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Directorate General of Food Hygiene and Safety and Nutrition

## **Botanicals and Claims**

**Rome, September 21th 2012**

**Regulation (EU) 432/2012**  
will apply from 14 December 2012

**HEALTH CLAIMS**  
permitted under Article 13.1 of Regulation (EC) 1924/2006

**222 claims**

over 70% for vitamins and minerals



## **HEALTH CLAIMS**

Regulation (EC) 1924/2006

**PENDING**



**Botanicals**

**Probiotics**

## **DEFINITIONS OF CLAIMS**

Regulation (EC) 1924/2006

- |   |                   |
|---|-------------------|
| <b>1) CLAIM</b>                           | <b>art. 2.2.1</b> |
| <b>2) NUTRITION CLAIM</b>                 | <b>art. 2.2.4</b> |
| <b>3) HEALTH CLAIM</b>                    | <b>art. 2.2.5</b> |
| <b>4) REDUCTION OF DISEASE RISK CLAIM</b> | <b>art. 2.2.6</b> |

## **CLAIM**

### **Regulation (EC) 1924/2006**

Art. 2.1

'**claim**' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has **particular characteristics**

## **Regulation (EU) 1169/2011**

### **on the provision of food information to consumers (FIC)**

*Article 7*

#### **Fair information practices**

1. Food information shall not be misleading, particularly:  
(a) as to the **characteristics of the food** and, in particular, as to its **nature, identity, properties, composition, quantity**, durability, country of origin or place of provenance, method of manufacture or production

....

## **NUTRITION CLAIMS**

### **Regulation (EC) 1924/2006**

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

- (a)** the energy (calorific value) it:
  - (i) provides;
  - (ii) provides at a reduced or increased rate; or
  - (iii) does not provide; and/or
  
- (b)** the nutrients or other substances it:
  - (i) contains;
  - (ii) contains in reduced or increased proportions; or
  - (iii) does not contain;

## **NUTRITION CLAIMS**

**Indication of the content or the level of the content of**

**1) NUTRIENTS**

**2) OTHER SUBSTANCES**



## **HEALTH CLAIM**

### **Regulation (EC) 1924/2006**

**'health claim'** means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health



## **REDUCTION OF DISEASE RISK CLAIM**

### **Regulation (EC) 1924/2006**

**'reduction of disease risk claim'** means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease



## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### *9° recital*

There is a wide range of nutrients and other substances including, but not limited to, vitamins, minerals including trace elements, amino-acids, essential fatty acids, fibre, various plants and herbal extracts with a nutritional or physiological effect that might be present in a food and be the subject of a **claim**.

Therefore, general principles applicable to **all claims made on foods** should be established .....

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### *16° recital*

It is important that **claims** on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims.

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### *19° recital*

Given the positive image conferred on foods bearing **nutrition and health claims** and the potential impact these foods may have on dietary habits and overall nutrient intakes, the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling should be compulsory and should be extensive on all foods bearing health claims.



## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### *36° recital*

Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards **nutrition and health claims** whilst providing a high level of consumer protection, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity..



## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### Article 1

#### Subject matter and scope

1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to **nutrition and health claims** in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

### National guidelines on food supplements

#### ESSENTIAL AMINO ACIDS



**CLAIM: help meet the "protein" requirements**



## CLAIMS ABOUT OTHER CHARACTERISTICS ?

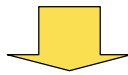
Regulation (EC) 1924/2006

**Guidelines on probiotics** - Revision May 2012

[www.salute.gov.it](http://www.salute.gov.it)

*Indication for use:*

**"It supports the intestinal flora balance"\***



**1) It isn't a nutritional claim**

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

**Guidelines on probiotics** - Revision May 2012

[www.salute.gov.it](http://www.salute.gov.it)

*Indication for use:*

**"It supports the intestinal flora balance"\***

\*In the Opinion reported in: "EFSA Journal 2009; 7(9):1232", the NDA panel of EFSA states: "Increasing the number of any group of bacteria is not in itself considered as beneficial".

The rationale for the above mentioned indication of use has been defined taking into account this Opinion.



**2) It isn't a health claim**

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

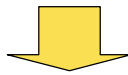
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*Indication for use:*

"It supports the intestinal flora balance"\*



**3) It is a claim**

## CLAIMS ABOUT OTHER CHARACTERISTICS ?

Regulation (EC) 1924/2006

Where is the line between

**CLAIMS and**

**NUTRITION AND HEALTH CLAIMS**

???



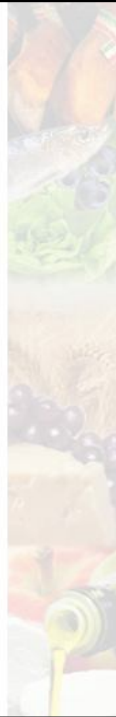
## **CLAIMS ABOUT OTHER CHARACTERISTICS ?**

**Regulation (EC) 1924/2006**

**beauty claims ?**

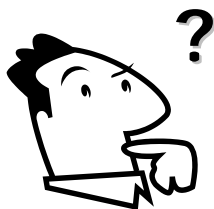
**claims about oral hygiene ?**

**claims about the nature or role of a nutrient or an other substance in the body ?**



**Regulation (EC) 1924/2006**

**What is the impact on food supplements?**



## **FOOD SUPPLEMENTS**

**DIRECTIVE 2002/46/EC ⇒ decreto legislativo 21 maggio 2004, n. 169**

### **DEFINITION**

**CONCENTRATED SOURCES OF NUTRIENTS OR OTHER SUBSTANCES WITH A NUTRITIONAL OR PHYSIOLOGICAL EFFECT, alone or in combination, marketed in dose form ... as capsules, pastilles, tablets ...**



## **FOOD SUPPLEMENTS**

**DIRECTIVE 2002/46/EC ⇒ decreto legislativo 21 maggio 2004, n. 169**

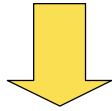
**CONCENTRATED SOURCES OF NUTRIENTS OR OTHER SUBSTANCES WITH A NUTRITIONAL OR PHYSIOLOGICAL EFFECT**



**Prohibition to indicate physiological effect (claim on health) if not previously authorized under Regulation (EC) 1924/2006**



## **FOOD SUPPLEMENTS AND REGULATION (EC) 1924/2006**



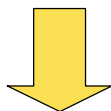
### **LAWS IN CONFLICT**

The national law for the implementation of Directive 2002/46/EC on food supplements provides as mandatory the indication of the physiological effects to properly orient the choices of consumers



## **FOOD SUPPLEMENTS**

**Nutrition claims**



**General conditions of Regulation (EC)  
1924/2006 are inadequate**



## **FOOD SUPPLEMENTS**

### **VITAMIN C**

Source of vitamin C (15% RDA) = 12 mg

High in vitamin C (30% RDA) = 24 mg

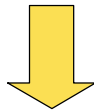
**?**

**Maximum daily dose admitted  
in food supplements: 500 mg**



## **REGULATION (EC) 1924/2006**

**Directive 2009/39/EC (PARNUTS)**

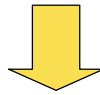


**REPEAL  
OF THE CONCEPT OF "DIETETIC"**



## CLAIMS AND PARNUTS

Food intended to help the control of cholesterol levels



**Dietetic product or food with an health claim ?**



**National Competent  
Authorities**



**EFSA**

## FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

A category of foods for particular nutritional uses specially processed or formulated and intended for **the dietary management of patients**



to be used under **medical supervision**

## FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

The indications of the dietary management



Are not nutritional or health claims



## FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

The indications of the dietary management are not nutritional or health claims



**BORDERLINE AREA WITH FOOD SUPPLEMENTS**

**National guidelines on FSMP**

(July 2012)





## **FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP) AND REGULATION (EC) 1924/2006**

### **National guidelines on FSMP (July 2012)**

The Regulation (EC) 1924/2006:

**Necessarily apply to the use of the indications same as health claims**

**For example: if a product is intended as AFMS for the dietary treatment of malnutrition the labeling cannot bear effects on its specific constituents that have been authorized as claims**

**Does not necessarily apply to nutritional claims**



## **CLAIMS ON BOTANICALS ? Regulation (EC) 1924/2006**

**Efficacy assessment disproportionate  
with disadvantage of substances other  
than vitamins and minerals**



## CLAIMS FOR VITAMINS AND MINERALS

### CALCIUM

**Calcium is needed for the maintenance of normal bones**

The claim may be used only for food which is at least a source of calcium as referred to in the claim **SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]** as listed in the Annex to Regulation (EC) No 1924/2006

## CLAIMS FOR VITAMINS AND MINERALS

### CALCIUM

**Calcium has a role in the process of cell division and specialisation**

## CLAIMS FOR VITAMINS AND MINERALS

### CALCIUM

Calcium has a role in the process of cell division and specialisation



Is it a health claim ?

## HEALTH CLAIMS ABOUT OTHER SUBSTANCES

Disproportionate levels of intake required as a condition

## Monascus purpureus (red yeast rice)

**Claim:** Monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol levels

### CONDITION

The claim may be used only for food which provides a daily intake of **10 mg of monacolin K** from red yeast rice.

### NATIONAL GUIDELINES ON FOOD SUPPLEMENTS

Maximum intake **3 mg**

## Regulation (EU) 432/2012

### 17° recital

The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff



**Harmonization?**

**MINISTRY OF HEALTH  
DECRETO 9 luglio 2012**

**Regulation on use in food supplements of  
substances and herbal preparations**

List of plants and their parts whose preparations or  
extracts (that have a history of significant  
consumption) can be used

**CLAIMS ON BOTANICALS**

**Until Community Action in the field**



**National Guidelines  
on physiological effect admitted**  
[www.salute.gov.it](http://www.salute.gov.it)

## National guidelines

*Hypericum perforatum* L.  
herba c. floribus:

Normal mood  
Relaxation and mental  
well-being



## National guidelines

*Ginkgo biloba* L.  
folium:

Antioxidant. Memory and  
cognitive functions. Normal  
blood circulation.  
Microcirculation

ADDITIONAL WARNING: hear  
the advice of your doctor if you  
are taking anticoagulants and  
antiplatelet





## **CLAIMS ON BOTANICALS**

**Plants traditionally used  
for "medicinal use"?**

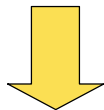


**The concept includes  
the effect of "physiological" effect"**



## **CLAIMS ON BOTANICALS**

**FOOD SUPPLEMENTS  
the purpose is to supplement the normal diet ?**



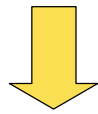
**Limit is the Regulation (EC) 258/97 on novel foods**





## CLAIMS ON BOTANICALS

**FOOD SUPPLEMENTS**  
the purpose is to supplement the normal diet ?



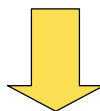
**Monacolin K (health claim ex 13.1) ?**

## CLAIMS ON BOTANICALS

**Directive 2004/24/EC on traditional herbal medicinal products**

**6° RECITAL**

The vast majority of medicinal products with a sufficiently long and coherent tradition are based on herbal substances. It therefore seems appropriate to limit the scope of the simplified registration in a first step to traditional herbal medicinal products



**TRADITIONAL USE FOR ALL SUBSTANCES ?!**

## CLAIMS ON BOTANICALS: WHAT FUTURE ?

**Debate is open!**



Dipartimento della sanità pubblica veterinaria,  
della sicurezza alimentare e degli organi collegiali per la tutela della salute  
Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione



***Thanks  
for your attention***