"Regulación de Health Claims en Europa"

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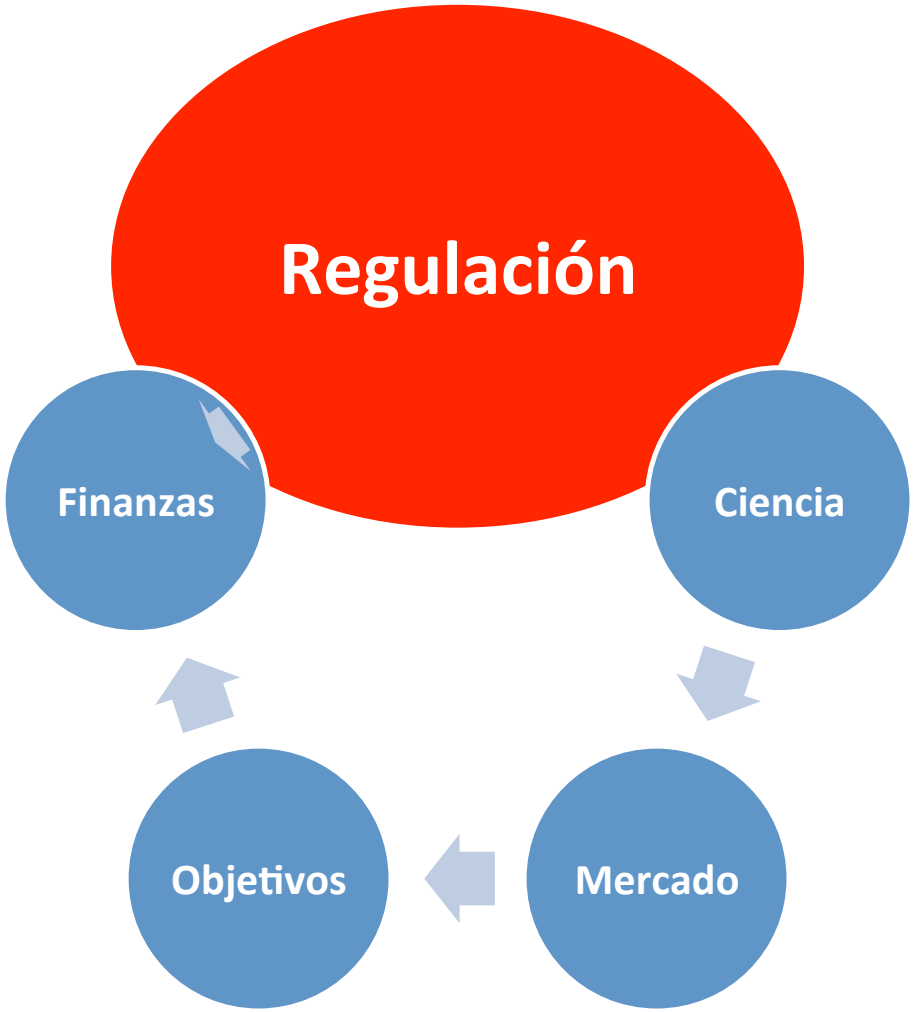
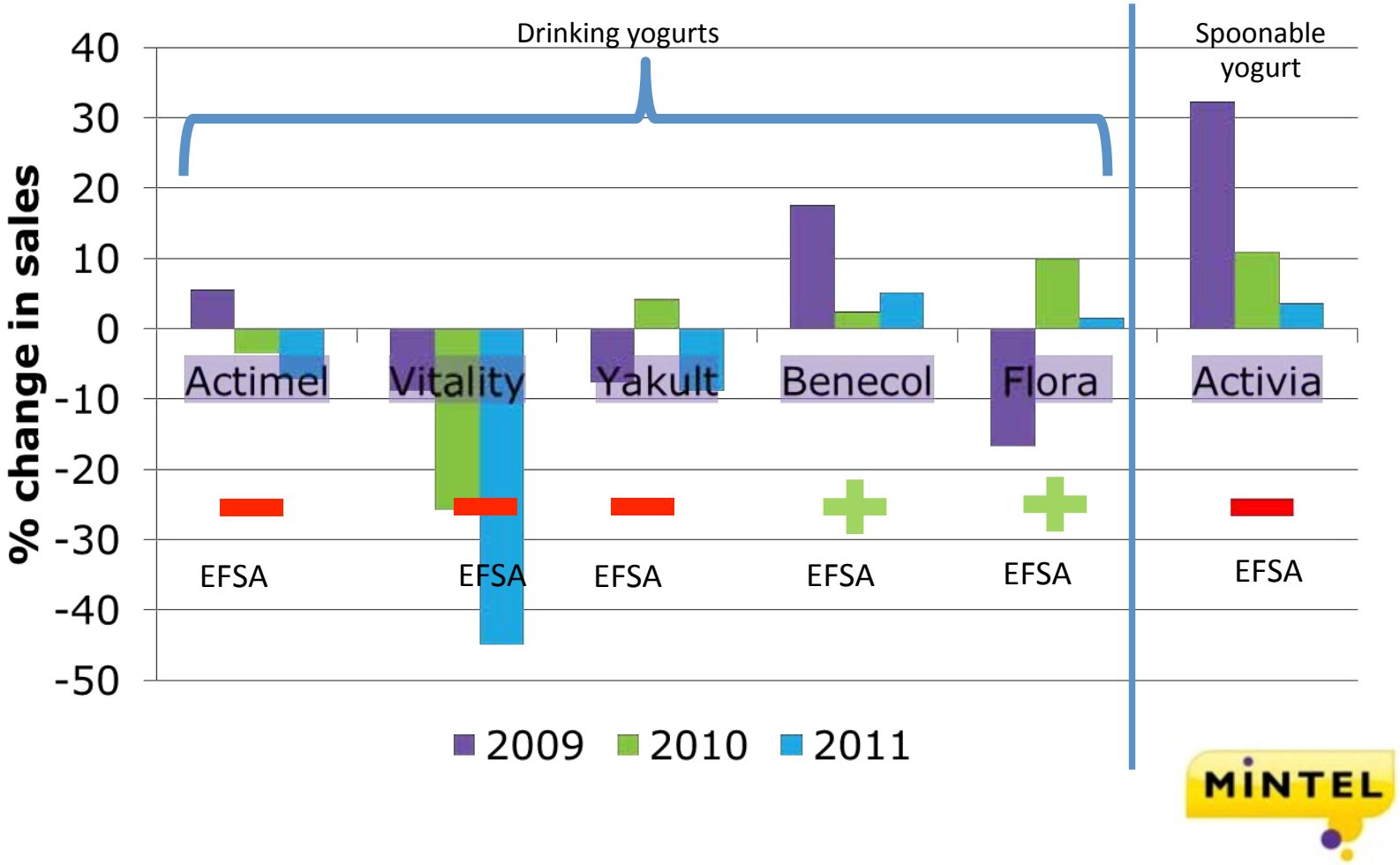
Qué hacer para vender más?

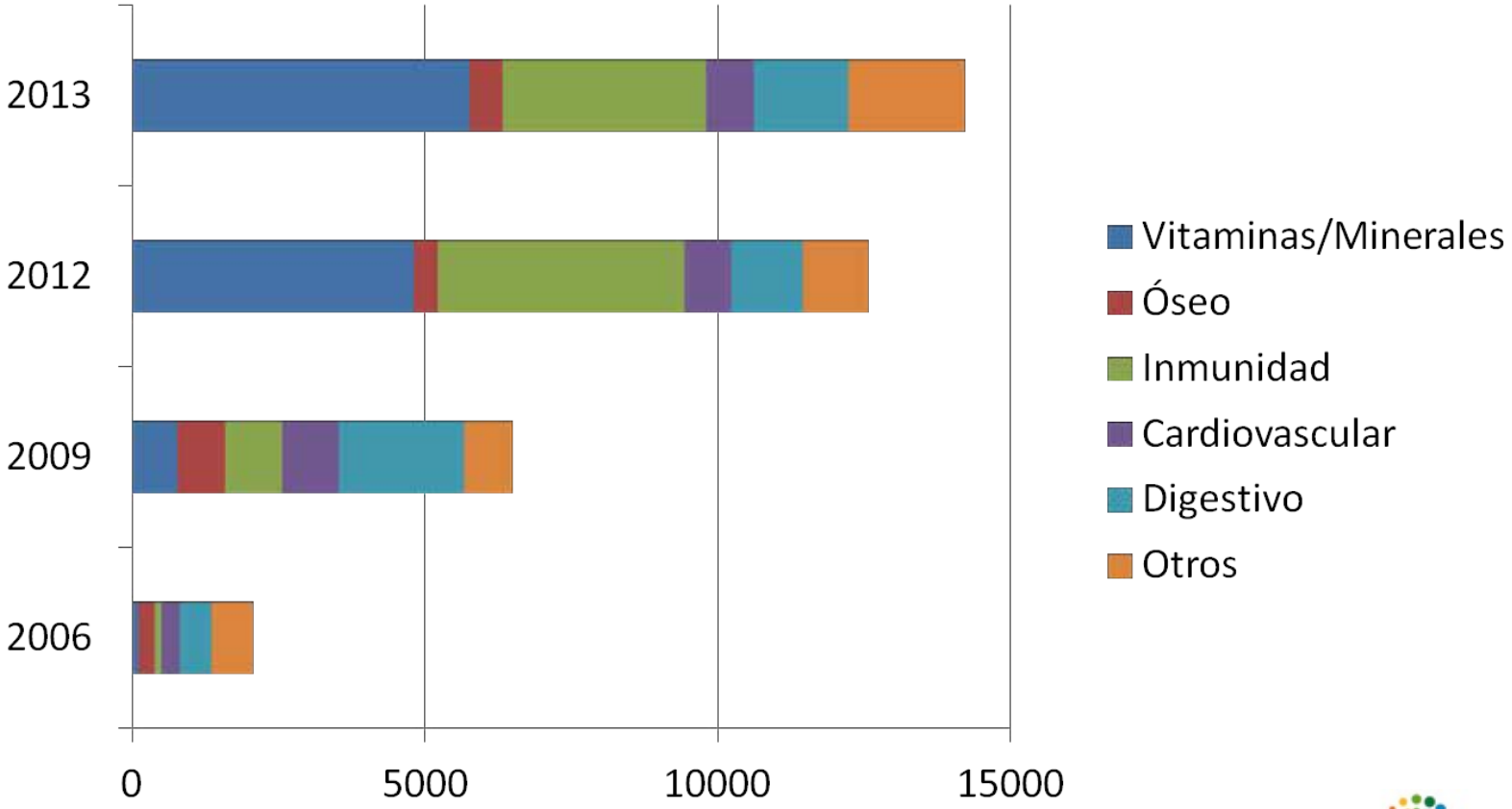
PERO la regulación se convierte en el punto clave de los nuevos lanzamientos



Does claims failure / success have an effect on sales performance?

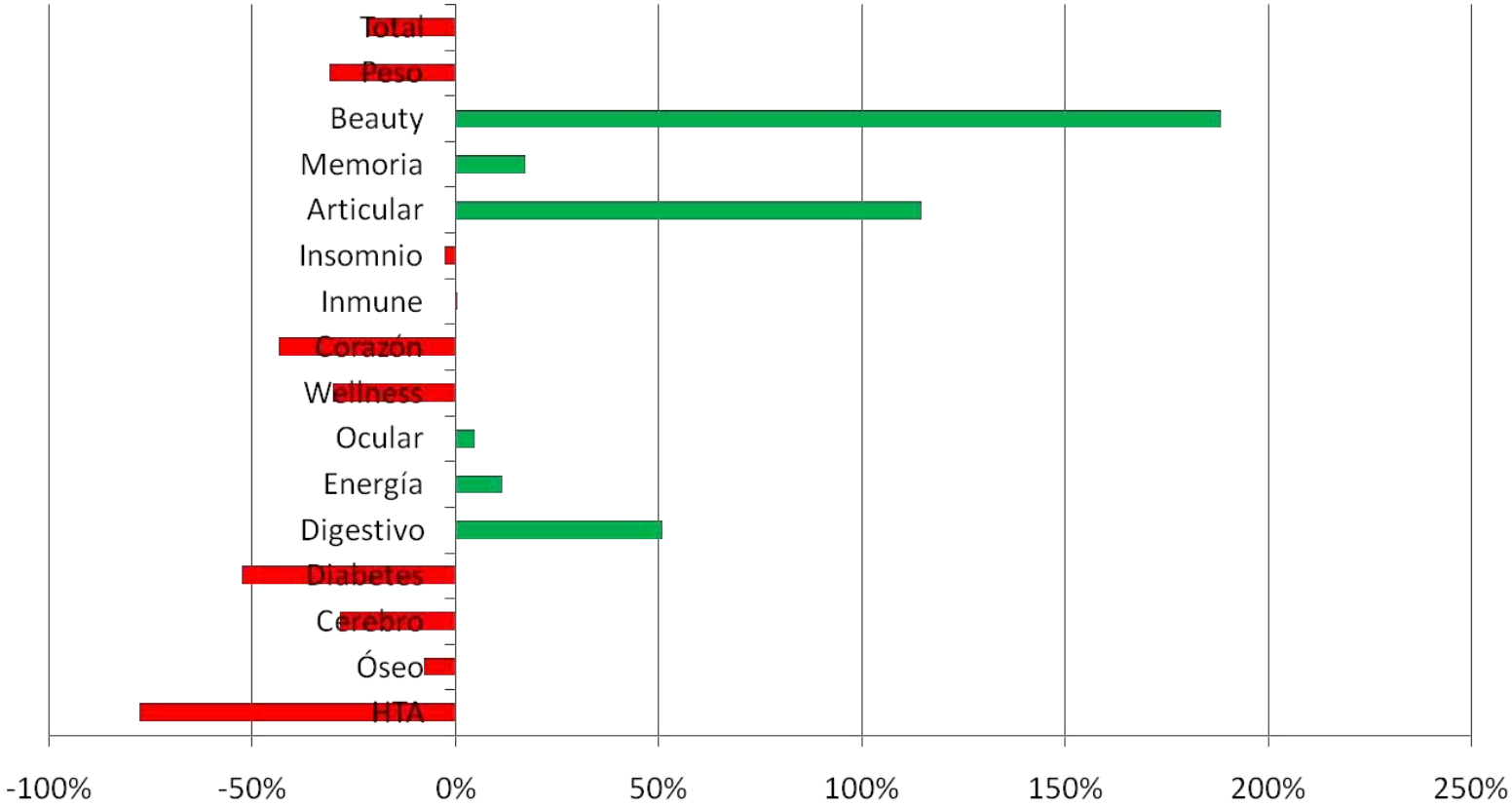


y la regulación modifica los lanzamientos



INNOVA MARKET INSIGHTS

Evolución de las declaraciones de salud en los 3 últimos años



INNOVA MARKET INSIGHTS

La regulación alimentaria cada vez se parece más a la farmacéutica

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

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

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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 elijan 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 dietéticos 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 beneficas 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 beneficas 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 9 de diciembre de 2005 (DO C 80 E de 4.4.2006, p. 43) y Posición del Parlamento Europeo de 14 de mayo 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.

Objetivos del Reglamento

PARA EL CONSUMIDOR:

Información veraz: Todo lo declarado avalado científicamente.

Información completa: Permita elegir con libertad.

Información clara: Comprensible para el consumidor medio.

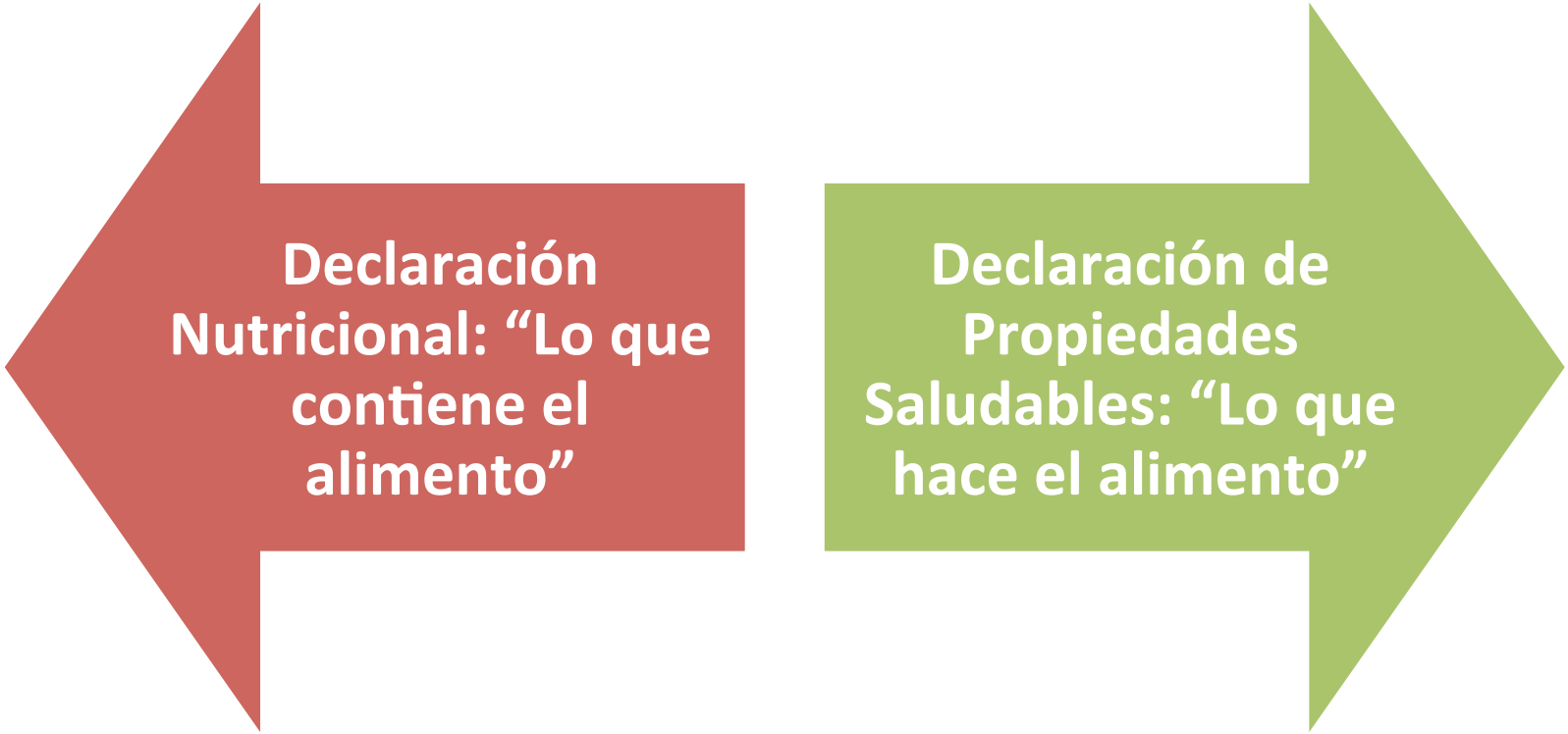
PARA LA INDUSTRIA:

Orientar/Potenciar la inversión en I+D+i.

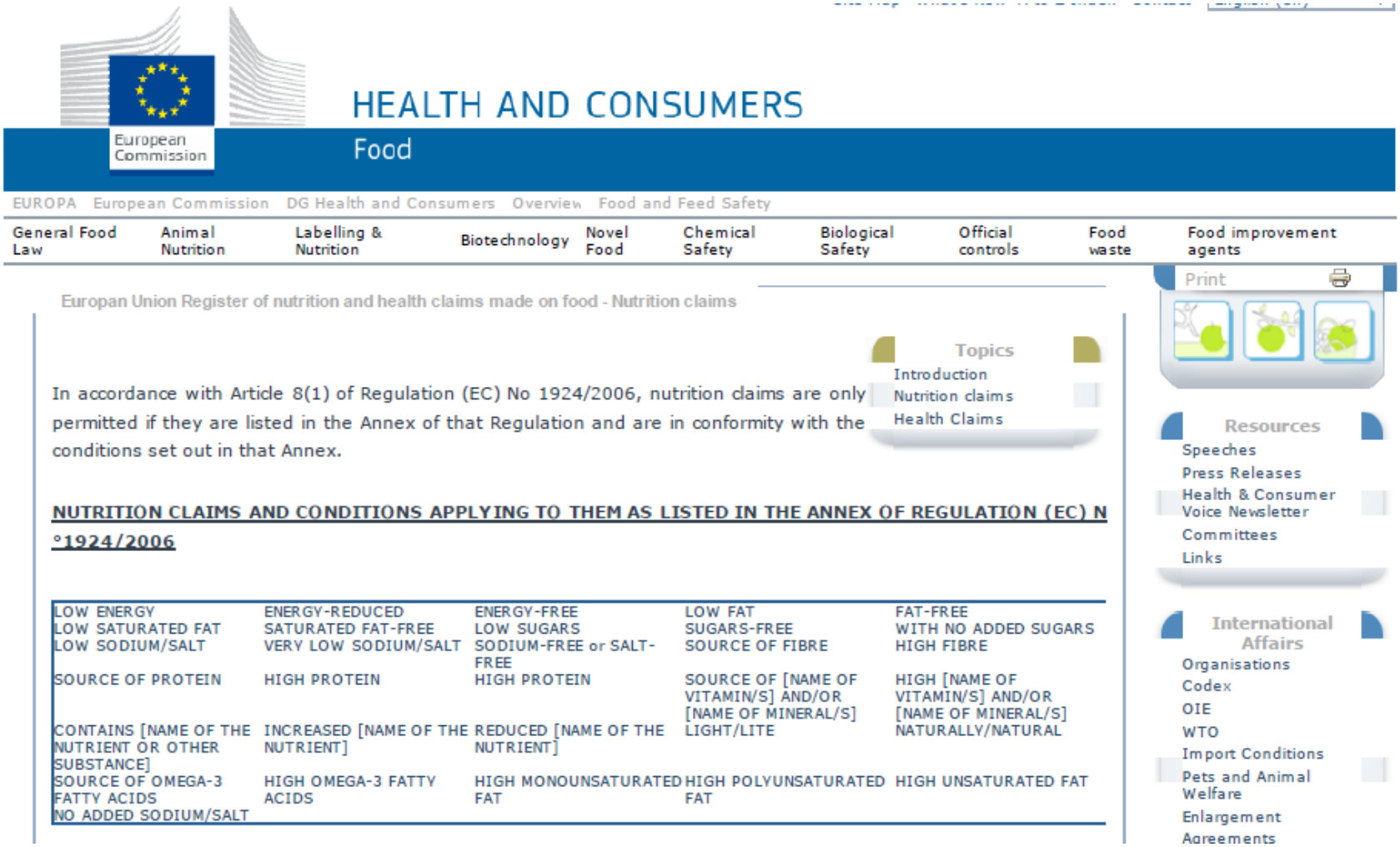
Protección frente a la competencia desleal

Oportunidad de mejorar el perfil nutricional de sus productos.

Diferencias



No olvidar los claims nutricionales!



European Commission

HEALTH AND CONSUMERS

Food

EUROPA European Commission DG Health and Consumers Overview Food and Feed Safety

General Food Law | Animal Nutrition | Labelling & Nutrition | Biotechnology | Novel Food | Chemical Safety | Biological Safety | Official controls | Food waste | Food improvement agents

Print

Europan Union Register of nutrition and health claims made on food - Nutrition claims

Topics
- Introduction
- Nutrition claims
- Health Claims

In accordance with Article 8(1) of Regulation (EC) No 1924/2006, nutrition claims are only permitted if they are listed in the Annex of that Regulation and are in conformity with the conditions set out in that Annex.

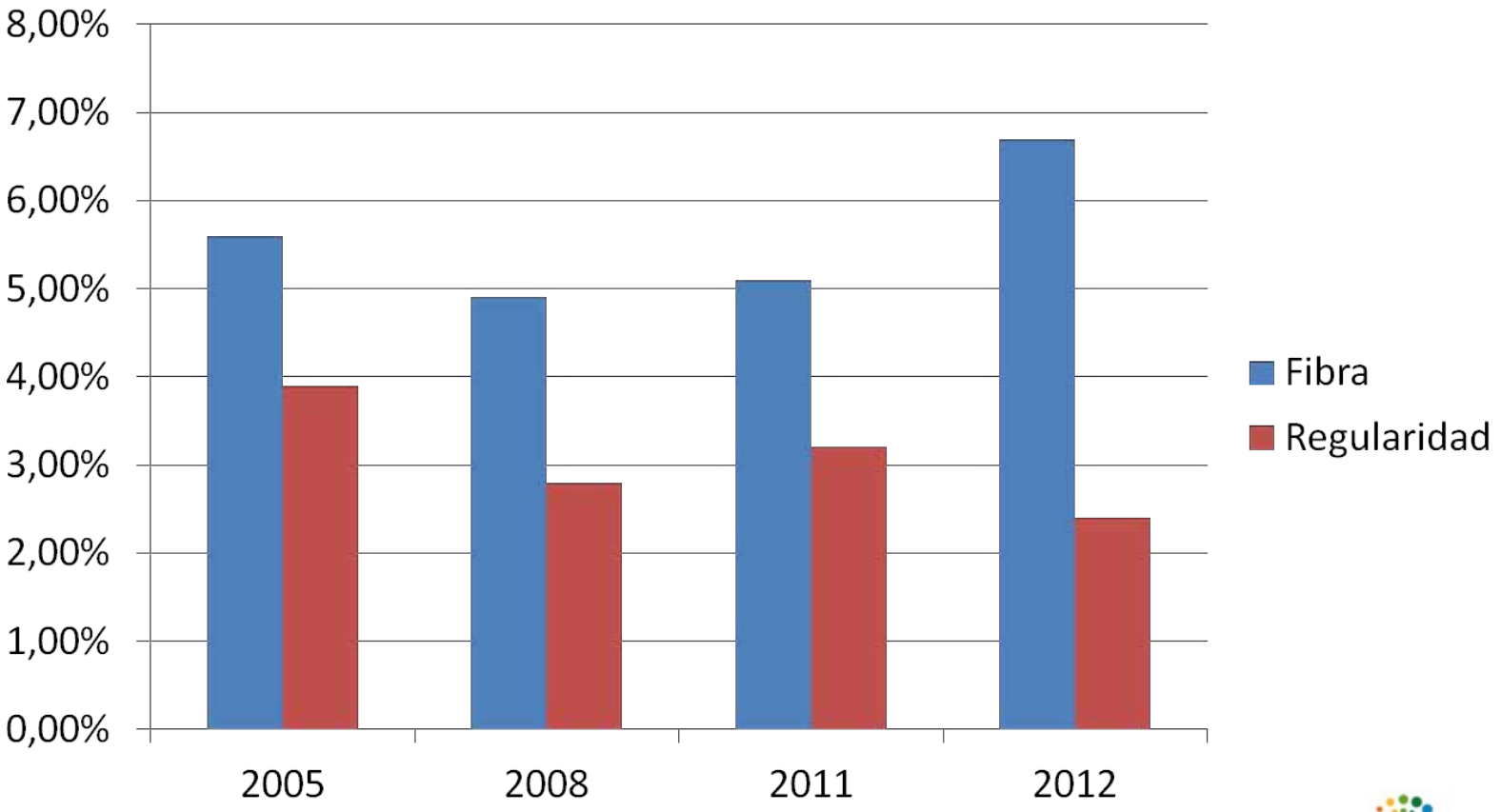
NUTRITION CLAIMS AND CONDITIONS APPLYING TO THEM AS LISTED IN THE ANNEX OF REGULATION (EC) N °1924/2006

LOW ENERGY	ENERGY-REDUCED	ENERGY-FREE	LOW FAT	FAT-FREE
LOW SATURATED FAT	SATURATED FAT-FREE	LOW SUGARS	SUGARS-FREE	WITH NO ADDED SUGARS
LOW SODIUM/SALT	VERY LOW SODIUM/SALT	SODIUM-FREE or SALT-FREE	SOURCE OF FIBRE	HIGH FIBRE
SOURCE OF PROTEIN	HIGH PROTEIN	HIGH PROTEIN	SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]	HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]
CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]	INCREASED [NAME OF THE NUTRIENT]	REDUCED [NAME OF THE NUTRIENT]	LIGHT/LITE	NATURALLY/NATURAL
SOURCE OF OMEGA-3 FATTY ACIDS	HIGH OMEGA-3 FATTY ACIDS	HIGH MONOUNSATURATED FAT	HIGH POLYUNSATURATED FAT	HIGH UNSATURATED FAT
NO ADDED SODIUM/SALT				

Resources
- Speeches
- Press Releases
- Health & Consumer Voice Newsletter
- Committees
- Links

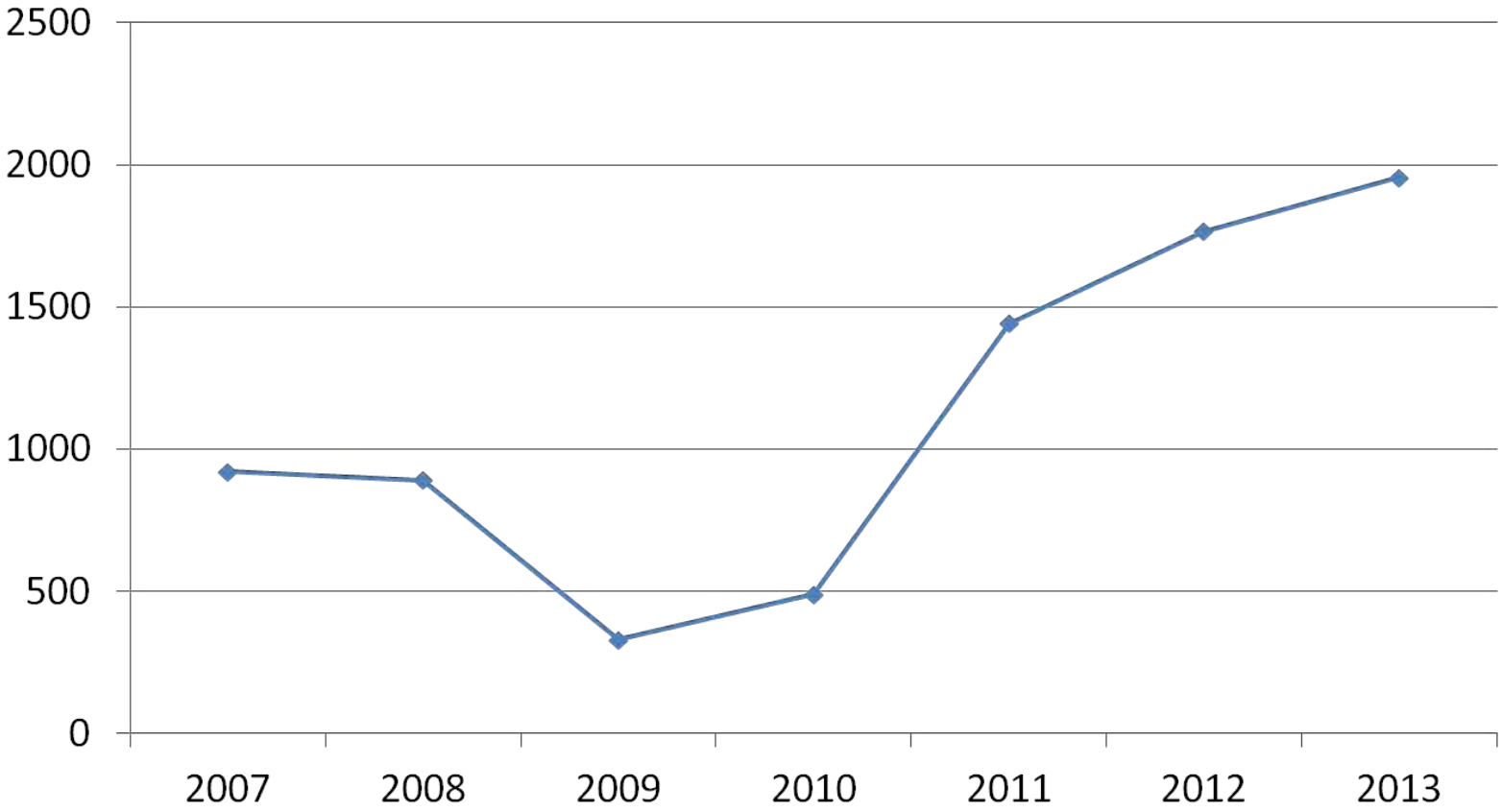
International Affairs
- Organisations
- Codex
- OIE
- WTO
- Import Conditions
- Pets and Animal Welfare
- Enlargement Agreements

En algunos segmentos es mejor un claim nutricional (fibra vs regularidad)



INNOVA MARKET INSIGHTS

Evolución de los lanzamientos con el claim "fibra" en Europa



INNOVA MARKET INSIGHTS

Artículo 2
Definiciones

5) Se entenderá por **«declaración de propiedades saludables»** cualquier declaración que afirme, sugiera o dé a entender que existe una relación entre una categoría de alimentos, un alimento o uno de sus constituyentes, y la salud.

6) Se entenderá por **«declaración de reducción del riesgo de enfermedad»** cualquier declaración de propiedades saludables que afirme, sugiera o dé a entender que el consumo de una categoría de alimentos, un alimento o uno de sus constituyentes reduce significativamente un factor de riesgo de aparición de una enfermedad humana.

Las declaraciones de salud en el Reglamento

Health Claims

Genéricos (13.1)

Nueva ciencia (13.5)

Niños (14)

Reducción riesgo (14)

Condiciones de las declaraciones

Demostrado el efecto nutricional o fisiológico benéfico mediante pruebas científicas generalmente aceptadas

Presente o ausente nutriente en cantidad significativa

Forma asimilable por el organismo

Cantidad que debe razonablemente esperar que se consuma

Condiciones específicas de cada declaración

El consumidor medio debe comprender los efectos beneficiosos tal como se expresan en la declaración

No debe dar a entender que una dieta equilibrada y variada no puede proporcionar cantidades adecuadas de nutrientes en general

Tipos de declaraciones

Declaraciones incluidas en el Artículo13.1

Basadas en evidencias científicas generalmente aceptadas sobre un efecto beneficiosos de los alimentos o componentes de los alimentos sobre las funciones fisiológicas

Declaraciones incluidas en Artículo 13.5 y 14

1. Basadas en nuevas evidencias científicas de efectos beneficiosos sobre el mantenimiento funciones fisiológicas con/sin derechos propiedad.

2. Reducción de un factor de riesgo de enfermedad.

3. Salud y desarrollo de niños

Qué no se puede declarar nunca?

1. Declaraciones que incumplan principios y condiciones generales (Art. 3 y 5).

2. Declaraciones expresamente prohibidas (Art. 12). Las referidas a:

a) Que la salud puede verse afectada si no se consume el alimento en cuestión.

b) Al ritmo o magnitud de la pérdida de peso.

c) Declaraciones de propiedades saludables genéricas sin la correspondiente específica (Art.10.3).

3. Declaraciones de prevención, tratamiento o curación de enfermedades humanas (Lo prohíbe la Norma de Etiquetado General) .

Condiciones específicas para Declaraciones Comparativas (Artículo 9)

La comparación se hace entre alimentos de la misma categoría

Se indicará la diferencia en la cantidad del nutriente y/o valor energético

La comparación hace referencia a la misma cantidad de alimento

No pueden hacerse declaraciones comparativas sobre vitaminas y minerales

Considerando 9 del Reglamento 1924/2006: Flexibilidad

(9) Existe una amplia serie de nutrientes y otras sustancias que incluye pero no se limita a las vitaminas, minerales, incluidos oligoelementos, aminoácidos, ácidos grasos esenciales, fibra, diversas plantas y extracto de hierbas con un efecto nutricional o fisiológico que pueden estar presentes en un alimento y ser objeto de una declaración. Por consiguiente, deben establecerse los principios generales aplicables a todas las declaraciones relativas a un alimento con el fin de garantizar un elevado nivel de protección de los consumidores, dar a los consumidores la información necesaria para elegir con pleno conocimiento de causa, y crear condiciones iguales de competencia para la industria alimentaria.

“Principios generales a respetar en la adaptación de la redacción de una declaración de propiedades saludables autorizada” Documento de trabajo EEMM-CM

GENERAL PRINCIPLES TO BE RESPECTED IF THE WORDING OF AN AUTHORISED HEALTH CLAIM IS ADAPTED.

RECOMMENDATIONS ELABORATED BY MEMBER STATES' EXPERTS WHO ATTEND THE EUROPEAN COMMISSION'S WORKING GROUP ON NUTRITION AND HEALTH CLAIMS

These general principles were presented for the first time at an informal meeting in Brussels on 19 June 2012. Experts from 17 Member States[1] met to discuss a common approach to advising food business operators (FBOs) about flexibility of wording for health claims. The recommendations in this document only relate to the general principles over which there was broad agreement. Discussions at the meeting took place in English therefore it is possible that the examples given in this document may need to be adapted for other languages.

These recommendations were agreed by Member States' experts in December 2012.

However, note that authorities in some Member States may have developed more detailed national recommendations on flexibility of wording.

Introduction

Recital (9) of Regulation 432/2012 states: "One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear, reliable and useful to the consumer. In that respect, the wording and presentation of such claims have to be taken into account. Where the wording of claims has the same meaning for consumers as that of an permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims." The terms and conditions of the EU Register of nutrition and health claims made on foods ("the Register") explain that some flexibility of wording is possible provided that its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population.

The aim of this document is to set out the principles that should be respected when authorised health claims are used but the wording used is not exactly as authorised. The same principles should be respected whenever authorised claims are used in commercial communications whether in labelling, presentation or advertising and in whatever medium including on websites, radio and television.

Recommendations

In general, we recommend that FBOs stick as closely as possible to the authorised wording of health claims. This should ensure that consumers are provided with appropriate information and it should help enforcement officers judge whether claims are being used in compliance with the law.

[1] Austria, Belgium, Denmark, Finland, France, Germany, Estonia, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden, United Kingdom.

PRINCIPIOS GENERALES DE FLEXIBILIDAD EN LA REDACCIÓN DE DECLARACIONES DE PROPIEDADES SALUDABLES

RECOMENDACIONES ELABORADAS POR LOS EXPERTOS DE LOS ESTADOS MIEMBROS QUE ASISTEN AL GRUPO DE TRABAJO DE LA COMISIÓN SOBRE DECLARACIOENS DE PROPIEDADES NUTRICIONALES Y SALUDABLES EN LOS ALIMENTOS.

Estos principios generales se presentaron por primera vez en una reunión informal el 19 de junio de 2012 en Bruselas. Expertos de 17 Estados Miembros[1] se reunieron para discutir un enfoque común con el fin de asesorar a los operadores de empresas alimentarias (OEA) acerca de la flexibilidad del texto de declaraciones de propiedades saludables. Las recomendaciones de este documento sólo se refieren a los principios generales sobre los cuales hubo un amplio acuerdo. Los debates de la reunión fueron en inglés por lo que es posible que los ejemplos que figuran en este documento puedan necesitar ser adaptados a otras lenguas.
Estas recomendaciones fueron acordadas por expertos de los Estados Miembros en diciembre de 2012.
Sin embargo, hay que tener en cuenta que las autoridades de algunos Estados Miembros pueden haber desarrollado recomendaciones nacionales más detalladas sobre la flexibilidad de la redacción.

Introducción

El considerando (9) del Reglamento 432/2012 establece: "Una de las finalidades del Reglamento (CE) Nº 1924/2006 es garantizar que las declaraciones de propiedades saludables sean veraces, claras, fiables y útiles para el consumidor. Este objetivo debe tenerse presente en la redacción y la presentación de las declaraciones.
Cuando el texto de las declaraciones tenga el mismo significado para los consumidores que el de una determinada declaración autorizada de propiedades saludables porque demuestra que existe la misma relación entre la salud y una categoría de alimentos, un alimento o uno de sus constituyentes, estas declaraciones deben estar sujetas a las mismas condiciones de uso que la declaración autorizada de propiedades saludables". Los términos y condiciones del Registro europeo de declaraciones nutricionales y de propiedades saludables hechas en alimentos ("el Registro") establecen que es posible una cierta flexibilidad en la redacción siempre que su objetivo sea ayudar a la comprensión del consumidor, teniendo en cuenta factores tales como las variaciones lingüísticas y culturales y la población a la que van destinadas.
El objetivo de este documento es establecer los principios que deberían ser respetados cuando se utilicen las declaraciones de salud autorizadas pero la redacción utilizada no sea exactamente la autorizada. Se deben respetar los mismos principios cuando se utilicen declaraciones autorizadas en comunicaciones comerciales ya sea en el etiquetado, presentación o publicidad y por cualquier medio incluyendo los sitios web, la radio y la televisión.

Recomendaciones

En general, recomendamos a los operadores de las empresas alimentarias (OEA) ceñirse lo más posible al texto autorizado para las declaraciones de propiedades saludables. Esto debería garantizar que los consumidores dispongan de información adecuada al tiempo que debería ayudar a las Autoridades competentes de juzgar si las declaraciones están siendo utilizadas de acuerdo con la ley.

[1] Austria, Bélgica, Dinamarca, Finlandia, Francia, Alemania, Estonia, Hungría, Irlanda, Lituania, Luxemburgo, Países Bajos, Noruega, Polonia, Portugal, Suecia y Reino Unido.

RECOMENDACIONES

1) Asegurar que la redacción adaptada tiene el mismo significado para el consumidor que la redacción autorizada.
2) Uso del término ‘normal’.
3) Relación entre el efecto que se alega y el nutriente, sustancia, alimento o categoría de alimento responsable del efecto.
4) Consideraciones particulares para declaraciones de propiedades saludables sobre complementos alimenticios.
5) Presentación de declaraciones generales, no específicas de salud.
6) Marca registrada, marca comercial o nombre de fantasía.
7) Referencias a extractos de dictámenes de la EFSA.

COMENTARIOS

Justificar que la redacción significa lo mismo que la declaración autorizada y es inteligible por el consumidor medio → LEGIBILIDAD

El término 'Normal' debería mantenerse en el texto adaptado y no debería ser sustituido por otro término ni eliminado AUNQUE determinadas traducciones lo sustituyen por "saludable" o "adecuado".

Las declaraciones autorizadas NO son para el "producto" AUNQUE podrían solicitarse por el artículo 19 del Reglamento 1924/2006.

El artículo 6(3) de la Directiva 2002/46/CE exige que en el etiquetado de un complemento alimenticio figuren los nombres de las categorías de nutrientes o sustancias que caracterizan al producto, o una indicación relativa a la naturaleza de dichos nutrientes o sustancias.

El artículo 10 (3) del Reglamento 1924/2006 establece que cuando se hace referencia a beneficios generales y no específicos del nutriente o del alimento para la buena salud general o el bienestar relativo a la salud debe estar acompañada de una declaración de propiedades saludables específica autorizada incluida en las listas previstas en el artículo 13 ó 14.

Cuando una relación de efecto saludable particular se sustenta por evidencia científica, el dictamen de la EFSA establece claramente la redacción apropiada de la declaración de salud. Esto no significa que todas las redacciones de las declaraciones de salud originalmente propuestas son validadas y por tanto no deberían ser utilizadas para adaptar la redacción de una declaración de salud autorizada.

No se han admitido claims "combinados" por el artículo 13

CLAIMS RELATING TO COMBINATIONS OF SUBSTANCES

Claims referring to the effect of combinations of vitamins, minerals and omega-3 fatty acids

There are no such substantiated health claims because a number of claims on individual vitamins, minerals and omega-3 fatty acids on various body functions have been authorised and appear in the list of authorised health claims which can be used alone or in combination.

The IDs (as found in the consolidated list) are given below.

1	10	112	179	362	1515	3095	4282	4287	4708
2	11	168	184	372	2872	4279	4284	4289	
3	12	173	201	717	2874	4280	4285	4291	
7	111	174	210	1464	3094	4281	4286	4292	

Porque debe hacerse por el artículo 19

Artículo 19

Modificación, suspensión y revocación de las autorizaciones

1. El solicitante/usuario de una declaración incluida en una de las listas contempladas en los artículos 13 y 14 podrá solicitar una modificación de la lista pertinente. Se aplicarán *mutatis mutandis* los procedimientos establecidos en los artículos 15 a 18.

2. Por propia iniciativa, o previa solicitud de un Estado miembro o de la Comisión, la Autoridad emitirá un dictamen en el que examinará si una declaración de propiedades saludables incluida en las listas contempladas en los artículos 13 y 14 sigue cumpliendo las condiciones establecidas en el presente Reglamento.

Transmitirá inmediatamente su dictamen a la Comisión, a los Estados miembros y, cuando proceda, al solicitante inicial de la declaración de que se trate. La Autoridad, de conformidad con el apartado 1 del artículo 38 del Reglamento (CE) nº 178/2002, hará público su dictamen.

El solicitante/usuario o un miembro del público podrá formular comentarios a la Comisión en un plazo de 30 días a partir de esa publicación.

La Comisión examinará el dictamen de la Autoridad y todos los comentarios recibidos lo antes posible. Cuando sea necesario, se modificará, suspenderá o revocará la autorización de conformidad con los procedimientos establecidos en los artículos 17 y 18.

Un ejemplo (de lo que podía haber sido)

European Food Safety Authority

EFSA Journal 2013;11(7):3327

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in Limicol® and reduction of blood LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

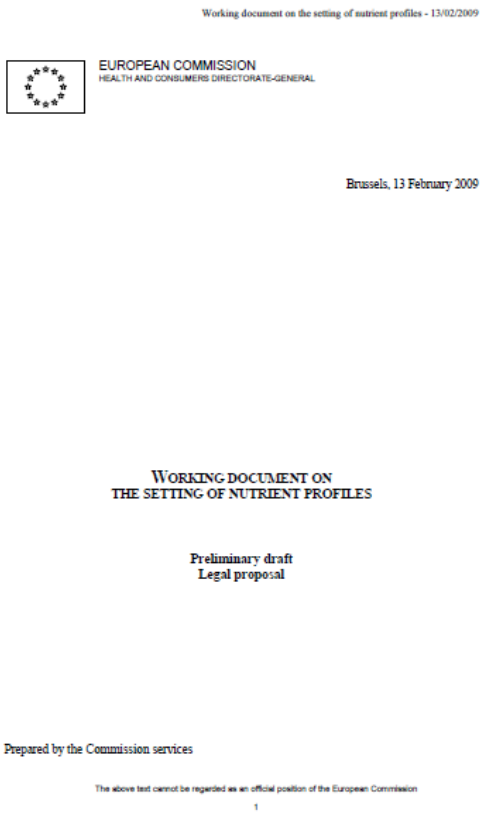
EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

Perfiles nutricionales

Artículo 4) Reglamento 1924/2006:

"las cantidades permitidas de determinados nutrientes y otras sustancias contenidas en los alimentos para que puedan realizar declaraciones".



Working document on the setting of nutrient profiles - 13/02/2009

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Brussels, 13 February 2009

WORKING DOCUMENT ON
THE SETTING OF NUTRIENT PROFILES

Preliminary draft
Legal proposal

Prepared by the Commission services

The above text cannot be regarded as an official position of the European Commission

1

ANNEX 1: specific nutrient profiles and conditions of use, which food or certain categories of food must comply with in order to bear nutrition or health claims

Food category		Specific conditions*	Thresholds		
			Sodium (mg/100g or 100ml)	Saturates (g/100g or 100ml except when specified otherwise)	Sugars (g/100g or 100ml)
Vegetable oils and spreadable fats as defined in Council Regulation (EC) No 2991/94		-	500	30 kcal /100g	-
Fruits, vegetables, seeds, and their products, except oils	Fruits, vegetables, and their products, except oils**	Minimum 50g of fruit and/or vegetable per 100g of finished products	400	5	15
	Seeds*** and their products, except oils	Minimum 50g of nuts per 100g of finished products	400	10	15
Meat or meat based products		Minimum 50g of meat per 100g of finished products	700	5	-
Fish, fishery products, crustaceans, and molluscs		Minimum 50g of fish per 100g of finished products	700	10	-
Dairy based products	Dairy based products, except cheeses	Minimum 50g of dairy constituents per 100g of finished products	300	2,5	15
	Cheeses	Minimum 50g of dairy constituents per 100g of finished products	600	10	15
Cereal and cereal products	Breads containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.	Minimum 50g of cereals per 100g of finished products	700 until [date of adoption + 6 years] 400 from [date of adoption + 6 years]	5	15
	Cereal and cereal products except breakfast cereals	Minimum 50g of cereals per 100g of finished products	400	5	15
	Breakfast cereals	Minimum 50g of cereals per 100g of finished products	500	5	25
Ready meals, soups and sandwiches		Minimum 200g per serving size Minimum 2 of the following for ready meals and sandwiches: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk	400	5	10
Non alcoholic beverages		Liquid foods, insofar as they do not qualify for one of the above mentioned food categories	-	-	8
Other foods		Solid foods, insofar as they do not qualify for one of the above mentioned food categories	300	2	10

* the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

** vegetables include potatoes, beans, and pulses.

*** seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.

ÁMBITO DE APLICACIÓN: "Todas las declaraciones nutricionales y de propiedades saludables efectuadas en las COMUNICACIONES COMERCIALES, en el etiquetado, la presentación o la publicidad de los alimentos que se suministren como tales al consumidor final"

-Las comunicaciones comerciales a los profesionales de la salud

-Las campañas publicitarias colectivas y de promoción (también las patrocinadas por autoridades públicas)

-Las marcas registradas, nombre comercial o denominación de fantasía

-Alimentos destinados a la restauración colectiva

Directrices para la aplicación de las condiciones específicas relativas a las declaraciones de propiedades saludables establecidas en el artículo 10 del Reglamento (CE) no 1924/2006

2. Información obligatoria que debe acompañar a las declaraciones de propiedades saludables autorizadas (artículo 10, apartado 2)

2.2. Cuatro elementos de información obligatoria:

a) Una declaración en la que se indique la importancia de una dieta variada y equilibrada y un estilo de vida saludable.

b) La cantidad de alimento y el patrón de consumo requeridos para obtener el efecto benéfico declarado.

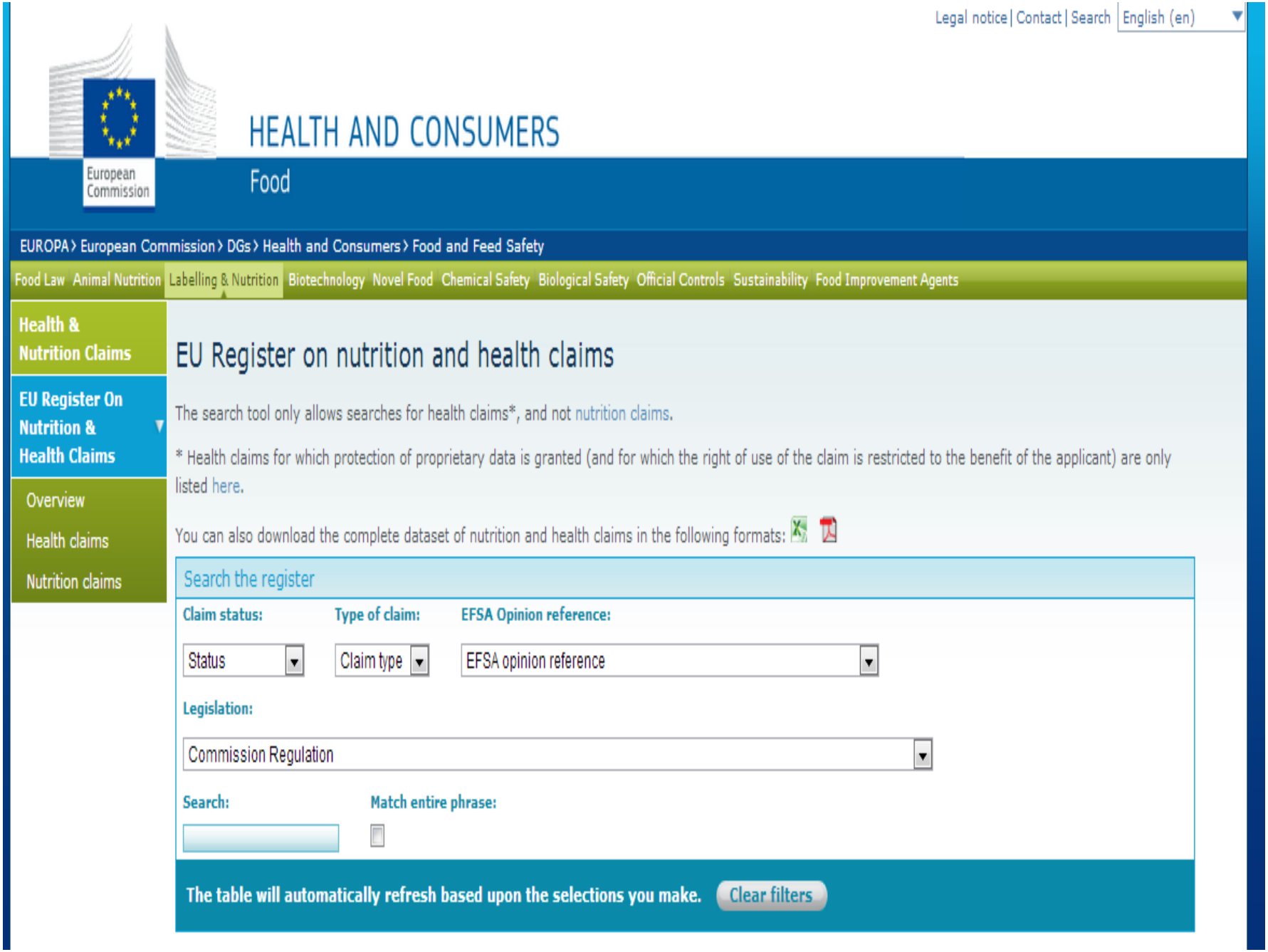
c) En su caso, una declaración dirigida a las personas que deberían evitar el consumo del alimento, y

d) Una advertencia adecuada en relación con los productos que pueden suponer un riesgo para la salud si se consumen en exceso.

Warning Claims

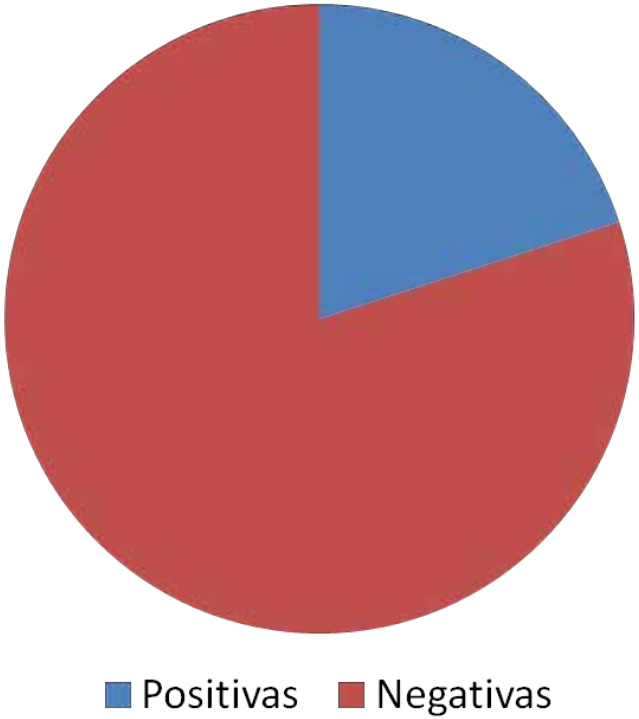
Una *declaración* dirigida a las personas que deberían evitar el consumo del alimento.

Una *advertencia* adecuada en relación con los productos que pueden suponer un riesgo para la salud si se consumen en exceso.

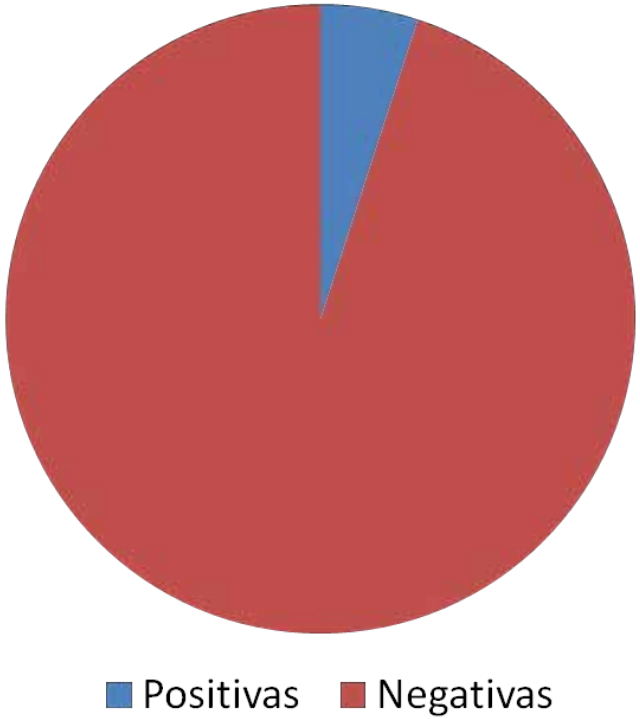

Legal notice | Contact | Search English (en)
European Commission
HEALTH AND CONSUMERS
Food
EUROPA › European Commission › DGs › Health and Consumers › Food and Feed Safety
Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official Controls Sustainability Food Improvement Agents
Health & Nutrition Claims
EU Register On Nutrition & Health Claims
Overview
Health claims
Nutrition claims
EU Register on nutrition and health claims
The search tool only allows searches for health claims*, and not nutrition claims.
* Health claims for which protection of proprietary data is granted (and for which the right of use of the claim is restricted to the benefit of the applicant) are only listed here.
You can also download the complete dataset of nutrition and health claims in the following formats:
Search the register
Claim status:
Status
Type of claim:
Claim type
EFSA Opinion reference:
EFSA opinion reference
Legislation:
Commission Regulation
Search:
Match entire phrase:
The table will automatically refresh based upon the selections you make.
Clear filters

Opiniones de EFSA

Todas las aplicaciones



Excepto vitaminas y minerales



Opiniones de EFSA

Conclusión EFSA	Causa/Efecto	Evaluación científica	GASE (Generally Accepted Scientific Evidence)
Categoría I	Establecida	Concluyente	Sí
Categoría II	Insuficiente	No concluyente	No
Categoría III	No establecida	Limitada	No

MEMO/12/346

Brussels, 16 May 2012

Questions and Answers on the list of permitted Health Claims on food products

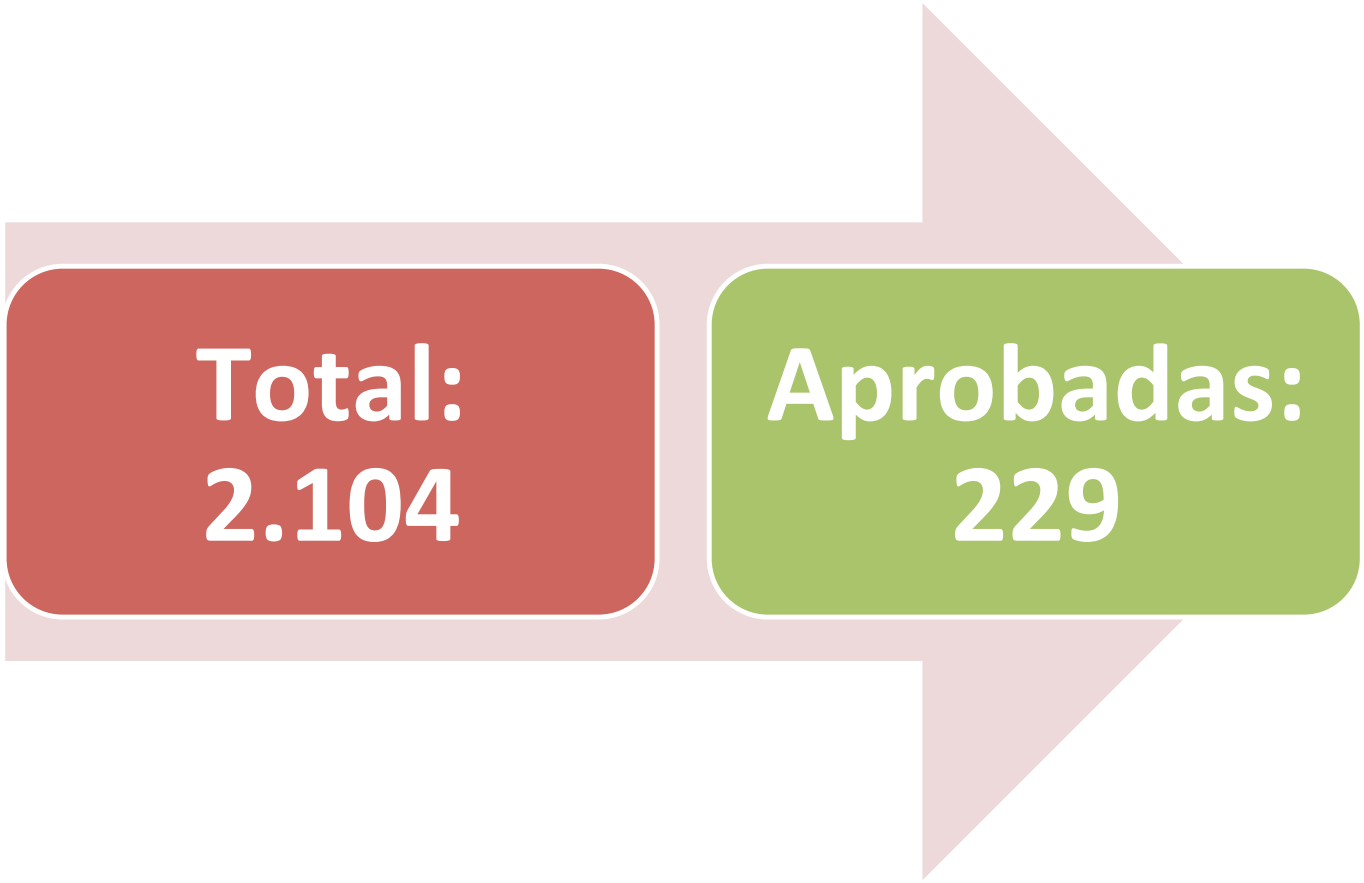
Are all claims in the list of non authorised claims not true?

This is not necessarily the case. A scientific assessment was the first requirement, followed by a test of compliance with the other requirements in the claims Regulation. In its assessments EFSA looked at three consecutive elements:

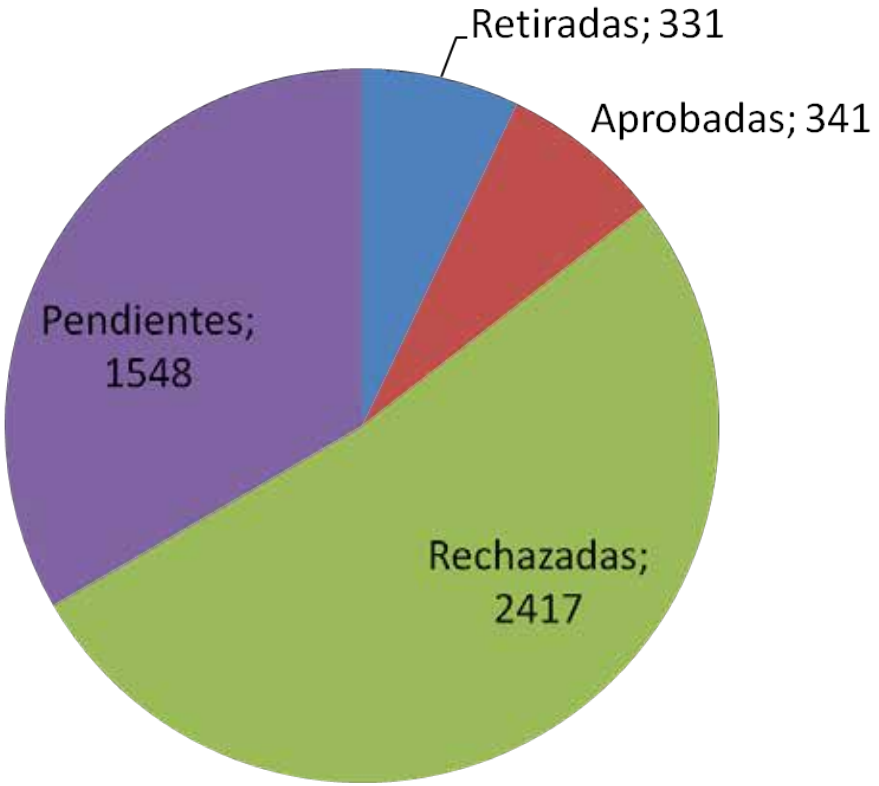
- whether the subject of the claimed effect (food, substance) can be defined sufficiently for a scientific assessment
- whether the claimed effect is indeed beneficial for health
- whether the studies considered as pertinent by EFSA could allow establishing of a cause and effect relationship between the food and the claimed effect

An unfavourable EFSA opinion could be linked to any of these elements. Some claims with a positive EFSA assessment were judged not to meet the other requirements of the claims Regulation. Claims that are not authorised are included in the Union Register with clear reasons as to why they are not authorised.

Declaraciones bajo el artículo 13.1 (de 44.000 solicitudes)



Lista comunitaria de declaraciones saludables bajo el artículo 13.3: 4.637 solicitudes recibidas



Claim	Biotin	Choline	Folate	Niacin	Panthotenic Acid	Riboflavin	Thiamine	Vitamin A	Vitamin B6	Vitamin B12	Vitamin C	Vitamin D	Vitamin E	Vitamin K
Minimum Quantity	**7,50 mcg**	**ND**	**30,00 mcg**	**2,40 mg**	**0,90 mg**	**0,21 mg**	**0,16 mg**	**120 mcg**	**0,21 mg**	**0,38 mcg**	**12 mg**	**0,75 mcg**	**1,80 mg**	**11,25 mcg**
Contributes to maintain the normal function of the immune system during and after intense physical exercise														
Contributes to maternal tissue growth during pregnancy														
Contributes to normal absorption/utilisation of calcium and phosphorus														
Contributes to normal amino acid synthesis														
Contributes to normal blood calcium levels														
Contributes to normal blood clotting														
Contributes to normal blood formation														
Contributes to normal collagen formation for the normal function of blood vessels														
Contributes to normal collagen formation for the normal function of bones, cartilage, gums, skin and teeth														
Contributes to normal cysteine synthesis														
Contributes to normal energy-yielding metabolism														
Contributes to normal functioning of the nervous system														
Contributes to normal homocysteine metabolism														
Contributes to normal iron metabolism														
Contributes to normal lipid metabolism														
Contributes to normal macronutrient metabolism														
Contributes to normal mental performance														
Contributes to normal protein and glycogen metabolism														
Contributes to normal psychological function														
Contributes to normal red blood cell formation														
Contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters														
Contributes to the maintenance of normal bones														
Contributes to the maintenance of normal hair														
Contributes to the maintenance of normal liver function														
Contributes to the maintenance of normal mucous membranes														
Contributes to the maintenance of normal muscle function														
Contributes to the maintenance of normal red blood cells														
Contributes to the maintenance of normal skin														
Contributes to the maintenance of normal teeth														
Contributes to the maintenance of normal vision														
Contributes to the normal function of the heart														
Contributes to the normal function of the immune system														
Contributes to the normal metabolism of iron														
Contributes to the protection of cells from oxidative stress														
Contributes to the protection of cells from oxidative stress														
Contributes to the reduction of tiredness and fatigue														
Contributes to the regeneration of the reduced form of vitamin E														
Contributes to the regulation of hormonal activity														
Has a role in the process of cell division														
Has a role in the process of cell specialisation														
Increases iron absorption														
Is needed for normal growth and development of bone in children														

Claim	Calcium	Chromium	Copper	Fluoride	Iodine	Iron	Manganese	Magnesium	Molybdenum	Phosphorus	Potassium	Selenium	Zinc
Minimum Quantity	**120,00 mg**	**6,00 mcg**	**0,15 mg**	**0,52 mg**	**22,5 mcg**	**2,10 mg**	**0,30 mg**	**56,25 mg**	**7,50 mcg**	**105,00 mg**	**300,00 mg**	**8,25 mcg**	**1,50 mg**
Contributes to a reduction of tiredness and fatigue								■					
Contributes to electrolyte balance								■					
Contributes to maintenance of normal connective tissues			■										
Contributes to normal acid-base metabolism													■
Contributes to normal blood clotting	■												
Contributes to normal carbohydrate metabolism													■
Contributes to normal cognitive development of children						■							
Contributes to normal cognitive function					■	■							■
Contributes to normal DNA synthesis													■
Contributes to normal energy-yielding metabolism	■		■		■	■	■	■		■			
Contributes to normal fertility and reproduction													■
Contributes to normal formation of red blood cells and haemoglobin						■							
Contributes to normal function of cell membranes										■			
Contributes to normal functioning of the nervous system			■		■			■			■		
Contributes to normal hair pigmentation			■										
Contributes to normal iron transport in the body			■										
Contributes to normal macronutrient metabolism		■											
Contributes to normal macronutrient metabolism													■
Contributes to normal metabolism of fatty acids													■
Contributes to normal metabolism of vitamin A													■
Contributes to normal muscle function	■							■			■		
Contributes to normal neurotransmission	■												
Contributes to normal oxygen transport in the body						■							
Contributes to normal protein synthesis								■					■
Contributes to normal psychological function								■					
Contributes to normal skin pigmentation			■										
Contributes to normal spermatogenesis												■	
Contributes to normal sulphur amino acid metabolism									■				
Contributes to the maintenance of normal blood glucose levels		■											
Contributes to the maintenance of normal blood pressure											■		
Contributes to the maintenance of normal bones							■	■		■			■
Contributes to the maintenance of normal hair												■	■
Contributes to the maintenance of normal nails												■	■
Contributes to the maintenance of normal skin					■								■
Contributes to the maintenance of normal teeth								■		■			
Contributes to the maintenance of normal testosterone levels in the blood													■
Contributes to the maintenance of normal vision													■
Contributes to the maintenance of tooth mineralisation				■									
Contributes to the normal formation of connective tissue							■						
Contributes to the normal function of digestive enzymes	■												
Contributes to the normal function of the immune system			■										
Contributes to the normal function of the immune system						■						■	■
Contributes to the normal growth of children					■								
Contributes to the normal production of thyroid hormones and normal thyroid function					■								
Contributes to the normal thyroid function												■	
Contributes to the protection of cells from oxidative stress			■				■					■	■
Contributes to the reduction of tiredness and fatigue						■							
Has a role in the process of cell division						■		■					■
Has a role in the process of cell division and specialisation	■												
Is needed for normal growth and development of bone in children	■									■			
Is needed for the maintenance of normal bones	■												
Is needed for the maintenance of normal teeth	■												

II

(Actos no legislativos)

REGLAMENTOS

REGLAMENTO (UE) Nº 432/2012 DE LA COMISIÓN

de 16 de mayo de 2012

por el que se establece una lista de declaraciones autorizadas de propiedades saludables de los alimentos distintas de las relativas a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños

(Texto pertinente a efectos del EEE)

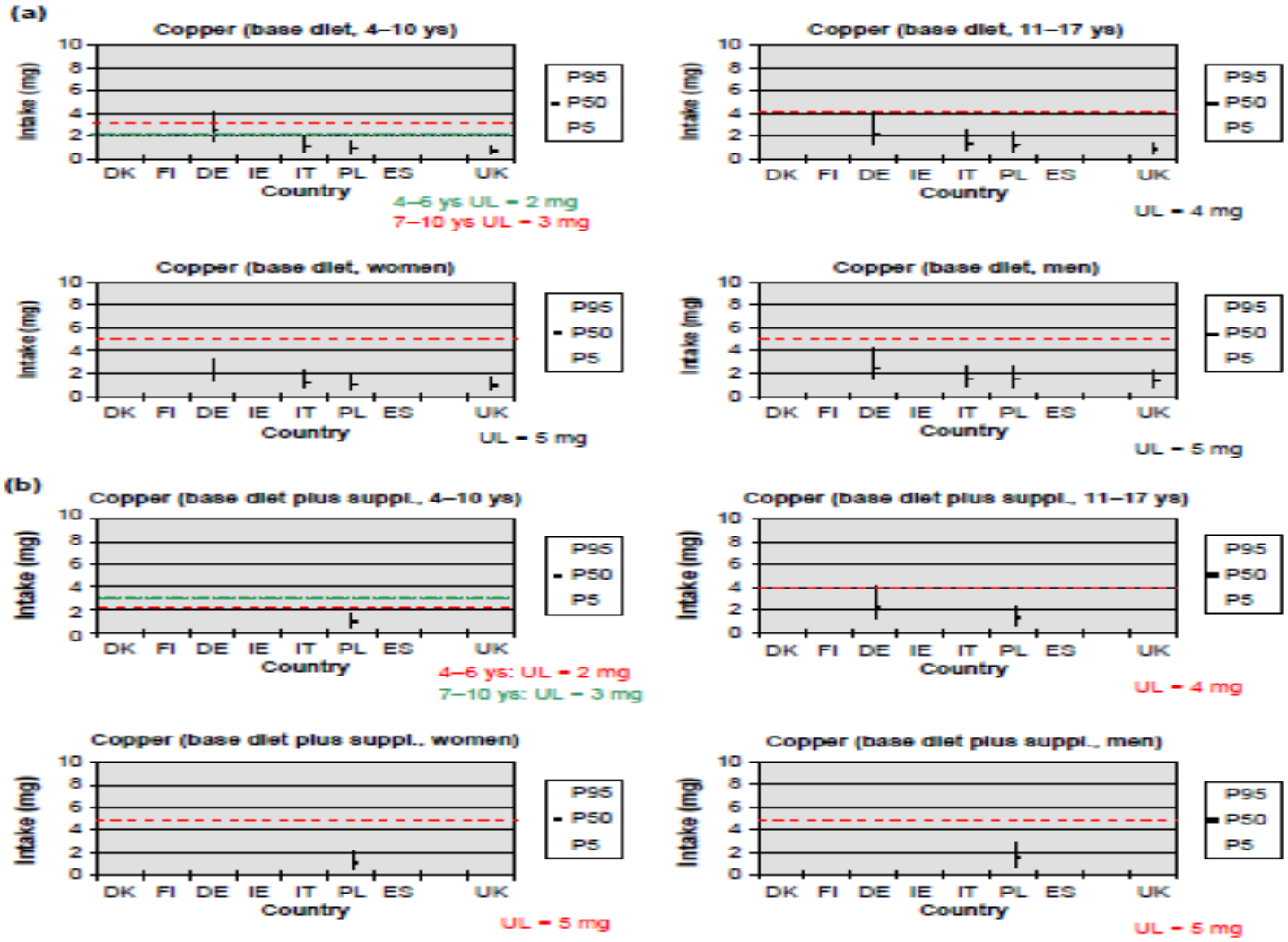
Dudas: Deficiencia o suplementación?

(8) El artículo 13, apartado 3, del Reglamento (CE) nº 1924/2006 dispone que las declaraciones autorizadas de propiedades saludables deben ir acompañadas de todas las condiciones (incluidas las restricciones) que se requieren para su uso. Por consiguiente, la lista de declaraciones autorizadas debe recoger el texto de las declaraciones y sus condiciones específicas de utilización así como, si procede, las condiciones o restricciones de uso, declaraciones complementarias o advertencias, de conformidad con lo dispuesto en el Reglamento (CE) nº 1924/2006 y, ateniéndose a los dictámenes de la Autoridad.

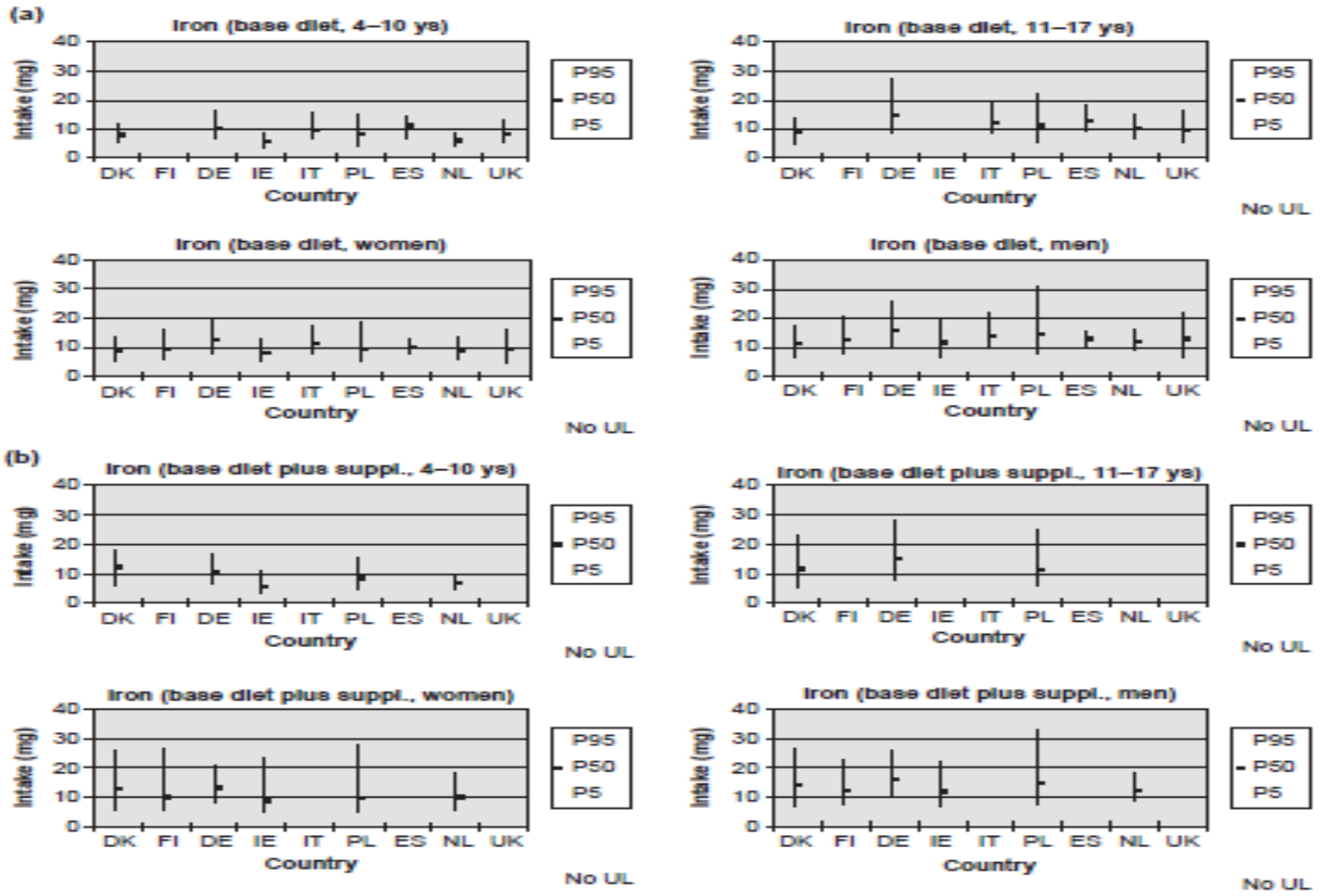
efsa
European Food Safety Authority

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Hay demasiadas declaraciones para micronutrientes: Y los riesgos de sobre-consumo?



Hay demasiadas declaraciones para micronutrientes: Y los riesgos de sobre-consumo?



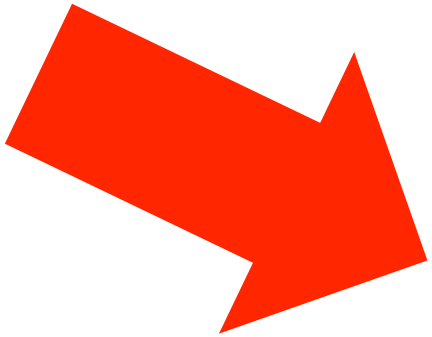
Y los riesgos?

ANNEX 3B INTAKE OF CARBOHYDRATES AND DIETARY FIBRE AMONG ADULTS AGED ~19-65 YEARS IN EU COUNTRIES.

Country	Age yrs	N	Total Carbohydrates (E%)			Mono- and Disaccharides (E%)			Polysaccharides (E%)			Sucrose (E%)			Dietary Fibre (g)			Dietary Fibre (g/MJ)		
			mean	*SD*	P5 - P95	*mean*	*SD*	P5 - P95	*mean*	*SD*	P5 - P95	*mean*	*SD*	P5 - P95	*mean*	*SD*	P5 - P95	*mean*	*SD*	P5 - P95
Males																				
AT	19-64	778	42.5	10.5								8.7	6.4		19.5	9.9				
BE	19-59	413	45.2	5.3		24.1	4.8		19.4	5.7										
CZ	19-64	1094	53.9	12.0																
DE	19-64	4912	45.3	8.4																
DK	18-74	1467	43	6.8	35.0-53.0[1]							8.0		3-15[1]	21.0		12.0-32.0[1]			
EE	19-64	900	42.7	14.0																
FI	25-64	730	47.1	8.8								9.7	5.9		24.0	11.0		2.7	1.1	
FR	19-64	852	43.4	0.3[2]											18.7	0.4[2]				
GR	19-64	8365	37.9	5.9																
HU	>18	473	45.0	6.6								7.6	5.2		24.2	6.6				
IE	18-64	662	43.5	6.4	32.6-54.3										23.2	8.5	12.1-38.9			
IT	19-64	660													21.8	6.5				
LT	19-65	849	38.9	9.3								10.8	5.6		20.9	12.4				
LV	19-65	1065	42.2	11.8																
NL	19-64	1836	44.2	7.5																
NO	19-64	1050	51.0	6.0								9.0	6.0		25.0	10.0				
PL	19-64	1106	48.0	8.4								11.0	5.2		29.7	11.4				
PT	19-64	917	47.0	6.8											23.5	9.0				
RO	19-64	177	43.3	9.4																
SE	18-74	589	46	6.0	37.0-56.0							9.0	4.0	3-16	18.0	7.0	9.0-29.0	1.8	0.5	1.1-2.7
ES	18-64	718	40.5			16.6			23.2						19.2					
UK	19-64	833	47.7	6.0	35.9-59.8[4]															

Dudas: "Wording"

(9) Una de las finalidades del Reglamento (CE) nº 1924/2006 es garantizar que las declaraciones de propiedades saludables sean veraces, claras, fiables y útiles para el consumidor. Este objetivo debe tenerse presente en la redacción y la presentación de las declaraciones. Cuando el texto de las declaraciones tenga el mismo significado para los consumidores que el de una determinada declaración autorizada de propiedades saludables porque demuestra que existe la misma relación entre la salud y una categoría de alimentos, un alimento o uno de sus constituyentes, estas declaraciones deben estar sujetas a las mismas condiciones de uso que la declaración autorizada de propiedades saludables.



GENERAL PRINCIPLES TO BE RESPECTED IF THE WORDING OF AN AUTHORISED HEALTH CLAIM IS ADAPTED.

RECOMMENDATIONS ELABORATED BY MEMBER STATES' EXPERTS WHO ATTEND THE EUROPEAN COMMISSION'S WORKING GROUP ON NUTRITION AND HEALTH CLAIMS

These general principles were presented for the first time at an informal meeting in Brussels on 19 June 2012. Experts from 17 Member States[1] met to discuss a common approach to advising food business operators (FBOs) about flexibility of wording for health claims. The recommendations in this document only relate to the general principles over which there was broad agreement. Discussions at the meeting took place in English therefore it is possible that the examples given in this document may need to be adapted for other languages.

These recommendations were agreed by Member States' experts in December 2012.

However, note that authorities in some Member States may have developed more detailed national recommendations on flexibility of wording.

Introduction

Recital (9) of Regulation 432/2012 states: "One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear, reliable and useful to the consumer. In that respect, the wording and presentation of such claims have to be taken into account. Where the wording of claims has the same meaning for consumers as that of an permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims." The terms and conditions of the EU Register of nutrition and health claims made on foods ("the Register") explain that some flexibility of wording is possible provided that its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population.

The aim of this document is to set out the principles that should be respected when authorised health claims are used but the wording used is not exactly as authorised. The same principles should be respected whenever authorised claims are used in commercial communications whether in labelling, presentation or advertising and in whatever medium including on websites, radio and television.

Recommendations

In general, we recommend that FBOs stick as closely as possible to the authorised wording of health claims. This should ensure that consumers are provided with appropriate information and it should help enforcement officers judge whether claims are being used in compliance with the law.

[1] Austria, Belgium, Denmark, Finland, France, Germany, Estonia, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden, United Kingdom.

1

Dudas: Botánicos

(10) La Comisión ha constatado que la Autoridad no ha concluido aún la evaluación científica de una serie de declaraciones sometidas a evaluación que se refieren a los efectos de determinadas sustancias vegetales o a base de plantas, comúnmente conocidas como sustancias «botánicas». Además, existe una serie de declaraciones de propiedades saludables respecto a las cuales la Comisión, o bien demanda una evaluación más exhaustiva antes de poder considerar su incorporación a la lista de declaraciones autorizadas o no puede decidir aún sobre su inclusión en la lista, aunque ya hayan sido evaluadas, debido a otros factores lícitos.

(11) Las declaraciones cuya evaluación por parte de la Autoridad o cuyo examen por parte de la Comisión no haya finalizado todavía se publican en el sitio web de la Comisión ([1]) y pueden seguir utilizándose, de conformidad con el artículo 28, apartados 5 y 6, del Reglamento (CE) nº 1924/2006.

MEMO/11/868

Brussels, 5 December 2011

Questions and Answers on the list of permitted Health Claims

What is the status of the claims on botanical ingredients?

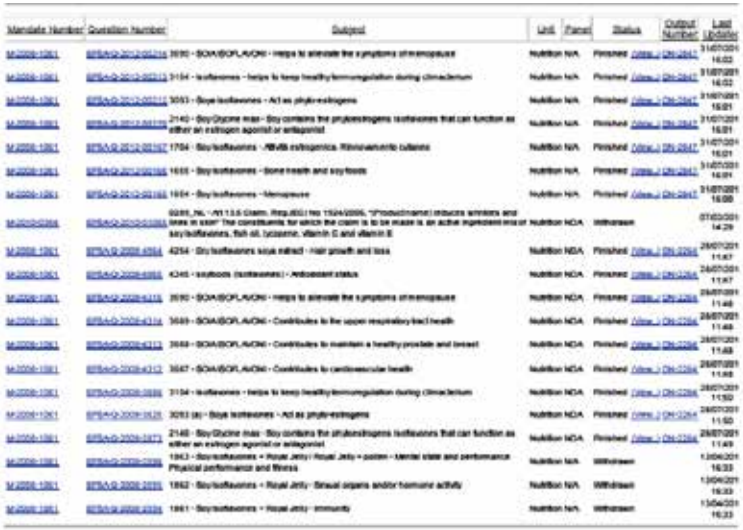
Certain herbal substances can be present in the composition of both Traditional Herbal Medicinal Products (THMPs) and in foods. It is therefore possible that, for the same substance, the therapeutic indication given by manufacturers of THMPs is similar (with the due distinctions, as medicinal claims are forbidden on foods) to a health claim made by food manufacturers.

Differences in legal requirements between health claims and THMPs could lead to a different treatment of the same substance, according to whether it is present in a food or in a medicine. This would create discriminations on the market of herbal products and potential confusion for consumers. Since the Commission and Member States need more time to decide how to address this issue, it was decided to put these claims on hold.

What will the Commission do on botanicals?

A reflection exercise is underway aimed at achieving a consistent and coherent treatment of botanicals in the future.

PERO …….



Mandate Number	Question Number	Subject	Unit	Panel	Status	Output Number	Last Updated
M-2008-1061	EFSA-Q-2012-00214	3030 - SOA/BOFLA/OKI - Helps to alleviate the symptoms of menopause	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:02
M-2008-1061	EFSA-Q-2012-00213	3154 - Isoflavones - helps to keep healthy thermoregulation during climacterium	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:02
M-2008-1061	EFSA-Q-2012-00112	3053 - Soja Isoflavones - Act as phyto-estrogens	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:01
M-2008-1061	EFSA-Q-2012-00109	2140 - Soy Glycine max - Soy contains the phytoestrogens isoflavones that can function as either an estrogen agonist or antagonist	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:01
M-2008-1061	EFSA-Q-2012-00107	1704 - Soy Isoflavones - Afli49 estrogenics. Rhinovaginitis cutanea	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:01
M-2008-1061	EFSA-Q-2012-00106	1655 - Soy Isoflavones - Bone health and soy foods	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:01
M-2008-1061	EFSA-Q-2012-00105	1654 - Soy Isoflavones - Menopause	Nutrition N/A		Finished	View / DN-2847	31/07/2012 16:00
M-2010-0356	EFSA-Q-2010-01053	0285_NL - Art 13.5 Claim. Reg(EC) no 1924/2006. "[Product name] induces wrinkles and lines in skin" The constituents for which the claim is to be made is an active ingredient mix of soy Isoflavones, fish oil, lycopene, vitamin C and vitamin E	Nutrition NDA		Withdrawn		07/02/2011 14:29
M-2008-1061	EFSA-Q-2008-4264	4254 - Dry Isoflavones soya extract - Hair growth and loss	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:47
M-2008-1061	EFSA-Q-2008-4265	4245 - soybeans (isoflavones) - Antioxidant status	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:47
M-2008-1061	EFSA-Q-2008-4315	3030 - SOA/BOFLA/OKI - Helps to alleviate the symptoms of menopause	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:48
M-2008-1061	EFSA-Q-2008-4314	3029 - SOA/BOFLA/OKI - Contributes to the upper respiratory tract health	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:48
M-2008-1061	EFSA-Q-2008-4313	3028 - SOA/BOFLA/OKI - Contributes to maintain a healthy prostate and breast	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:48
M-2008-1061	EFSA-Q-2008-4312	3027 - SOA/BOFLA/OKI - Contributes to cardiovascular health	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:48
M-2008-1061	EFSA-Q-2008-3888	3154 - Isoflavones - helps to keep healthy thermoregulation during climacterium	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:50
M-2008-1061	EFSA-Q-2008-3625	3053 (a) - Soja Isoflavones - Act as phyto-estrogens	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:50
M-2008-1061	EFSA-Q-2008-3473	2140 - Soy Glycine max - Soy contains the phytoestrogens isoflavones that can function as either an estrogen agonist or antagonist	Nutrition NDA		Finished	View / DN-3264	29/07/2011 11:49
M-2008-1061	EFSA-Q-2008-3389	1942 - Soy Isoflavones + Royal Jelly / Royal Jelly + pollen - Mental state and performance. Physical performance and fitness	Nutrition N/A		Withdrawn		13/04/2011 16:33
M-2008-1061	EFSA-Q-2008-3055	1862 - Soy Isoflavones + Royal Jelly - Sexual organs and/or hormone activity	Nutrition N/A		Withdrawn		13/04/2011 16:33
M-2008-1061	EFSA-Q-2008-4328	1861 - Soy Isoflavones + Royal Jelly - Immunity	Nutrition N/A		Withdrawn		13/04/2011 16:33

			substantiated.					
Art.13(1)	Soy Isoflavones	Helps to maintain a calm and comfortable menopause /helps women coping with the telltale signs associated with menopause, such as hot flushes, sweating, restlessness and irritability	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, the evidence provided is insufficient to substantiate this claimed effect for this food.	Reduction of vasomotor symptoms associated with menopause	2011;9(7):2264, 2012;10(8):2847		Non-authorised (expiry of transitional period 02/01/2014)	1654
Art.13(1)	Soy Isoflavones	Maintenance of healty bones /(natural) /support to bone health /contributes to the maintenance of normal bone strength in post-menopausal women	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, the evidence provided is insufficient to substantiate this claimed effect for this food.	Maintenance of bone mineral density	2009;7(9):1270, 2012;10(8):2847		Non-authorised (expiry of transitional period 02/01/2014)	1655

Hay que mirar el listado de la Comisión

FOR THE ATTENTION OF THE MEMBER STATES AND THE COMMISSION

SUPPORTING WORKING DOCUMENT (NOT FOR VOTE)
STANDING COMMITTEE OF THE FOOD CHAIN AND ANIMAL HEALTH
4 FEBRUARY 2013
AGENDA ITEM B.1 (SANCO/12712/2012)

ARTICLE 13.1 CLAIMS FOR WHICH THE EVALUATION BY THE EUROPEAN FOOD SAFETY AUTHORITY AND THE CONSIDERATION BY THE COMMISSION AND THE MEMBER STATES IS NOT FINALISED

Especies botánicas

Directiva 2004/24: Seguridad

DIRECTIVA 2004/24/CE DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 31 de marzo de 2004

por la que se modifica, en lo que se refiere a los medicamentos tradicionales a base de plantas, la Directiva 2001/83/CE, por la que se establece un código comunitario sobre medicamentos para uso humano

Reglamento 1924/2006: Función

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

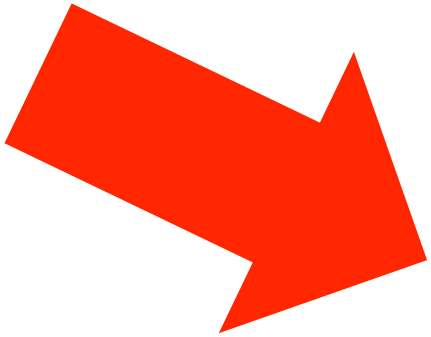
de 20 de diciembre de 2006

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

Dudas: Declaraciones no autorizadas aún

(10) La Comisión ha constatado que la Autoridad no ha concluido aún la evaluación científica de una serie de declaraciones sometidas a evaluación que se refieren a los efectos de determinadas sustancias vegetales o a base de plantas, comúnmente conocidas como sustancias «botánicas». Además, existe una serie de declaraciones de propiedades saludables respecto a las cuales la Comisión, o bien demanda una evaluación más exhaustiva antes de poder considerar su incorporación a la lista de declaraciones autorizadas o no puede decidir aún sobre su inclusión en la lista, aunque ya hayan sido evaluadas, debido a otros factores lícitos.

(11) Las declaraciones cuya evaluación por parte de la Autoridad o cuyo examen por parte de la Comisión no haya finalizado todavía se publican en el sitio web de la Comisión ([1]) y pueden seguir utilizándose, de conformidad con el artículo 28, apartados 5 y 6, del Reglamento (CE) nº 1924/2006.



(13) El presente Reglamento debe aplicarse seis meses después de la fecha de su entrada en vigor para que los explotadores de empresas alimentarias puedan adaptarse a sus requisitos, lo que incluye la prohibición, conforme a lo dispuesto en el artículo 10, apartado 1, del Reglamento (CE) nº 1924/2006, de determinadas declaraciones de propiedades saludables cuya evaluación por parte de la Autoridad o cuyo examen por parte de la Comisión haya finalizado.

Declaraciones 13(1) pendientes o en espera

Declaraciones pendientes

Hidratos De carbono

Cafeína

Nueva legislación dietéticos:

Very Low Calory Diet

Contenido reducido en lactosa

Homepage

Food Labelling

Health & Nutrition Claims

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Nutrition Labelling

Mineral Waters

Health claims subject to individual authorisation procedure

- Claims based on new scientific evidence and/or including a request for the protection of proprietary data - Article 13(5)
- Claims referring to the reduction of a risk factor in the development of a disease - Article 14(1)(a)
- Claims referring to children's development and health - Article 14(1)(b)

The Commission makes publicly available comments it has received from applicants and the public (according to Article 16(6) of the Regulation) until it makes a decision on the relevant health claim.

Processing of personal data is handled according to Regulation (EC) No 45/2001 and a specific privacy statement

You can see health claims for which a decision has been taken on the EU Register

Search criteria

Search:

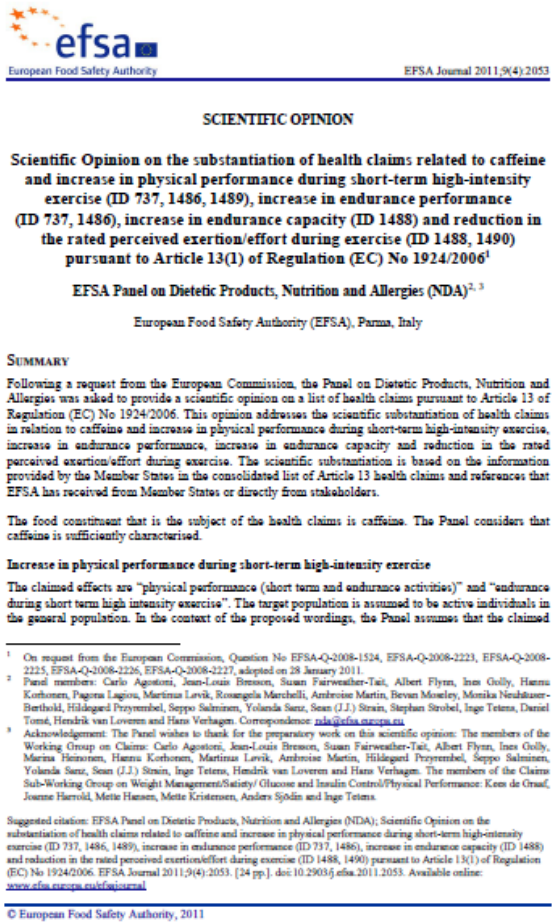
EFSA Opinion reference: EFSA opinion reference ▼

EFSA reference year: EFSA reference year ▼

EFSA Opinion receipt date: EFSA opinion receipt date ▼

The table will automatically refresh based upon the selections you make. **Clear filters**

Pendiente: Valoración de riesgo



European Food Safety Authority EFSA Journal 2011;9(4):2053

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to caffeine and increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489), increase in endurance performance (ID 737, 1486), increase in endurance capacity (ID 1488) and reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to caffeine and increase in physical performance during short-term high-intensity exercise, increase in endurance performance, increase in endurance capacity and reduction in the rated perceived exertion/effort during exercise. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is caffeine. The Panel considers that caffeine is sufficiently characterised.

Increase in physical performance during short-term high-intensity exercise

The claimed effects are "physical performance (short term and endurance activities)" and "endurance during short term high intensity exercise". The target population is assumed to be active individuals in the general population. In the context of the proposed wordings, the Panel assumes that the claimed

[1] On request from the European Commission, Question No EFSA-Q-2008-1524, EFSA-Q-2008-2223, EFSA-Q-2008-2225, EFSA-Q-2008-2226, EFSA-Q-2008-2227, adopted on 28 January 2011.

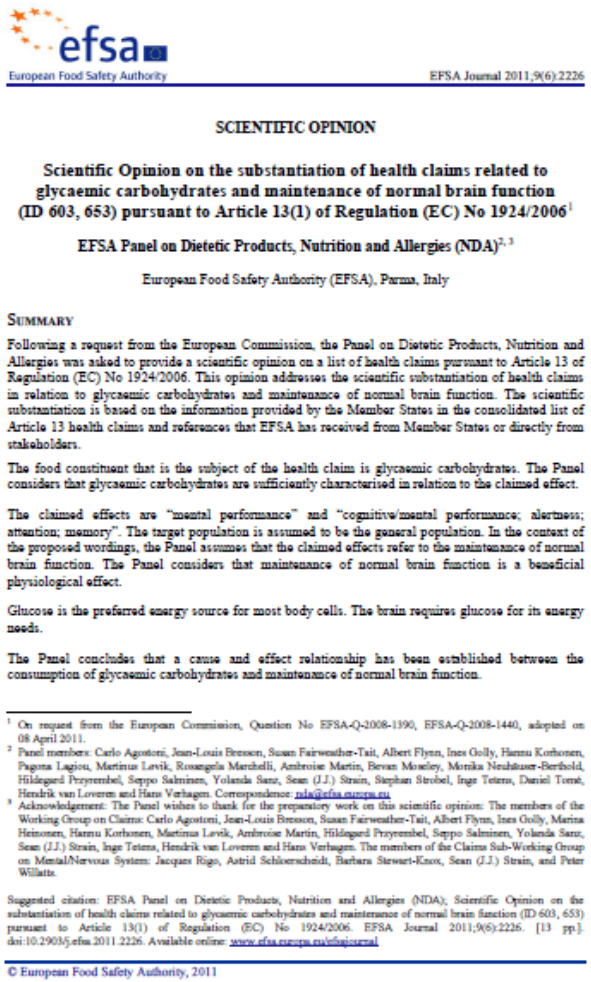
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Weight Management/Satiety/ Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to caffeine and increase in physical performance during short-term high-intensity exercise (ID 737, 1486, 1489), increase in endurance performance (ID 737, 1486), increase in endurance capacity (ID 1488) and reduction in the rated perceived exertion/effort during exercise (ID 1488, 1490) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2053. [24 pp.]. doi:10.2903/j.efsa.2011.2053. Available online: www.efsa.europa.eu/efsajournal

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Glycaemic carbohydrates	Glycaemic carbohydrates contribute to the maintenance of normal brain function	[*Conditions of use to be discussed – EFSA's proposed CoU:* A daily intake of 130 g of glycaemic carbohydrates has been estimated to cover the glucose requirement of the brain. Such amounts can be consumed as part of a balanced diet. The target population is the general population.]		2011;9(6):2226	603, 653

Pendiente: Condiciones de uso



European Food Safety Authority

EFSA Journal 2011;9(6):2226

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function (ID 603, 653) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to glycaemic carbohydrates and maintenance of normal brain function. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is glycaemic carbohydrates. The Panel considers that glycaemic carbohydrates are sufficiently characterised in relation to the claimed effect.

The claimed effects are "mental performance" and "cognitive/mental performance; alertness; attention; memory". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal brain function. The Panel considers that maintenance of normal brain function is a beneficial physiological effect.

Glucose is the preferred energy source for most body cells. The brain requires glucose for its energy needs.

The Panel concludes that a cause and effect relationship has been established between the consumption of glycaemic carbohydrates and maintenance of normal brain function.

[1] On request from the European Commission, Question No EFSA-Q-2008-1390, EFSA-Q-2008-1440, adopted on 08 April 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to glycaemic carbohydrates and maintenance of normal brain function (ID 603, 653) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2226. [13 pp.]. doi:10.2903/j.efsa.2011.2226. Available online: www.efsa.europa.eu/efsajournal

Pendientes: Nueva legislación de Dietéticos

Very Low Calory Diets

efsa

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to very low calorie diets (VLCDs) and reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), reduction in body fat mass while maintaining lean body mass (ID 1412), reduction of post-prandial glycaemic responses (ID 1414), and maintenance of normal blood lipid profile (1421) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to very low calorie diets (VLCDs) and reduction in body weight, reduction in the sense of hunger, reduction in body fat mass while maintaining lean body mass, reduction of post-prandial glycaemic responses, and maintenance of normal blood lipid profile. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The diet that is the subject of the claims is "very low calorie diet (VLCD) program". The Panel considers that whereas the diet that is the subject of the claim, very low calorie diet, is sufficiently characterised in relation to the following claimed effects: reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), and reduction in body fat mass while maintaining lean body mass (ID 1412), very low calorie diet is not sufficiently characterised in relation to reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile

Reducido en Lactosa

efsa

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to foods with reduced lactose content and decreasing gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals (ID 646, 1224, 1238, 1339) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to foods with reduced lactose content and decreasing gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is lactose, which should be "decreased" or "reduced" in foods in order to obtain the claimed effect. The Panel considers that lactose is sufficiently characterised.

The claimed effects are "lactose intolerance", "decrease lactose malabsorption symptoms" and "lactose digestion". The target population is assumed to be lactose intolerant individuals. The Panel assumes that the claimed effects refer to decreasing gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals. The Panel considers that decreasing gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals is a beneficial physiological effect for lactose intolerant individuals.

Symptoms of lactose intolerance, which may develop one to three hours after lactose-deficient and lactose intolerant individuals ingest lactose in food, include abdominal pain, bloating, flatulence and

Pendientes: Sin condiciones de uso o ininteligibles

L-Arginine	L-Arginine contributes to the maintenance of normal ammonia clearance	*[Conditions of use to be discussed – EFSA proposed no CoU]*		2011;9(4):2051	4683
L-Tyrosine	L-Tyrosine contributes to normal synthesis of catecholamines	The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(6):2270	1928

Dudas: Es el Registro un "instrumento legal"?

(14) De conformidad con el artículo 20, apartado 1, del Reglamento (CE) nº 1924/2006, la Comisión debe establecer y mantener un registro de la Unión de declaraciones nutricionales y de propiedades saludables relativas a los alimentos, denominado en lo sucesivo «el Registro». El Registro debe recoger todas las declaraciones autorizadas y las condiciones de uso aplicables a las mismas. Asimismo, ha de incluir una lista de las declaraciones de propiedades saludables denegadas junto con los motivos de la denegación.

Dudas: Qué prevalece?

(17) La adición de sustancias a los alimentos y su utilización en ellos se rigen por la legislación nacional y de la Unión correspondiente, al igual que sucede con la clasificación de los productos como alimentos o medicamentos. Cualquier decisión sobre una declaración de propiedades saludables de conformidad con el Reglamento (CE) nº 1924/2006, como es el caso de la incorporación de una declaración a la lista de declaraciones autorizadas a la que se refiere su artículo 13, apartado 3, no constituye una autorización de comercialización de la sustancia a la que concierne la declaración, ni una decisión sobre la posibilidad de utilizar la sustancia en productos alimenticios ni la clasificación de un determinado producto como alimento.

Oggetto: Rivalutazione degli apporti ammessi di melatonina negli integratori alimentari

Il Regolamento (UE) 432/2012 ha istituito l'elenco dei claims sulla salute autorizzati ai sensi dell'articolo 13.1 del Regolamento (CE) 1924/2006 per vitamine, minerali e altre sostanze (ad eccezione di quelli sui "botanicals" che restano tuttora in sospeso).

Nell'elenco suddetto sono riportate per ogni sostanza le "condizioni d'uso" con l'indicazione dell'apporto quantitativo richiesto per il claim ed eventuali "restrizioni d'uso" e/o avvertenze supplementari.

Ciò premesso, va considerato che gli apporti quantitativi di una sostanza per la quale è autorizzato un claim sulla salute hanno una valenza di tipo "fisiologico" perché sono finalizzati a contribuire al normale svolgimento delle funzioni dell'organismo.

Per quanto riguarda la melatonina, il regolamento (UE) 432/2012 consente due tipi di claims:

- *"contribuisce ad alleviare gli effetti del jet lag"*, indicando in etichetta al consumatore che l'effetto benefico si ottiene con l'assunzione, poco prima di coricarsi, di un minimo di 0,5 mg della sostanza il primo giorno di viaggio e per alcuni giorni dopo l'arrivo a destinazione;
- *"contribuisce alla riduzione del tempo richiesto per prendere sonno"*, indicando in etichetta al consumatore che l'effetto benefico si ottiene con l'assunzione, poco prima di coricarsi, di 1 mg della sostanza.

Oggi risultano quindi definiti i livelli di melatonina utili per effetti fisiologici sulla base delle valutazioni scientifiche dell'EFSA e, nel contempo, vi sono sul mercato dell'Unione europea prodotti a base della stessa sostanza autorizzati come medicinali con dosaggi giornalieri pari a 2 mg

Occorre pertanto ridurre i livelli di apporto di melatonina ammessi finora in Italia negli integratori alimentari per una demarcazione dell'impiego della sostanza per finalità di tipo fisiologico rispetto a quelle di tipo terapeutico.

A tal fine, nella situazione attuale, si ritiene che negli integratori alimentari l'apporto giornaliero di melatonina di 1 mg, utile a supportare i claims sulla salute autorizzati, debba essere considerato nello stesso tempo anche l'apporto massimo ammissibile per finalità di tipo fisiologico.

Per quanto sopra **si invitano le imprese interessate a conformarsi, a partire dalle prossime produzioni, al nuovo limite di impiego affinché l'apporto di melatonina negli integratori alimentari rientri entro 1 mg con le quantità di assunzione giornaliera consigliate in etichetta.**

In ogni caso la commercializzazione di integratori alimentari con l'apporto di melatonina ammesso in precedenza è consentita non oltre il 30 settembre 2013.

Si invita a dare la massima diffusione alla presente nota e si ringrazia per la collaborazione.

Firmato Silvio Borrello

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD · agencia española de seguridad alimentaria y nutrición

Agencia Española de Seguridad Alimentaria y Nutrición

Actualización condiciones de uso de MELATONINA en complementos alimenticios

04/07/2013

El pasado 24 de junio el Ministerio de la Salud Italiano publicó en su página web una nota informando de la reevaluación del aporte permitido de melatonina en los complementos alimenticios.

En dicha nota, se concluye que la dosis diaria permitida de melatonina en los complementos alimenticios pasa de 5 mg a 1 mg, por lo que se solicita a las empresas que adapten el contenido de sus productos a la nueva dosis establecida (1 mg dosis máxima diaria recomendada), permitiendo la comercialización de los complementos alimenticios con la dosis de melatonina admitida anteriormente hasta el 30 de septiembre de 2013.

En España los complementos alimenticios que contienen melatonina se han comercializado hasta el momento por aplicación del principio de reconocimiento mutuo al estar legalmente comercializados en Italia, siempre y cuando la dosis fuera inferior a 2 mg diarios, ya que por encima de esa dosis, en España tiene consideración de medicamento.

Debido a la revisión de la dosis de melatonina en complementos alimenticios permitida en Italia, las empresas que comercialicen en España complementos alimenticios con melatonina deberán adaptar sus productos al nuevo límite establecido para que la dosis máxima diaria esté dentro de los límites de 1 mg de melatonina al día.

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006	The Panel considers that the claim "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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European Food Safety Authority
EFSA Journal 2011;9(6):2169

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from EJP Pharmaceutical ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath. The Panel considers that the proposed claim is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006. © European Food Safety Authority, 2011

KEY WORDS

Zinc, bad breath, health claims.

[1] On request from the Competent Authority of Denmark following an application by EJP Pharmaceutical ApS, Question No EFSA-Q-2010-01092, adopted on 13 May 2011.

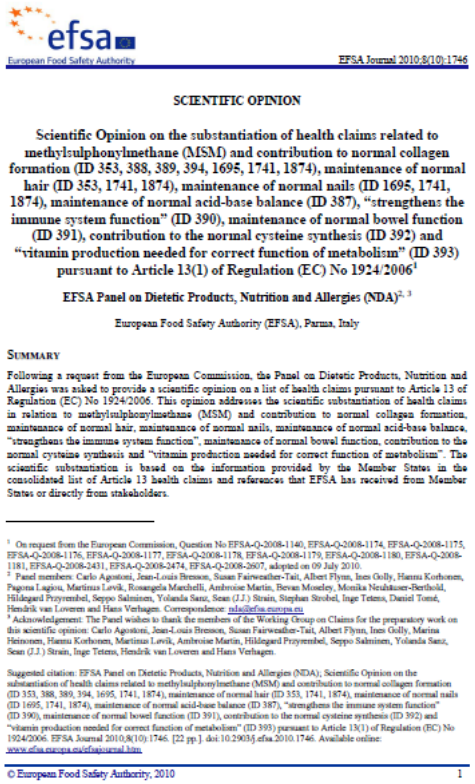
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2169. [7 pp.]. doi:10.2903/j.efsa.2011.2169. Available online: www.efsa.europa.eu/efsajournal

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to methylsulphonylmethane (MSM) and contribution to normal collagen formation (ID 353, 388, 389, 394, 1695, 1741, 1874), maintenance of normal hair (ID 353, 1741, 1874), maintenance of normal nails (ID 1695, 1741, 1874), maintenance of normal acid-base balance (ID 387), "strengthens the immune system function" (ID 390), maintenance of normal bowel function (ID 391), contribution to the normal cysteine synthesis (ID 392) and "vitamin production needed for correct function of metabolism" (ID 393) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	"Vitamin production needed for correct function of metabolism" The claimed effect is "metabolism of vitamins". The target population is assumed to be the general population. In the context of the proposed wording and the clarifications provided by Member States, the Panel notes that the claim refers to "vitamin production needed for correct function of metabolism" and "supports the production of vitamin C, H, B5, B13" which cannot be considered as a health relationship applicable to humans. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.



efsa
European Food Safety Authority
EFSA Journal 2010;8(10):1746

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to methylsulphonylmethane (MSM) and contribution to normal collagen formation (ID 353, 388, 389, 394, 1695, 1741, 1874), maintenance of normal hair (ID 353, 1741, 1874), maintenance of normal nails (ID 1695, 1741, 1874), maintenance of normal acid-base balance (ID 387), "strengthens the immune system function" (ID 390), maintenance of normal bowel function (ID 391), contribution to the normal cysteine synthesis (ID 392) and "vitamin production needed for correct function of metabolism" (ID 393) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to methylsulphonylmethane (MSM) and contribution to normal collagen formation, maintenance of normal hair, maintenance of normal nails, maintenance of normal acid-base balance, "strengthens the immune system function", maintenance of normal bowel function, contribution to the normal cysteine synthesis and "vitamin production needed for correct function of metabolism". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

[1] On request from the European Commission, Question No EFSA-Q-2008-1140, EFSA-Q-2008-1174, EFSA-Q-2008-1175, EFSA-Q-2008-1176, EFSA-Q-2008-1177, EFSA-Q-2008-1178, EFSA-Q-2008-1179, EFSA-Q-2008-1180, EFSA-Q-2008-1181, EFSA-Q-2008-2431, EFSA-Q-2008-2474, EFSA-Q-2008-2607, adopted on 09 July 2010.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to methylsulphonylmethane (MSM) and contribution to normal collagen formation (ID 353, 388, 389, 394, 1695, 1741, 1874), maintenance of normal hair (ID 353, 1741, 1874), maintenance of normal nails (ID 1695, 1741, 1874), maintenance of normal acid-base balance (ID 387), "strengthens the immune system function" (ID 390), maintenance of normal bowel function (ID 391), contribution to the normal cysteine synthesis (ID 392) and "vitamin production needed for correct function of metabolism" (ID 393) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1746. [22 pp.]. doi:10.2903/j.efsa.2010.1746. Available online: www.efsa.europa.eu/efsajournal.htm

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to gamma linolenic acid (GLA) and maintenance of normal blood LDL cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The claimed effect is "function of the cell membrane". The target population is assumed to be the general population. The Panel notes that several properties of cell membranes have been mentioned in the proposed wordings and that a specific effect related to the function of cell membranes has not been identified. The Panel considers that the claim is general and non-specific and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006. Maintenance of normal structure, elasticity and appearance of the skin The claimed effects are "helps to maintain elasticity, tenderness and health of skin, structure and function of skin and mucous membrane", and "membranes cell structure". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of the normal structure, elasticity and appearance of the skin. The Panel considers that the claims do not refer to a function of the body as required by Regulation (EC) No 1924/2006.

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), "function of the cell membrane" (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and "anti-inflammatory properties" (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to gamma-linolenic acid and maintenance of normal blood LDL-cholesterol concentrations, maintenance of normal blood pressure, reduction of menstrual discomfort, contribution to normal cognitive function, maintenance of the barrier function of the skin, "function of the cell membrane", maintenance of normal structure, elasticity and appearance of the skin, and "anti-inflammatory properties". The scientific substantiation is based on the information provided by the Member States

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Hay muchas dudas sobre si los “claims cosméticos” están sujetos al Reglamento (se han excluido de la lista del artículo 13)

Committee of Advertising Practice
Mid City Place 71 High Holborn London WC1V 6QT
Telephone 020 7492 2200 Fax 020 7404 3404
Textphone 020 7242 8159 Email enquiries@cap.org.uk
Online www.cap.org.uk

Committee of Advertising Practice
(Non-broadcast)

Help Note on Substantiation for Health, Beauty and Slimming Claims

CAP Help Notes offer guidance for non-broadcast marketing communications under the British Code of Advertising, Sales Promotions and Direct Marketing (the CAP Code). For advice on the rules for TV or radio commercials, contact Clearcast www.clearcast.co.uk for TV ads or the RACC www.racc.co.uk for

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to Lactobacillus rhamnosus LB21 NCIMB 40564 and decreasing potentially pathogenic intestinal microorganisms (ID 1064), digestive health (ID 1064), and reduction of mutans streptococci in the oral cavity (ID 1064) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The claimed effect "digestive health" is not sufficiently defined. In the context of the proposed wording ('supporting gastrointestinal conditions during antibiotic treatment') and from the references provided, the Panel assumes that the claimed effect relates to acute diarrhoea associated with antibiotic treatment, and that the target group is subjects receiving antibiotic treatment under medical supervision. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to *Lactobacillus rhamnosus* LB21 NCIMB 40564 and decreasing potentially pathogenic intestinal microorganisms (ID 1064), digestive health (ID 1064), and reduction of mutans streptococci in the oral cavity (ID 1064) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

European Food Safety Authority (EFSA), Parma, Italy

Summary

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming an increase in renal water elimination, “kidneys health”, “urinary health”, “bladder health”, “health of lower urinary tract”, “blood health”, “elimination”, “urinary system benefits” and/or “supports/promotes the excretory function of the kidney”, and treatment/prevention of renal gravel/kidney stones and urinary tract infections pursuant to Article 13(1) of Regulation (EC) No 1924/2006	Treatment/prevention of renal gravel/kidney stones and urinary tract infections The claimed effects are “système urinaire, diurétique, anti-inflammatoire des voies urinaires, prévention des calculs rénaux” and “health of urinary tract”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect is related to the treatment/prevention of renal gravel/kidney stones and urinary tract infections. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.


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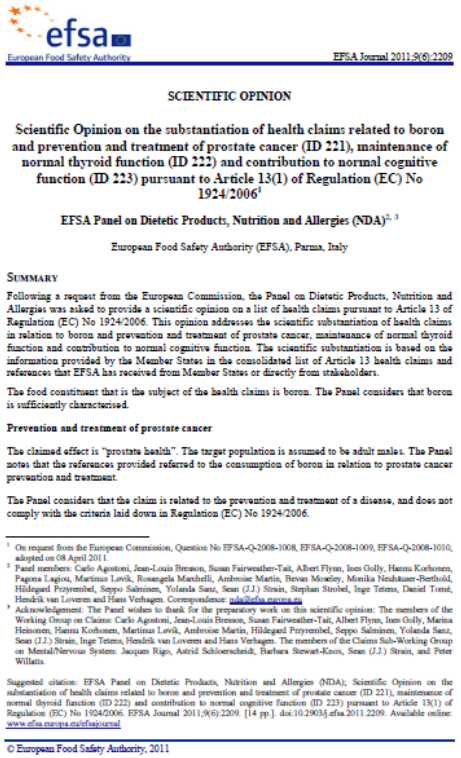
SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming an increase in renal water elimination, “kidneys health”, “urinary health”, “bladder health”, “health of lower urinary tract”, “blood health”, “elimination”, “urinary system benefits” and/or “supports/promotes the excretory function of the kidney”, and treatment/prevention of renal gravel/kidney stones and urinary tract infections pursuant to Article 13(1) of Regulation (EC) No 1924/2006

Un asunto interesante: Los claims que no son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	Prevention and treatment of prostate cancer The claimed effect is "prostate health". The target population is assumed to be adult males. The Panel notes that the references provided referred to the consumption of boron in relation to prostate cancer prevention and treatment. The Panel considers that the claim is related to the prevention and treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.



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European Food Safety Authority
EFSA Journal 2011;9(6):2209

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to boron and prevention and treatment of prostate cancer, maintenance of normal thyroid function and contribution to normal cognitive function. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is boron. The Panel considers that boron is sufficiently characterised.

Prevention and treatment of prostate cancer

The claimed effect is "prostate health". The target population is assumed to be adult males. The Panel notes that the references provided referred to the consumption of boron in relation to prostate cancer prevention and treatment.

The Panel considers that the claim is related to the prevention and treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

[1] On request from the European Commission, Question No EFSA-Q-2008-1008, EFSA-Q-2008-1009, EFSA-Q-2008-1010, adopted on 08 April 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2209. [14 pp.]. doi:10.2903/j.efsa.2011.2209. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to Vitis vinifera L. seeds extract and “helps to decrease swollen legs” pursuant to Article 13(5) of Regulation (EC) No 1924/2006	The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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EFSA Journal 2012;10(12):2997

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs” pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs”. The Panel considers that the food constituent which is the subject of the health claim is sufficiently characterised. Upon EFSA’s request for clarification, the applicant stated that the claimed effect was “helps to decrease swollen legs”, and that the beneficial physiological effect could be related to “helps to refine legs”. In the context of the references provided for the scientific substantiation of the claim, and in particular of the human intervention study which was conducted with the food constituent that is the subject of the health claim, the Panel notes that the claim refers to the reduction of peripheral oedema in the context of chronic clinical conditions (e.g. chronic venous insufficiency) where the reduction of peripheral oedema is a therapeutic target for the treatment of the condition. The Panel considers that the reduction of peripheral oedema in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Vitis vinifera, swollen legs, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00388, adopted on 28 November 2012.

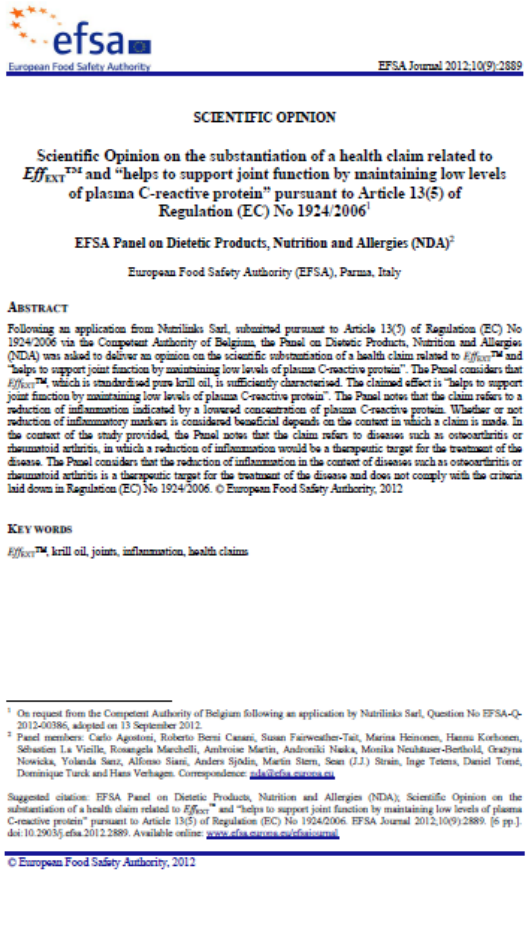
[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Dominique Turck, Hendrik van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to *Vitis vinifera* L. seeds extract and “helps to decrease swollen legs” pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(12):2997. [8 pp.]. doi:10.2903/j.efsa.2012.2997. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of a health claim related to EffEXT™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.	Scientific Opinion on the substantiation of a health claim related to EffEXT™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.



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EFSA Journal 2012;10(9):2889

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel considers that *Eff*$_{EXT}$™, which is standardised pure krill oil, is sufficiently characterised. The claimed effect is "helps to support joint function by maintaining low levels of plasma C-reactive protein". The Panel notes that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein. Whether or not reduction of inflammatory markers is considered beneficial depends on the context in which a claim is made. In the context of the study provided, the Panel notes that the claim refers to diseases such as osteoarthritis or rheumatoid arthritis, in which a reduction of inflammation would be a therapeutic target for the treatment of the disease. The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Eff$_{EXT}$™, krill oil, joints, inflammation, health claims

[1] On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00386, adopted on 13 September 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to *Eff*$_{EXT}$™ and "helps to support joint function by maintaining low levels of plasma C-reactive protein" pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2012;10(9):2889. [6 pp.]. doi:10.2903/j.efsa.2012.2889. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to gamma linolenic acid (GLA) and maintenance of normal blood LDL cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), “function of the cell membrane” (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and “anti-inflammatory properties” (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The Panel considers that the reduction of inflammation in the context of chronic clinical conditions is a therapeutic target for the treatment of the condition.

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EFSA Journal 2011;9(4):2059

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), “function of the cell membrane” (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and “anti-inflammatory properties” (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to gamma-linolenic acid and maintenance of normal blood LDL-cholesterol concentrations, maintenance of normal blood pressure, reduction of menstrual discomfort, contribution to normal cognitive function, maintenance of the barrier function of the skin, “function of the cell membrane”, maintenance of normal structure, elasticity and appearance of the skin, and “anti-inflammatory properties”. The scientific substantiation is based on the information provided by the Member States

[1] On request from the European Commission, Question No EFSA-Q-2008-1282, EFSA-Q-2008-1286, EFSA-Q-2008-1378, EFSA-Q-2008-1426, EFSA-Q-2008-1427, EFSA-Q-2008-1463, EFSA-Q-2008-2291, EFSA-Q-2008-2502, EFSA-Q-2008-2503, EFSA-Q-2008-2506, EFSA-Q-2008-2508, EFSA-Q-2008-2736, EFSA-Q-2008-2798, EFSA-Q-2008-3393, EFSA-Q-2008-3394, EFSA-Q-2008-3395, EFSA-Q-2010-00249, EFSA-Q-2010-00405, EFSA-Q-2010-00406, EFSA-Q-2010-00407, adopted on 28 January 2011.

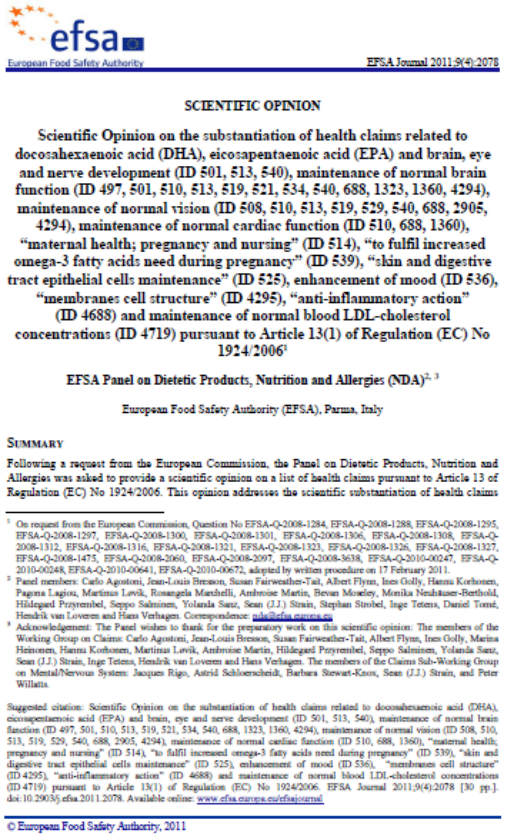
[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), “function of the cell membrane” (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and “anti-inflammatory properties” (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2059. [27 pp.]. doi:10.2903/j.efsa.2011.2059. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), “maternal health; pregnancy and nursing” (ID 514), “to fulfil increased omega-3 fatty acids need during pregnancy” (ID 539), “skin and digestive tract epithelial cells maintenance” (ID 525), enhancement of mood (ID 536), “membranes cell structure” (ID 4295), “anti-inflammatory action” (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006	The Panel considers that the reduction of inflammation in the context of inflammatory diseases is a therapeutic target for the treatment of a disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.



efsa
European Food Safety Authority

EFSA Journal 2011;9(4):2078

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), “maternal health; pregnancy and nursing” (ID 514), “to fulfil increased omega-3 fatty acids need during pregnancy” (ID 539), “skin and digestive tract epithelial cells maintenance” (ID 525), enhancement of mood (ID 536), “membranes cell structure” (ID 4295), “anti-inflammatory action” (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims

[1] On request from the European Commission, Question No EFSA-Q-2008-1284, EFSA-Q-2008-1288, EFSA-Q-2008-1295, EFSA-Q-2008-1297, EFSA-Q-2008-1300, EFSA-Q-2008-1301, EFSA-Q-2008-1306, EFSA-Q-2008-1308, EFSA-Q-2008-1312, EFSA-Q-2008-1316, EFSA-Q-2008-1321, EFSA-Q-2008-1323, EFSA-Q-2008-1326, EFSA-Q-2008-1327, EFSA-Q-2008-1475, EFSA-Q-2008-2060, EFSA-Q-2008-2097, EFSA-Q-2008-3638, EFSA-Q-2010-00247, EFSA-Q-2010-00248, EFSA-Q-2010-00641, EFSA-Q-2010-00672, adopted by written procedure on 17 February 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

Suggested citation: Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and brain, eye and nerve development (ID 501, 513, 540), maintenance of normal brain function (ID 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294), maintenance of normal vision (ID 508, 510, 513, 519, 529, 540, 688, 2905, 4294), maintenance of normal cardiac function (ID 510, 688, 1360), “maternal health; pregnancy and nursing” (ID 514), “to fulfil increased omega-3 fatty acids need during pregnancy” (ID 539), “skin and digestive tract epithelial cells maintenance” (ID 525), enhancement of mood (ID 536), “membranes cell structure” (ID 4295), “anti-inflammatory action” (ID 4688) and maintenance of normal blood LDL-cholesterol concentrations (ID 4719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2078 [30 pp.]. doi:10.2903/j.efsa.2011.2078. Available online: www.efsa.europa.eu/efsajournal

Otro asunto interesante: Los claims terapéuticos que tampoco son claims!

EFSA Opinion	Conclusion
"Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006"	The Panel considers that the reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of the disease, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006

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EFSA Journal 2011;9(4):2033

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to polyphenols in olive and protection of LDL particles from oxidative damage, maintenance of normal blood HDL-cholesterol concentrations, maintenance of normal blood pressure, "anti-inflammatory properties", "contributes to the upper respiratory tract health", "can help to maintain a normal function of gastrointestinal tract", and "contributes to body defences against external agents". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

[1] On request from the European Commission, Question No EFSA-Q-2008-2070, EFSA-Q-2008-2374, EFSA-Q-2008-2375, EFSA-Q-2008-2432, EFSA-Q-2008-2615, EFSA-Q-2008-3598, EFSA-Q-2008-4195, EFSA-Q-2008-4196, EFSA-Q-2008-4498, EFSA-Q-2008-4500, adopted on 12 November 2010.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL-cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468), "can help to maintain a normal function of gastrointestinal tract" (3779), and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2033 [25 pp.]. doi:10.2903/j.efsa.2011.2033. Available online: www.efsa.europa.eu/efsajournal

Diferencias

Declaraciones de Reducción de Riesgo de Enfermedad	Declaraciones Medicinales
Referencia a la reducción de un factor de riesgo de desarrollo de la enfermedad.	Referencia a la reducción del riesgo de desarrollo de la enfermedad.
No relación directa causa-efecto.	Relación directa causa-efecto.
Futuro / Efecto benéfico a largo plazo (enfoque basado en la nutrición).	Inmediato/ Efecto benéfico a corto plazo.
Población objetivo- sana.	Población objeto-diagnosticada.

Claims que no son claims. Los no aplicables a humanos

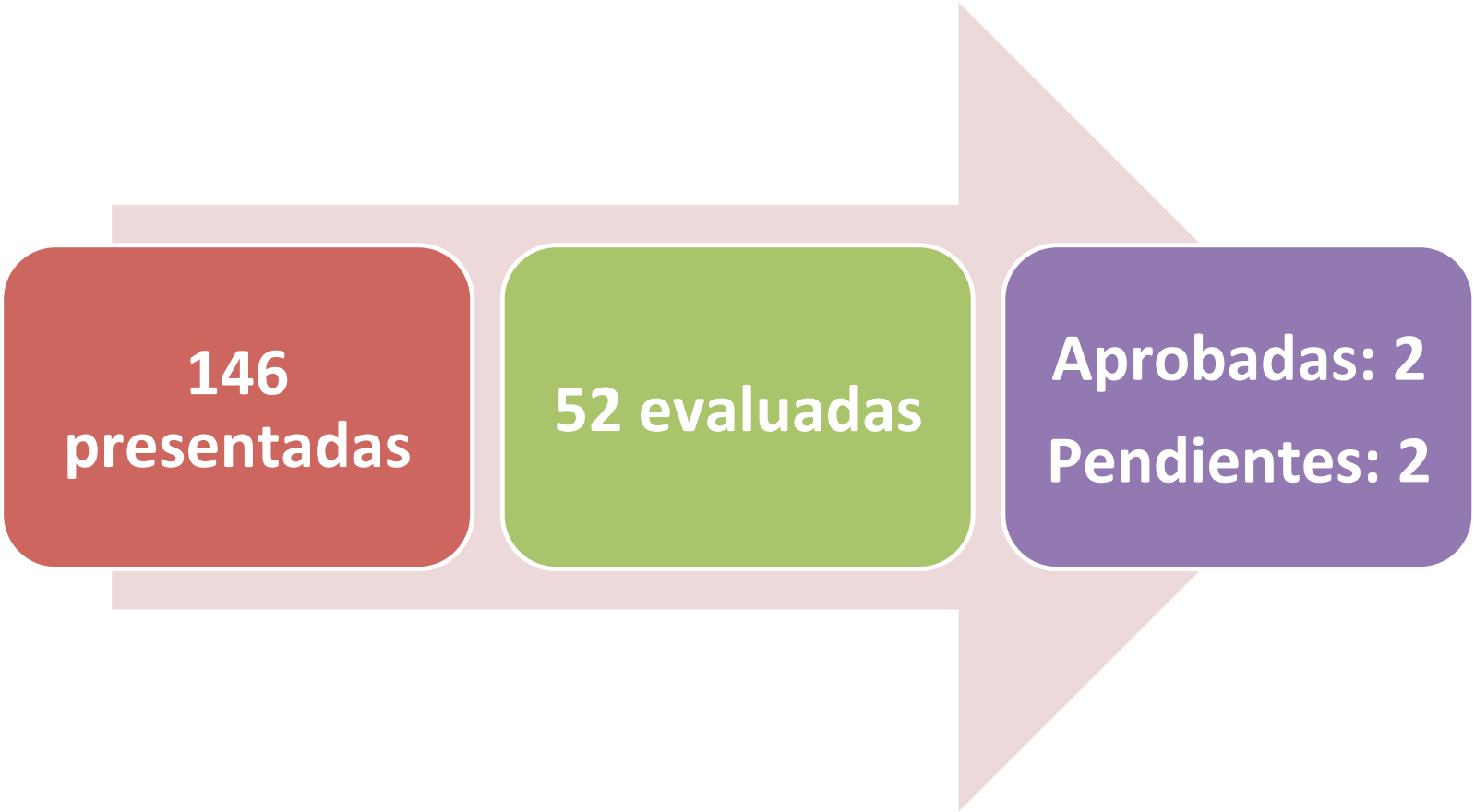
CLAIMS NOT RELATING TO HUMAN HEALTH

Non-compliance with the Regulation because on the basis of the evidence assessed this claim relates to effects which cannot be considered applicable to humans.

The IDs (as found in the consolidated list) are given below.

393

Declaraciones saludables bajo el artículo 13.5



Declaraciones por el 13(5)

WSTE.

Fibra de remolacha.

Flavanoles de cacao (Barry Callebaut). Consumo en “dieta equilibrada”.

Almidón de digestibilidad lenta (Kraft). Control de inspección

Atención: Expiración del periodo transitorio!

Art.13(5)	Spermidine	Spermidine prolongs the growing phase (anagen) of the hair cycle	this claimed effect relates to the treatment of a disease which is prohibited for foods Non-compliance with the Regulation because on the basis of the scientific evidence assessed,		Q-2011-00896	Commission Regulation (EU) No 1017/2013 of 23/10/2013	Non-authorised (expiry of transitional period 13/05/2014)	N/A
Art.13(5)	Bimuno® (Bimuno® GOS)	Regular daily consumption of 1.37 g galacto-oligosaccharides from Bimuno® may reduce intestinal discomfort	Non-compliance with the Regulation because on the basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated		Q-2011-00401	Commission Regulation (EU) No 1017/2013 of 23/10/2013	Non-authorised (expiry of transitional period 13/05/2014)	N/A

Declaraciones saludables bajo el artículo 14 (285 presentadas)

14.1.a

- **Aprobadas: 9.**
- **Denegadas: 15.**

14.1.b

- **Aprobadas: 11.**
- **Denegadas: 36.**

Declaraciones aprobadas por el 14

Beta-Glucanos.

Fitoesteroles/Fitoestanoles.

Xylitol.

Chicle sin azúcar.

DHA.

LA/LNA.

Calcio.

Calcio + vitamina D.

Fósforo.

Yodo.

Hierro.

Proteína.

Qué se puede declarar hoy?

13: 229

13.5: 1*

14.1.a: 9

14.1.b: 11

Codex Alimentarius. Etiquetado Engañoso de Alimentos (2001)

COMUNICACIONES	DESCRIPCIÓN
Omisión de hechos materiales	Una comunicación es engañosa debido a que se ha omitido un hecho pertinente.
Engaños basados en la confusión	Una comunicación es engañosa debido a lenguaje, símbolos o imágenes confusas.
Engaños debidos al mismo atributo	Una comunicación verídica sobre un atributo de un producto lleva a inferencias engañosas sobre el mismo atributo en ese producto o en otros productos en la misma categoría o en una categoría similar.
Engaños debidos a diferentes atributos	Una comunicación verídica sobre un atributo de un producto lleva a inferencias engañosas sobre un atributo diferente en ese producto o en otros productos en la misma categoría o en una categoría similar.
Engaños debidos a la fuente citada	Una declaración de apoyo de una organización o individuo (s) lleva a inferencias engañosas.

Futuras acciones contra los fraudes?

P7_TA-PROV(2014)0011

Crisis alimentaria, fraudes en la cadena alimentaria y control al respecto

Resolución del Parlamento Europeo, de 14 de enero de 2014, sobre la crisis alimentaria, los fraudes en la cadena alimentaria y el control al respecto (2013/2091(INI))

El Parlamento Europeo,

– Visto el plan de actuación basado en cinco ejes[1] que presentó la Comisión en marzo de 2013 tras el descubrimiento de una amplia red de fraude que comercializaba carne de caballo como carne de vacuno,

– Visto el Reglamento (CE) nº 882/2004 del Parlamento Europeo y del Consejo, de 29 de abril de 2004, sobre los controles oficiales efectuados para garantizar la verificación del cumplimiento de la legislación en materia de piensos y alimentos y la normativa sobre salud animal y bienestar de los animales,

– Visto el Reglamento (CE) nº 178/2002 del Parlamento Europeo y del Consejo, de 28 de enero de 2002, por el que se establecen los principios y los requisitos generales de la legislación alimentaria, se crea la Autoridad Europea de Seguridad Alimentaria y se fijan procedimientos relativos a la seguridad alimentaria,

– Visto el Reglamento (UE) nº 1169/2011 del Parlamento Europeo y del Consejo, de 25 de octubre de 2011, sobre la información alimentaria facilitada al consumidor y por el que se modifican los Reglamentos (CE) nº 1924/2006 y (CE) nº 1925/2006 del Parlamento Europeo y del Consejo, y por el que se derogan la Directiva 87/250/CEE de la Comisión, la Directiva 90/496/CEE del Consejo, la Directiva 1999/10/CE de la Comisión, la Directiva 2000/13/CE del Parlamento Europeo y del Consejo, las Directivas 2002/67/CE, y 2008/5/CE de la Comisión, y el Reglamento (CE) nº 608/2004 de la Comisión,

– Vista la propuesta de Reglamento relativo a los controles oficiales y las demás actividades oficiales realizados con el fin de garantizar la aplicación de la legislación sobre los alimentos y los piensos, y de las normas sobre salud y bienestar de los animales, fitosanidad, materiales de reproducción vegetal y productos fitosanitarios (COM(2013)0265),

– Visto el informe del Tribunal de Cuentas Europeo sobre la gestión de conflictos de intereses en cuatro agencias de la Unión Europea, de 11 de octubre de 2012;

– Visto el artículo 48 de su Reglamento,

– Vistos el informe de la Comisión de Medio Ambiente, Salud Pública y Seguridad Alimentaria y las opiniones de la Comisión de Mercado Interior y Protección del Consumidor y de la Comisión de Agricultura y Desarrollo Rural (A7-0434/2013),

A. Considerando que los principios generales de la legislación alimentaria de la UE en

[1] http://ec.europa.eu/food/food/horsemeat/plan_en.htm.

L 48/28 ES Diario Oficial de la Unión Europea 21.2.2013

RECOMENDACIONES

RECOMENDACIÓN DE LA COMISIÓN

de 19 de febrero de 2013

sobre un plan coordinado de control para establecer la prevalencia de prácticas fraudulentas en la comercialización de determinados alimentos

(2013/99/UE)

LA COMISIÓN EUROPEA,

Visto el Tratado de Funcionamiento de la Unión Europea,

Visto el Reglamento (CE) nº 882/2004 del Parlamento Europeo y del Consejo, de 29 de abril de 2004, sobre los controles oficiales efectuados para garantizar la verificación del cumplimiento de la legislación en materia de piensos y alimentos y la normativa sobre salud animal y bienestar de los animales (1), y, en particular, su artículo 53,

Considerando lo siguiente:

(1) El artículo 53 del Reglamento (CE) nº 882/2004 autoriza a la Comisión a recomendar planes coordinados si lo estima necesario, de manera puntual, con el fin, en particular, de determinar la prevalencia de riesgos en piensos, alimentos o animales.

(2) 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 (2), establece en la Unión normas de etiquetado aplicables a todos los productos alimenticios.

(3) Con arreglo a la Directiva 2000/13/CE, el etiquetado y los métodos utilizados no deben inducir a error al consumidor, sobre todo en lo que respecta a las características del producto alimenticio, su verdadera naturaleza y su identidad. Además, en ausencia de normas de la Unión o nacionales de carácter específico, la denominación de venta está constituida por el nombre consagrado por el uso en el Estado miembro en el que se efectúe la venta, o por una descripción del producto alimenticio lo suficientemente precisa para permitir al comprador conocer su naturaleza real.

(4) Por otra parte, todos los ingredientes deben mencionarse en la etiqueta de los productos alimenticios envasados destinados al consumidor final o a las colectividades. En particular, los productos alimenticios que contienen carne como ingrediente y se destinan al consumidor final o a las colectividades deben indicar también las especies animales de las que proviene la carne, directamente en el envase o en una etiqueta pegada al mismo. Si se menciona un ingrediente en la denominación del alimento, su cantidad expresada en porcentaje deberá también aparecer en la lista de ingredientes para no inducir a error al consumidor sobre la identidad y la composición de los alimentos.

(5) El Reglamento (CE) nº 853/2004 del Parlamento Europeo y del Consejo, de 29 de abril de 2004, por el que se establecen normas específicas de higiene de los alimentos de origen animal (3), establece requisitos adicionales de etiquetado aplicables a alimentos específicos. Dispone, en particular, que los embalajes destinados al consumidor final que contengan carne picada, entre otros, de solípedos, deben llevar un rótulo en el que se indique que los productos han de cocinarse antes de su consumo, en la medida en que así lo exijan las normas nacionales vigentes en el Estado miembro en cuyo territorio se pone en el mercado el producto.

(6) En el anexo II, sección III, del Reglamento (CE) nº 853/2004 se establece que los operadores de empresa alimentaria que exploten mataderos deben solicitar, recibir, verificar e intervenir en la información sobre la cadena alimentaria en relación con todos los animales, distintos de la caza silvestre, que se hayan enviado o que se vayan a enviar al matadero. La información de la cadena alimentaria debe incluir, en particular, los medicamentos veterinarios administrados a los animales durante un período adecuado y con un tiempo de espera superior a cero, junto con las fechas de su administración y plazos de retirada. El Reglamento (CE) nº 854/2004 del Parlamento Europeo y del Consejo, de 29 de abril de 2004, por el que se establecen normas específicas para la organización de controles oficiales de los productos de origen animal destinados al consumo humano (4), establece entre otras cosas que el veterinario oficial efectúe funciones de auditoría y de inspección. El veterinario oficial debe comprobar y analizar la información pertinente de los registros de la explotación de procedencia de los animales destinados al matadero y tener presentes los resultados documentados de estas comprobaciones y análisis al realizar inspecciones *ante mortem* y *post mortem*.

(1) DO L 165 de 30.4.2004, p. 1.
(2) DO L 109 de 6.5.2000, p. 29.
(3) DO L 139 de 30.4.2004, p. 55.
(4) DO L 139 de 30.4.2004, p. 206.

49. Considera que el sector minorista tiene una responsabilidad especial de garantizar la integridad de los productos alimentarios y de exigir a sus proveedores una cadena de suministro segura y protegida; considera que es responsabilidad de los minoristas comprobar como mínimo el cumplimiento formal de las normas de etiquetado; lamenta la presión ejercida sobre los productores primarios para que produzcan de manera cada vez más barata, a menudo a expensas de la calidad de los alimentos o sus ingredientes;

#1	Comprobar el estatus de la claim en el Registro de la Comisión y de EFSA
#2	Comprobar el status de las marcas que sugieren un beneficio
#3	La declaración debe estar relacionada con el nutriente o la sustancia
#4	Comprobar que el wording utilizado esté dentro del margen de flexibilidad
#5	No sugerir que la salud podría verse afectada por no consumir el producto promocionado
#6	No exagerar los beneficios ni hacer promesas, sino ser moderados en su descripción
#7	No sugerir que los productos poseen propiedades medicinales
#8	Prestar atención a la publicidad sobre el proceso de producción
#9	Atención a las claims cosméticas, pueden ser consideradas de propiedades saludables
#10	Las declaraciones de salud generales [10(3)] deben ir acompañadas de una declaración específica
#11	No hacer referencia a estudios clínicos cuando la claim ha sido rechazada
#12	Las declaraciones de reducción de riesgo de enfermedad no se pueden utilizar hasta que se aprueben caso por caso
#13	No unificar dos o más claims si los beneficios de las mismas han sido aprobados por separado


Muchas gracias!