folate is protective against NTDs is possible at best.

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Aotearoa me Aotearoa

Food for Specified Health Uses (FOSHU)

厚生労働省

厚生労働省

Specified Health Uses	Principal Ingredients (ingredients exhibiting health functions)
Foods to modify gastrointestinal conditions	Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber 8 ingestible dextrin, polydextrol, guar gum, psyllium seed coat, etc.)
Foods related to blood cholesterol level	Chitosan, soybean protein, degraded sodium alginate
Foods related to blood sugar levels	Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.
Foods related to blood pressure	Lactotripeptide, casein dodecaneptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.

厚生労働省

Specified Health Uses	Principal Ingredients (ingredients exhibiting health functions)
Foods related to dental hygiene	Paratinose, maltitiose, erythrytol, etc.
Cholesterol plus gastrointestinal conditions, triacylglycerol plus cholesterol	Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.
Foods related to mineral absorption	Calcium citrated malate, casein phosphopeptide, hem iron, fracuto-oligosaccharide, etc.
Foods related to osteogenesis	Soybeen isoflavone, MBP (Milk basic protein), etc.
Foods related to triacylglycerol	Middle chain fatty acid, etc.

厚生労働省

CARBOHYDRATES

polydextrose
indigestible dextrin
galacto oligosaccharides
lactulose
lactosucrose
isomalto oligosaccharides
maltitol
palatinose
soybean oligosaccharides
fructo oligosaccharides
xylo oligosaccharides
wheat bran

PROTEINS

casein phospho peptide
casein dodeca peptide
soy protein

MINERALS

phosphorus
calcium as citrate
malate
heme iron

OTHER

rice globulin
eucommia leaf glycoside
lactobacillus GG

厚生労働省

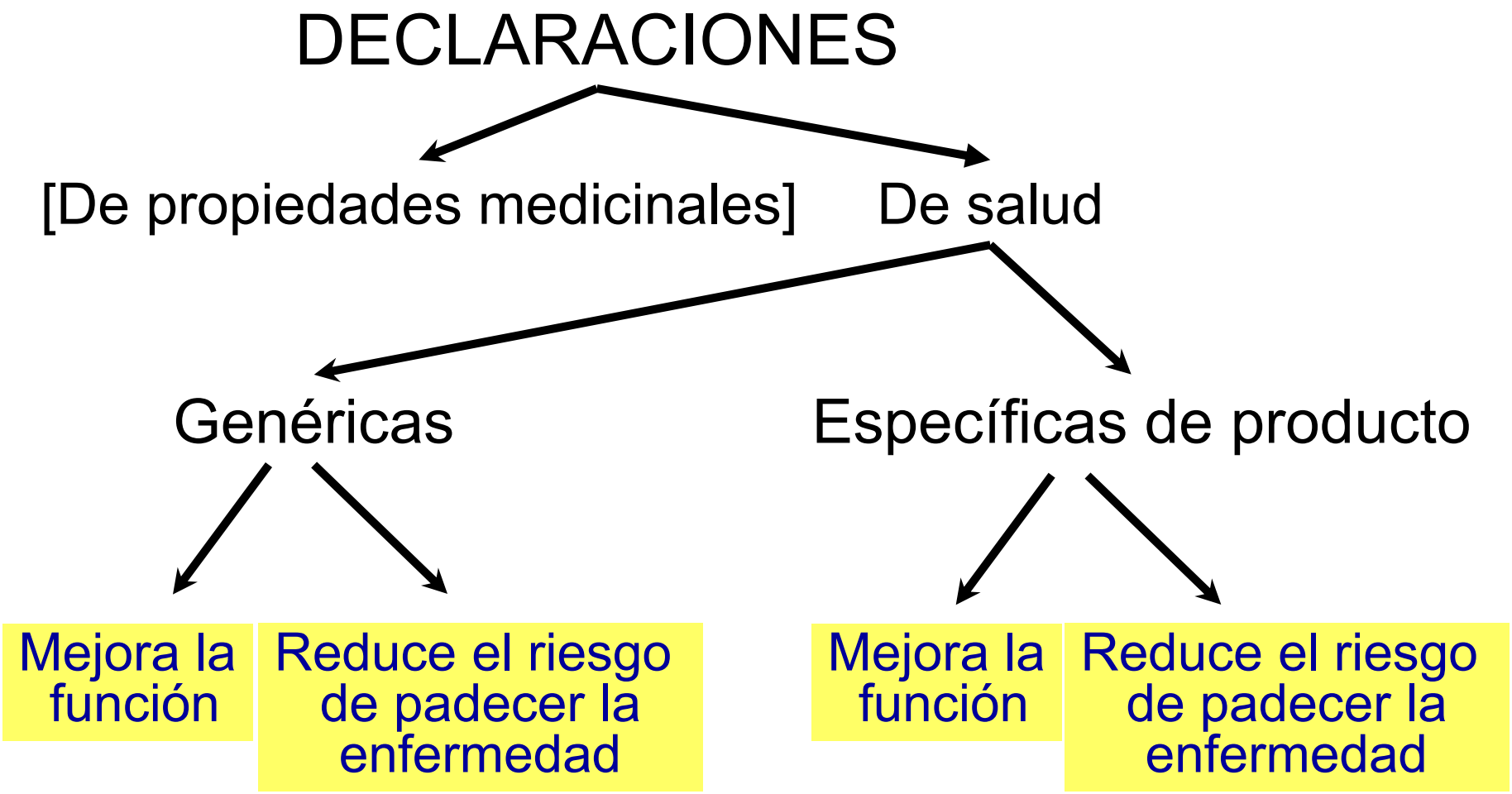
Food or ingredient with FOSHU status	Number of approved products
rice globulin	
phosphorus	
xylo oligosaccharides	3 products
calcium as citrate malate	3 products
fructo oligosaccharides	10 products
soybean oligosaccharides	8 products
palatinose	4 products
maltitol	3 products
isomalto oligosaccharides	2 products
soy protein	5 products
wheat bran	
lactosucrose	15 products
casein dodeca peptide	
casein phospho peptide	2 products
lactulose	

厚生労働省

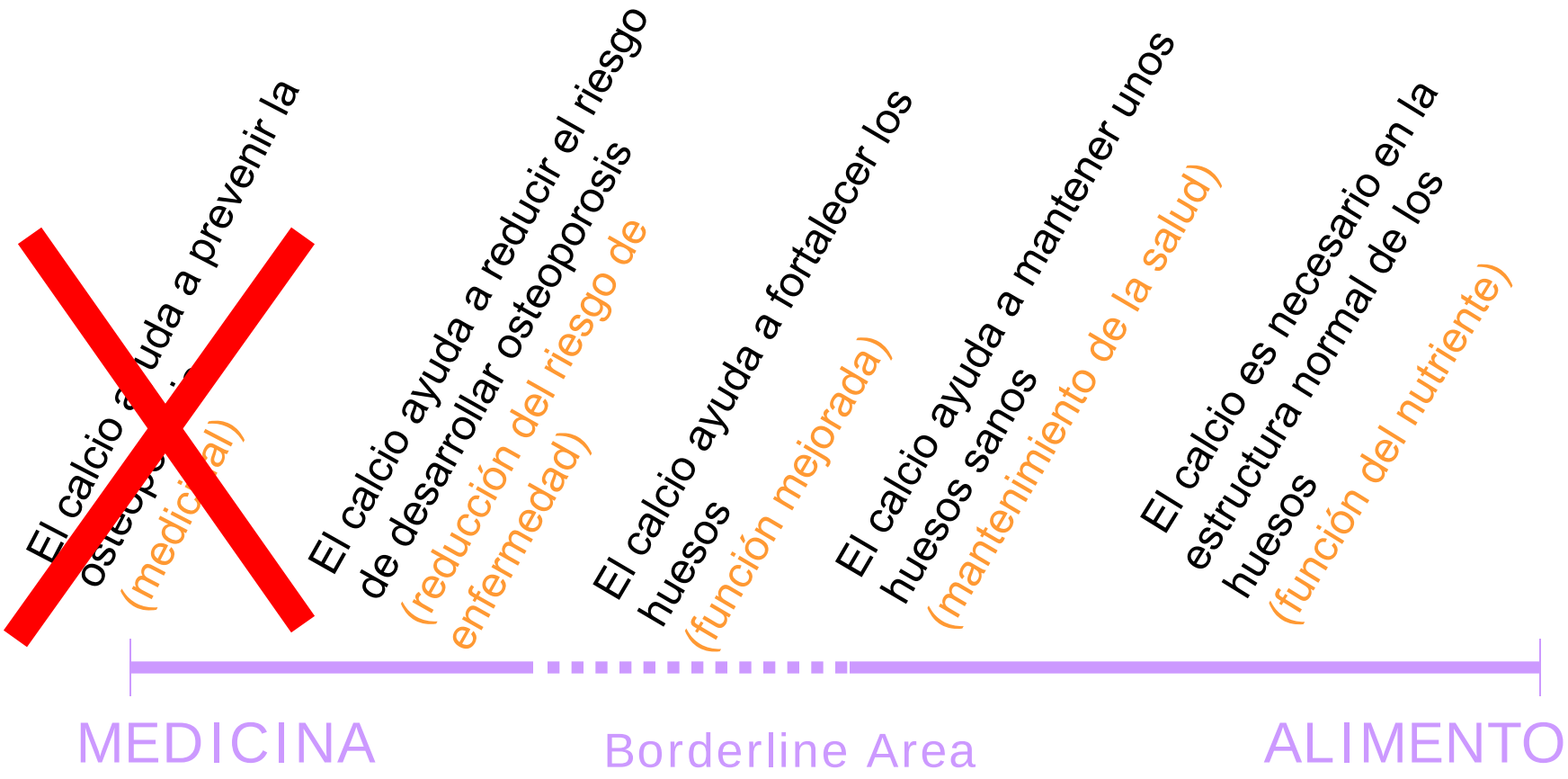
Food or ingredient with FOSHU status	Number of approved products
galacto oligosaccharides	
citosan	3 products
indigestible dextrin	4 products
polydextrose	3 products
partially hydolyzed guar gum	
green tea polyphenols	3 products
ertthritol	
heme iron	
lactobacillus gg	
eucommia leaf glycoside	

¿Cuáles son los pasos que debemos seguir para proceder a sustanciar un claim?

Clasificación esquemática de declaraciones para alimentos funcionales



Tipos de declaraciones



PASSCLAIM

Process for the Assessment of Scientific Support for Claims on Foods

A European Commission Concerted Action
Coordinated by ILSI-Europe
Duration of the Project: April 2001 - April 2005

Background

Food can provide us with much more than energy and nutrients for growth and metabolism. Good food enhances normal function and thereby improves quality of life. Food also plays an important role in preventing disease. Rather than having adequate nutrition, we should now aim for optimal nutrition.

This new concept of optimal nutrition has stimulated the food industry to produce functional foods – that is foods which benefit an individual beyond the normal provision of energy and nutrients.

Following on from the development of functional foods has come the need to be able to claim their ability to enhance physiological and psychological functions and to reduce disease risk.

Against this background the EU agreed in 1996 to fund a Concerted Action entitled "Functional Food Science in Europe (FUFOSE)" with the aim "to develop and establish a science based approach for the emerging concepts in functional food development". FUFOSE, in its final consensus document (*Brit.J.Nutr.* 1999 81 Suppl 1) concluded that the development of functional foods must be based on sound scientific knowledge of the target function of the body and show that the effects are relevant to improved health or reduction of disease risk. It identified the development of "validated markers for these target functions and the evaluation of sound scientific data from human studies for their possible modulation by foods and food components" as an important part of the validation process.

PASSCLAIM, an EU funded, ILSI Europe initiated Concerted Action commenced in April 2001 and built on these FUFOSE principles.

The principal objectives of PASSCLAIM are:

- To produce a generic tool with principles for assessing the scientific support for health-related claims for foods and food components
- To evaluate critically the existing schemes which assess the scientific substantiation of claims
- To select common criteria for how markers should be identified, validated and used in well-designed studies to explore the links between diet and health

Outline of the project

- A network of 53 academics, regulatory experts and representatives from public interest groups and industry across Europe has been set up.
- A Steering Committee oversees the work of the Concerted Action
- Eight Individual Theme Groups (ITGs) have been established, comprising members of the network, and are tasked with:
  - collating current and potential claims and describing scientific principles needed to support these claims
  - developing criteria to substantiate claims and basic science support
  - assessing the utility and validity of biomarkers to support claims.

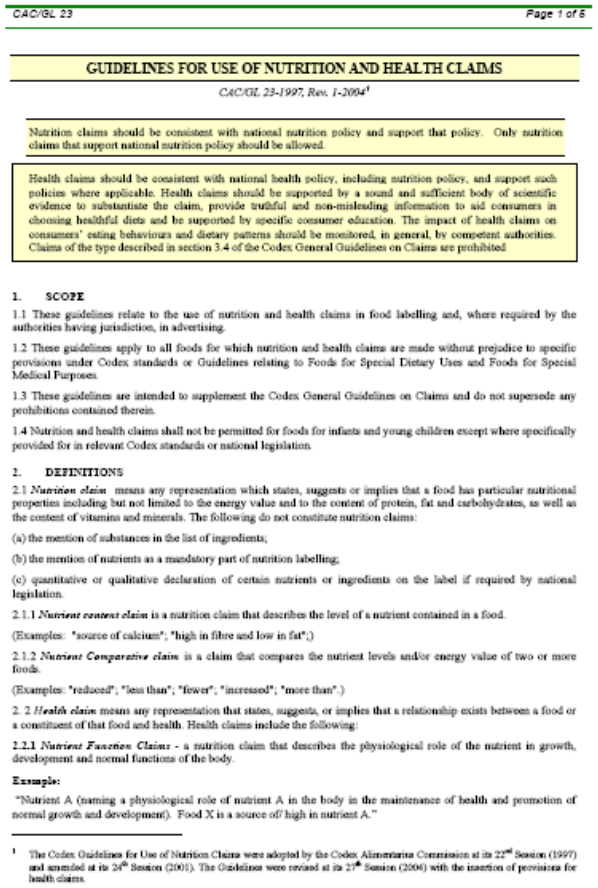
The topics for the ITGs are

ITG A - Diet-related cardiovascular disease
ITG B - Bone health and osteoporosis
ITG C - Physical performance and fitness
ITG D - Review of existing processes
ITG E - Insulin sensitivity and diabetes risk
ITG F - Diet-related cancer
ITG G - Mental state and performance
ITG H - Gut health and immunity

- ITGs A-D have met on three occasions and produced four papers*
- On the basis of these papers, the Steering Committee has drawn up a Draft Set of Interim Criteria for the Scientific Substantiation of Claims on Foods
- The draft criteria were discussed by all members of the network, invited delegates from 20 countries and representatives from ILSI Japan, ILSI North America and ILSI Southeast Asia Region at the first Plenary Meeting in Berlin in September 2002

* *These papers, together with the Report of the First Plenary Meeting will be published in the European Journal of Nutrition early in 2003*

Codex Alimentarius



CAC/GL 23 Page 1 of 6

GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

CAC/GL 23-1997, Rev. 1-2004[1]

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited.

1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising.

1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.

1.3 These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibitions contained therein.

1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

2. DEFINITIONS

2.1 ***Nutrition claim*** means any representation which states, suggests or implies that a food has 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 minerals. The following do not constitute nutrition claims:

(a) the mention of substances in the list of ingredients;

(b) the mention of nutrients as a mandatory part of nutrition labelling;

(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

2.1.1 ***Nutrient content claim*** is a nutrition claim that describes the level of a nutrient contained in a food.

(Examples: "source of calcium"; "high in fibre and low in fat";)

2.1.2 ***Nutrient Comparative claim*** is a claim that compares the nutrient levels and/or energy value of two or more foods.

(Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

2. 2 ***Health claim*** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

2.2.1 ***Nutrient Function Claims*** - a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

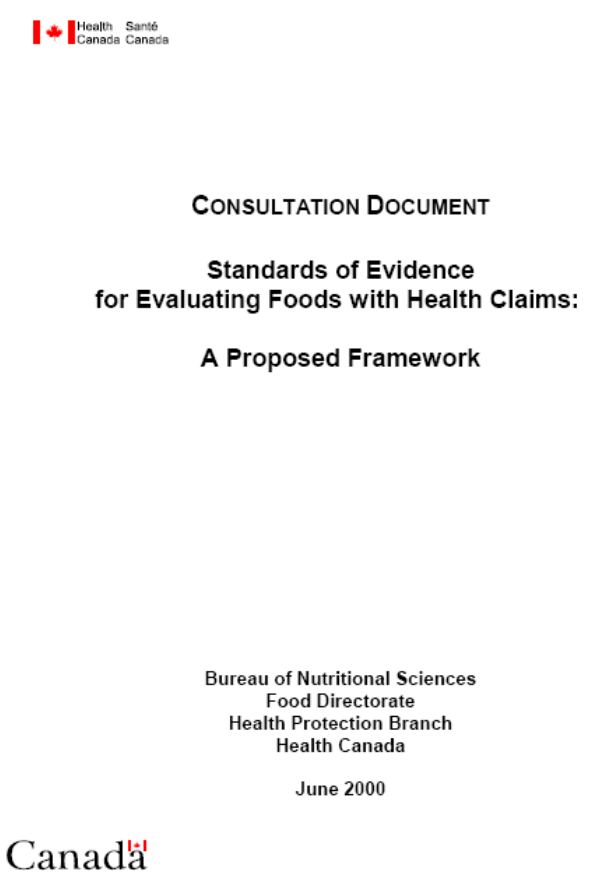
Example:

"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

[1] The Codex Guidelines for Use of Nutrition Claims were adopted by the Codex Alimentarius Commission at its 22nd Session (1997) and amended at its 24th Session (2001). The Guidelines were revised at its 27th Session (2004) with the insertion of provisions for health claims.

- *7.1.1 <u>Health claims must be based on current relevant scientific substantiation</u> and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.*

Health Canada



- *With growing consumer awareness of the potential benefits of nutraceuticals/ functional foods, there is a growing need for solid information. Information is required to better inform health professionals and the public about these products to explain what these products can and can not do for them.*

Joint Health Claims Initiative

JHCI

Joint Health Claims Initiative

JHCI/21/02

Guidelines for Preparing Dossiers to Substantiate Health Claims

February 2002

- *The Code indicates that a health claim should be based on the studies in humans which are the most methodologically sound. In general experimental studies in humans are more useful when substantiating a claim than observational studies. This is because experimental studies are less susceptible to bias than observational studies i.e. the researcher can be more sure that any observed effect is attributable to the proposed cause and not to other factors.*

Swedish Nutrition Foundation

Health Claims in the Labelling and Marketing of Food Products
The Food Industry's Rules (Self-Regulating Programme)

c/o SNF Swedish Nutrition Foundation
Ideon Research Park • SE-223 70 Lund • Sweden
Phone + 46 46 286 22 82 • Fax + 46 46 286 22 81
susanne.bryngelsson@snf.ideon.se
www.snf.ideon.se

Health Claims in the Labelling and Marketing of Food Products

Since 1990 a Swedish Code of Practice has existed: *"Health Claims in the Labelling and Marketing of Food Products"*: The Food Industry's Rules (Self-Regulating Programme), henceforth referred to as the Code. The Code was first revised in 1997 and extended to include product specific physiological claims (PFP) in 2001. The extended Code also include the Assessment Board for Diet-Health Information (BKH), henceforth referred to as the Board (BKH). A second revision of the code as well as an evaluation of the extended Code will take place during 2004.

Health claims

Nutrient function claims. Generic claims where a nutrition claim, e.g. a nutrient content claim, is connected to a generally accepted nutritional-physiological function. Examples and criterias will be included in the revised version.

Generic disease risk reduction claims. Generic claims related to well-established diet and health relationships. Originally eight connections were included: 1) *Obesity* – energy content, 2) *Cholesterol level in the blood* – fat quality/some soluble dietary fibre, 3) *Blood pressure* – salt (NaCl), 4) *Atherosclerosis* – factors affecting blood cholesterol level/blood pressure (see above) and omega-3 fatty acids in fat fish and fish products, 5) *Constipation* – dietary fibre, 6) *Osteoporosis* – calcium, 7) *Caries* – absence of easily fermented carbohydrates, 8) *Iron deficiency* – iron content. Recently, a ninth connection was included: 9) *(Coronary) heart disease - whole grain*.

Generic disease risk reduction claims may be used for all products that fulfil certain criteria regarding composition and importance for the diet. Documentation concerning the effects of the food product itself is therefore not needed for these kinds of claims.

Product-specific physiological claims (PFP). Claims related to a specific physiological effect of the product itself. Independent experts evaluate the scientific documentation supporting the effects of the food product before the product is put on the market with a product-specific physiological claim.

Applicability

The food products referred to in the Code should be *part of a normal diet* and not dietary supplements or other substances in the form of capsules, tablets, dragées, powders or the like.

Scientific documentation

Product-specific physiological claims must be based on studies that are scientifically sound and unobjectionable, showing the effects that are claimed. *The studies must be performed on human beings*, and the study group must be representative of the group of people that the marketing is aimed to reach. Furthermore, the studies must be performed with a supply relating to the normal use of the food product during the study period, and must be long enough to show a lasting effect.

Evaluation of the Scientific documentation

Evaluation of scientific documentation has been possible since 1 September 2001. *SNF Swedish Nutrition Foundation* has an *advisory role* defined in the Code and administrates the evaluation. Application forms for scientific evaluation can be obtained from SNF (susanne.bryngelsson@snf.ideon.se), SNF's website *(www.snf.ideon.se)* or the website of the Code *(hp-info.nu*, in Swedish).

Within 4 working weeks after receiving the application and after informing the Applicant, the Research Committee of SNF will appoint a panel of at least three experts. Normally the evaluation will be completed within 90 days after the experts have received the documentation. The evaluation will consider the scientific documentation in relation to the type of claim the Applicant wishes to make – not the exact wording of the claim. The process is strictly confidential but the report will become public as soon as the product is put on the market with a product-specific physiological claim. In labelling and marketing it is permitted to state that the product has undergone evaluation of the scientific documentation by using a certain logotype *(see hp-info.nu)*. The evaluation process is described in detail in a separate document that can be obtained from SNF.

The amount of necessary studies will be decided from case to case, depending on how well-established the physiological effect is considered to be.

The responsible organisations

The responsible organisations behind the Code are The *Swedish Food Federation (LI)* and *The Swedish Grocery Federation*.

Assessment Board for Diet-Health Information (BKH)

The Board (BKH) was established on 23 November 2001, and is independent of SNF.

The Board (BKH) will *deal with complaints* as to whether a particular marketing and labelling action complies with the Code. After giving the marketer an opportunity to explain and to justify the marketing, the Board (BKH) will decide whether the complaint is to be upheld or not. The statements from the Board (BKH) must be made in writing and are public. The Board (BKH) consists of a chairman, a vice-chairman and a secretary, all lawyers with a good knowledge of marketing laws. Six Board members represent the responsible organisations, two represent medical and nutritional expertise and two members represent public interest, especially consumer interest. Besides this, nine deputy members have the right to attend the meetings.

Additional information concerning the Board (BKH):
BKH, Dalenum 29, 181 70 Lidingö, Sweden
Phone: +46 8 636 22 30, Fax: +46 8 636 22 39
E-mail: brink@brilex.se

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- *Product-specific physiological claims must be based on studies that are scientifically sound and unobjectionable, showing the effects that are claimed. The studies must be performed on human beings, and the study group must be representative of the group of people that the marketing is aimed to reach. Furthermore, the studies must be performed with a supply relating to the normal use of the food product during the study period, and must be long enough to show a lasting effect.*

Food & Drug Administration

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals
December 22, 1999

Guidance for Industry
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements

Comments and suggestions regarding this document should be submitted by February 22, 2000, to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number 99D-5424.

For questions concerning the content of the document contact Sharon Ross at 202-205-4168.

Additional copies of this guidance document are available upon written request from the Office of Special Nutritionals (HFS-450), Food and Drug Administration, 200 C Street SW, Washington, DC 20204, by calling 202-205-4168, by faxing a request to 202-205-5295, or from the Internet at http://www.cfsan.fda.gov/~dms/guidance.html#hh.

U. S. Department of Health and Human Services
Food and Drug Administration

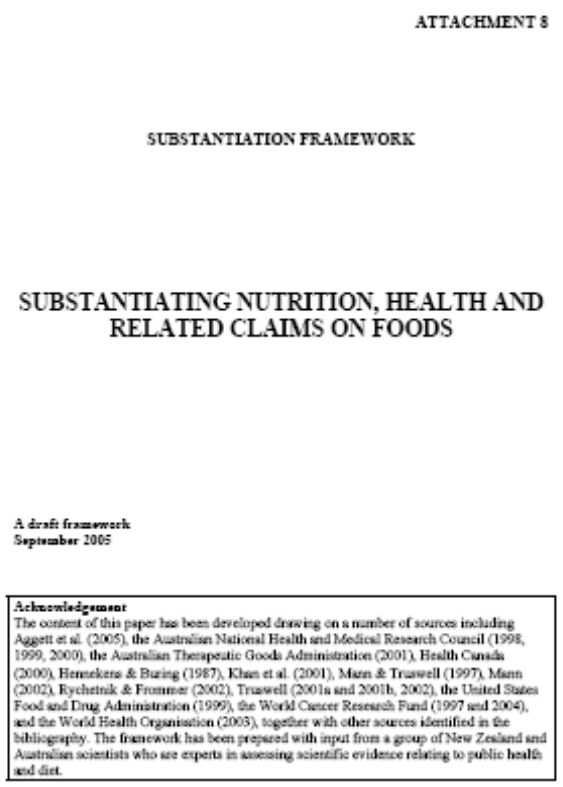
- *An evidence-based rating system is a science-based systematic evaluation of the strength of the evidence behind a statement. In the case of health claims, it would rate the strength of the evidence behind a proposed substance/disease relationship.*

Health Council of the Netherlands

Foods and dietary supplements with health claims

- *A claim should always be based on scientific research involving <u>human subjects</u> and use of the <u>substance in the form it is found</u> in the food or dietary supplement for which the claim is made.*

Food Standards Australia New Zealand



ATTACHMENT 8

SUBSTANTIATION FRAMEWORK

SUBSTANTIATING NUTRITION, HEALTH AND RELATED CLAIMS ON FOODS

A draft framework
September 2005

Acknowledgement
The content of this paper has been developed drawing on a number of sources including Aggett et al. (2005), the Australian National Health and Medical Research Council (1998, 1999, 2000), the Australian Therapeutic Goods Administration (2001), Health Canada (2000), Hennekens & Buring (1987), Khan et al. (2001), Mann & Truswell (1997), Mann (2002), Rychetnik & Frommer (2002), Truswell (2001a and 2001b, 2002), the United States Food and Drug Administration (1999), the World Cancer Research Fund (1997 and 2004), and the World Health Organisation (2003), together with other sources identified in the bibliography. The framework has been prepared with input from a group of New Zealand and Australian scientists who are experts in assessing scientific evidence relating to public health and diet.

- *All nutrition and health claims on food will have to be <u>scientifically substantiated</u>.*

Agence Française de Sécurité Sanitaire des Aliments

Afssa – Saisine n° 2006-SA-0182

Maisons-Alfort, le 10 janvier 2007

AVIS

de l'Agence française de sécurité sanitaire des aliments relatif aux lignes directrices pour la constitution et l'évaluation de dossiers portant sur les allégations nutritionnelles et de santé revendiquées pour les denrées alimentaires

Dans l'attente du vote définitif du règlement européen sur les allégations nutritionnelles et de sa mise en application, l'Agence française de sécurité sanitaire des aliments (Afssa) s'est auto-saisie le 18 novembre 2004 d'une demande d'élaboration de lignes directrices pour la constitution et l'évaluation de dossiers portant sur les allégations nutritionnelles et de santé revendiquées pour les denrées alimentaires.

Après consultation du Comité d'experts spécialisé (CES) « Nutrition humaine » réuni les 25 janvier et 23 mars 2006, l'Afssa rend l'avis suivant :

L'objectif de ce document est double :
contribuer à l'homogénéisation et la cohérence de l'évaluation des allégations nutritionnelles et de santé par les experts du CES « Nutrition humaine »,
proposer un guide aux industriels pour la constitution de dossiers en vue de l'évaluation des allégations nutritionnelles et de santé.

Les présentes lignes directrices répertorient un ensemble des critères jugés pertinents par les experts du CES « Nutrition humaine » pour l'évaluation des allégations. Ils sont regroupés en 4 grands thèmes :

- les critères d'exclusion définitive de l'allégation,
- l'évaluation du produit portant l'allégation,
- l'évaluation de l'allégation
  - données établissant un lien entre le nutriment et l'effet revendiqué
  - pertinence en termes de santé publique
- la formulation de l'allégation et sa compréhension par le consommateur.

De l'intégration de l'ensemble de ces critères dépend l'avis définitif rendu quant à la justification scientifique de l'allégation.

Des lignes directrices sont en phase avec des documents antérieurs émis au niveau européen (Howlett & Shortt 2004 ; Conseil de l'Europe 2001).
Elles viennent compléter celles relatives à la constitution de dossiers industriels soumis au Comité d'experts « Nutrition humaine » (Avis Afssa du 19 avril 2001) et doivent être uniquement considérées comme un outil d'aide à la démonstration et à l'expertise scientifiques. En effet, elles présentent les principales questions que soulève la justification scientifique d'une allégation et constituent le support de l'évaluation des allégations par les experts.
Ce guide constitue donc un repère auquel l'industriel pourra se référer, chaque fois que nécessaire, de manière à s'assurer que le dossier soumis intègre les éléments jugés indispensables à l'évaluation. Il est amené à s'enrichir compte tenu des discussions nationales et européennes actuelles dans le cadre de la mise en place de la future réglementation communautaire en matière d'allégations.

Enfin, ces lignes directrices générales ne remettent pas en cause les recommandations spécifiques de l'Afssa en matière d'évaluation de certaines catégories de produits : notamment, les produits portant des allégations et destinés aux enfants de moins de 3 ans (Avis Afssa du 26 avril 2006), produits contenant des pro- ou pré-biotiques et portant des allégations relative à la flore et l'immunité chez le sujet adulte (Rapport Afssa, février 2006), produits à base de plantes (Rapport Afssa, février 2003), produits contenant des acides gras oméga 3 et portant des allégations relatives au système cardiovasculaire (Rapport Afssa, juillet 2003).

1/6

- *Analyse de la bibliographie. Plausibilité biologique : <u>Concordance avec les expérimentations animales et in vitro</u> (mécanistiques).*

Principales aspectos para sustentar las declaraciones de salud de los alimentos funcionales

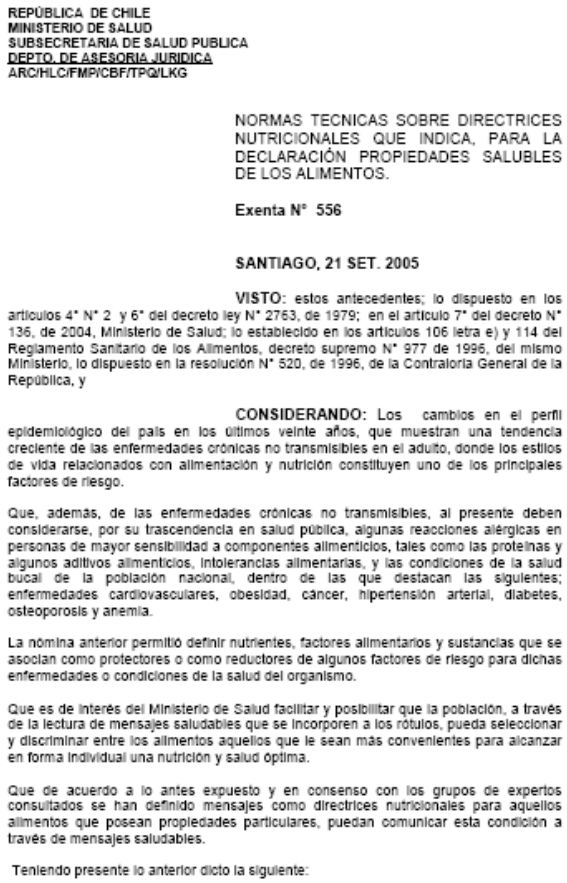
- Naturaleza alimentaria del alimento funcional.
- El nutriente objeto de la declaración está contenido en el producto final (en la cantidad del producto que cabe razonablemente esperar que se consuma) en una cantidad significativa y en una forma asimilable por el organismo.
- Las declaraciones de propiedades saludables harán referencia a los alimentos listos para su consumo de conformidad con las instrucciones del fabricante.
- La demostración de sus efectos debe satisfacer las exigencias de la comunidad científica.
- Debe producir efectos beneficiosos sobre las funciones orgánicas, además de sus efectos nutricionales intrínsecos, apropiados para mejorar la salud y el bienestar, reducir el riesgo de enfermedad o ambas cosas.
- Deben consumirse como parte de un régimen normal.
- El consumidor medio deberá comprender los efectos benéficos tal como se expresan en la declaración.

La situación en América Latina

Agência Nacional de Vigilância Sanitária

- *Evidências científicas aplicáveis, conforme o caso, à comprovação da alegação de propriedade funcional e ou de saúde: ensaios nutricionais e ou fisiológicos e ou toxicológicos em animais de experimentação; ensaios bioquímicos; estudos epidemiológicos; ensaios clínicos; comprovação de uso tradicional, observado na população, sem danos à saúde; evidências abrangentes da literatura científica, organismos internacionais de saúde e legislação internacionalmente reconhecida sobre as propriedades e características do produto.*

Ministerio de Salud de Chile



REPÚBLICA DE CHILE
MINISTERIO DE SALUD
SUBSECRETARIA DE SALUD PUBLICA
DEPTO. DE ASESORIA JURIDICA
ARC/HLC/FMP/CBF/TPQ/LKG

NORMAS TECNICAS SOBRE DIRECTRICES NUTRICIONALES QUE INDICA, PARA LA DECLARACIÓN PROPIEDADES SALUBLES DE LOS ALIMENTOS.

Exenta N° 556

SANTIAGO, 21 SET. 2005

VISTO: estos antecedentes; lo dispuesto en los artículos 4° N° 2 y 6° del decreto ley N° 2763, de 1979; en el artículo 7° del decreto N° 136, de 2004, Ministerio de Salud; lo establecido en los artículos 106 letra e) y 114 del Reglamento Sanitario de los Alimentos, decreto supremo N° 977 de 1996, del mismo Ministerio, lo dispuesto en la resolución N° 520, de 1996, de la Contraloría General de la República, y

CONSIDERANDO: Los cambios en el perfil epidemiológico del país en los últimos veinte años, que muestran una tendencia creciente de las enfermedades crónicas no transmisibles en el adulto, donde los estilos de vida relacionados con alimentación y nutrición constituyen uno de los principales factores de riesgo.

Que, además, de las enfermedades crónicas no transmisibles, al presente deben considerarse, por su trascendencia en salud pública, algunas reacciones alérgicas en personas de mayor sensibilidad a componentes alimenticios, tales como las proteínas y algunos aditivos alimenticios, intolerancias alimentarias, y las condiciones de la salud bucal de la población nacional, dentro de las que destacan las siguientes; enfermedades cardiovasculares, obesidad, cáncer, hipertensión arterial, diabetes, osteoporosis y anemia.

La nómina anterior permitió definir nutrientes, factores alimentarios y sustancias que se asocian como protectores o como reductores de algunos factores de riesgo para dichas enfermedades o condiciones de la salud del organismo.

Que es de interés del Ministerio de Salud facilitar y posibilitar que la población, a través de la lectura de mensajes saludables que se incorporen a los rótulos, pueda seleccionar y discriminar entre los alimentos aquellos que le sean más convenientes para alcanzar en forma individual una nutrición y salud óptima.

Que de acuerdo a lo antes expuesto y en consenso con los grupos de expertos consultados se han definido mensajes como directrices nutricionales para aquellos alimentos que posean propiedades particulares, puedan comunicar esta condición a través de mensajes saludables.

Teniendo presente lo anterior dicto la siguiente:

- *República de Chile. Exenta Nº 556 de 21 de septiembre de 2005 sobre normas técnicas sobre directrices nutricionales que indica para la declaración de propiedades saludables de los alimentos.*

Comisión Federal para la Protección contra Riesgos Sanitarios

CRITERIOS PARA LA ELABORACION DE LAS DECLARACIONES DE PROPIEDADES NUTRIMENTALES Y SALUDABLES EN LOS ALIMENTOS Y BEBIDAS NO ALCOHOLICAS

CONSIDERANDO

La principal función de la dieta es aportar los nutrimentos necesarios para satisfacer las necesidades nutricionales de las personas. De tal forma que los alimentos por sí mismos tienen efectos benéficos en el organismo, gracias al aporte de los nutrimentos básicos.

Actualmente, la investigación científica se ha centrado principalmente en la identificación de componentes biológicamente activos que, al estar o incorporarse en los alimentos o bebidas no alcohólicas, ofrezcan la posibilidad de favorecer ciertas condiciones físicas y/o mentales, así como de reducir el riesgo de padecer enfermedades, ya que se ha resaltado la importancia de que algunos alimentos convencionales, como las frutas, las verduras, la soya, los granos enteros y la leche, entre otros, contienen componentes que pueden resultar en beneficios para ciertas condiciones ya sean fisiológicas o metabólicas y en algunos casos, beneficios superiores al aporte nutrimental asociado con dichos componentes.

El avance de la ciencia y la tecnología en los últimos años ha permitido conocer más y mejor la relación entre la dieta humana y la salud. Este conocimiento junto con la innovación de alimentos, permite proporcionar al cuerpo humano sustancias que faciliten u orienten hacia un mejor balance nutrimental y dietético que coadyuve en el desarrollo físico y la posible reducción de riesgos a la salud. Así, en los últimos años se ha observado que los individuos modifican sus hábitos alimentarios y buscan productos innovadores que satisfagan sus necesidades personales.

Los alimentos deben consumirse en una dieta completa, suficiente, variada y equilibrada para contribuir a mejorar, mantener o alcanzar un estado nutricional apropiado y por tanto, contribuir a la salud de los individuos de la sociedad mexicana. Las propiedades de los alimentos y sus efectos en la fisiología humana deben estar sustentados en evidencia científica sólida que acredite dichos beneficios en el desarrollo del cuerpo humano y la posible reducción de riesgos a la salud, así como las condiciones en las que permitan prevenir enfermedades y consecuentemente, contribuir a una mejor calidad de vida. Es responsabilidad de los fabricantes que los alimentos que produzcan sean seguros y correspondan a las características con las que los promueven.

Aunado a lo anterior, debe considerarse el interés de los consumidores por conocer la relación que existe entre la dieta y la salud. Hoy en día, la gente reconoce en mayor medida, que llevar un estilo de vida sano, incluida la dieta en combinación con actividad física regular, puede contribuir a reducir el riesgo de padecer enfermedades y dolencias, y a mantener el estado de salud y bienestar.

En consecuencia, actualmente se comercializan productos que declaran que su consumo tiene efectos en la salud y bienestar de las personas. Desafortunadamente, los datos que podrían contribuir a informar adecuadamente al consumidor ya sea en la etiqueta o publicidad no son siempre claros. El derecho a estar informado se consolida y se actualiza con el fortalecimiento de la libertad de decidir en los sistemas de libre mercado y dentro de las sociedades democráticas como la nuestra. El consumidor debe disponer de datos veraces y comprobables, exentos de artificios que engañen o induzcan al error sobre las propiedades de los ingredientes de los alimentos, es decir, que para que los alimentos puedan aportar todos los beneficios

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- *Toda declaración de propiedades saludables en los alimentos y bebidas debe contar con el respaldo científico que apoye el beneficio en cuestión.*

Ministerio de Protección Social de Colombia

Por la cual se adopta el reglamento técnico sobre requisitos de rotulado o etiquetado nutricional que deben cumplir los alimentos envasados para consumo humano

EL MINISTRO DE LA PROTECCIÓN SOCIAL

En ejercicio de sus atribuciones legales, en especial las conferidas por las Leyes 09 de 1979 y 170 de 1994, Decreto 205 de 2003 y

C O N S I D E R A N D O:

Que mediante la Ley 170 de 1994, Colombia adhirió al Acuerdo de la Organización Mundial del Comercio, el cual contiene, entre otros, el Acuerdo sobre Obstáculos Técnicos al Comercio

Que el Decreto 1112 de 1996, crea el Sistema Nacional de Información sobre Medidas de Normalización y Procedimientos de Evaluación de la Conformidad y dicta normas para armonizar la expedición de reglamentos técnicos.

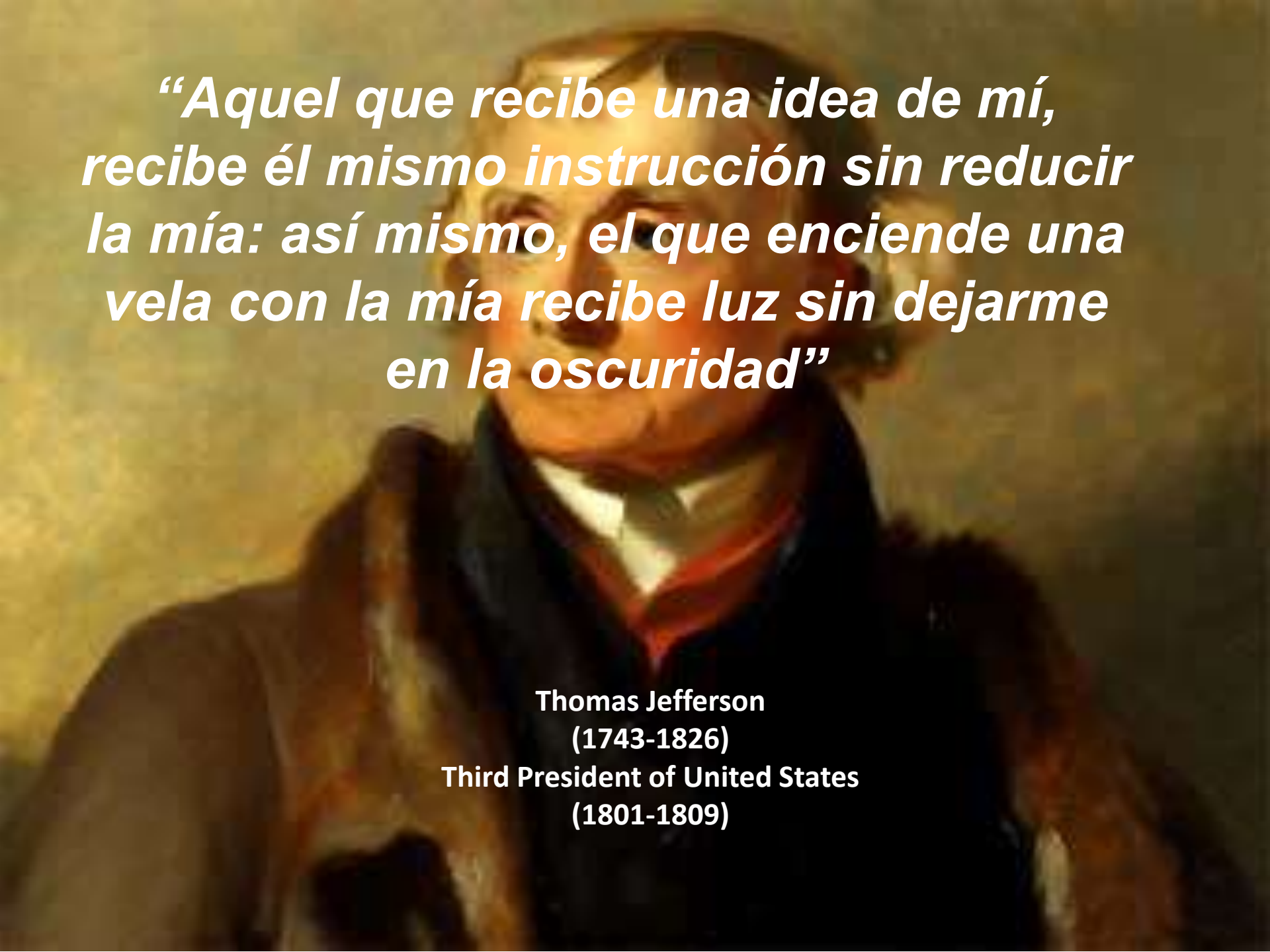
Que la Superintendencia de Industria y Comercio, mediante Resolución 03742 de 2001 señaló los criterios y condiciones que deben cumplirse para la expedición de un Reglamento Técnico de carácter obligatorio, cuyo propósito sea el de establecer las características de un producto, servicio o los procesos y métodos de producción.

Que en mérito de lo expuesto,

R E S U E L V E:

TITULO I

- *Reglamento técnico sobre requisitos de rotulado o etiquetado nutricional que deben cumplir los alimentos envasados para consumo humano.*


“Aquel que recibe una idea de mí, recibe él mismo instrucción sin reducir la mía: así mismo, el que enciende una vela con la mía recibe luz sin dejarme en la oscuridad”
Thomas Jefferson
(1743-1826)
Third President of United States
(1801-1809)