



Role in Nutrition and Claims

Scientific Symposium on Food Safety, Nutrition and Nanotechnology

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SCIENCE
H. Koeter (Deputy Executive Director)

RISK ASSESSMENT
R. Maijala

FOOD ADDITIVES
& PACKAGING (AFC)

T. Hallas-Moller

ANIMAL HEALTH
& WELFARE
(AHAW)

J. Serratosa Vilageliu

BIOLOGICAL
HAZARDS (BIOHAZ)

M. Hugas

CONTAMINANTS
(CONTAM)

C. Heppner

FEED ADDITIVES
(FEEDAP)

C. Roncancio Pena

GENETICALLY
MODIFIED
ORGANISMS (GMO)

S. Renckens

NUTRITION
(NDA)

P. Rodriguez Iglesias

PLANT PROTECTION
PRODUCTS (PPR)

M. Dunier-Thomann

PLANT HEALTH
(PLH)

E. Ceglarska

SCIENTIFIC COOPERATION & ASSISTANCE
H. Deluyker

SCIENTIFIC
COOPERATION

Post Accepted

EMERGING
RISKS

Post Accepted

PESTICIDES
(PRAPeR)

H. Bruno

DATA COLLECTION
EXPOSURE

S. Fabiansson

ASSESSMENT
METHODOLOGY

.....

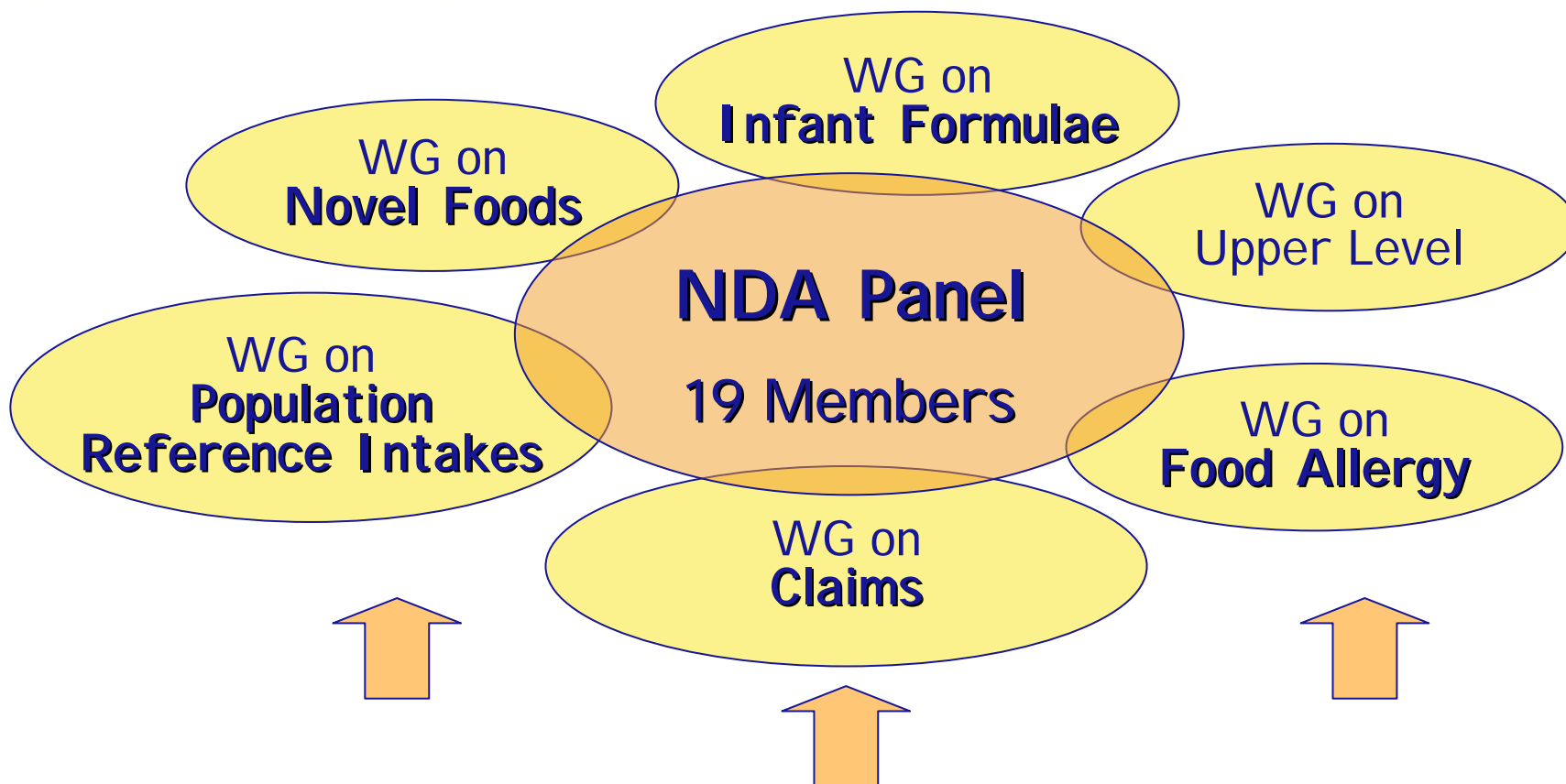
ZOONOSES
(Data Collection)

P. Makela

NDA Mandate:

Questions on human nutrition,
dietetic products and food
allergy, and other associated
subjects such as novel foods.

NDA Panel & Working Groups (WG)



Supported by the EFSA Secretariat (NDA Unit)

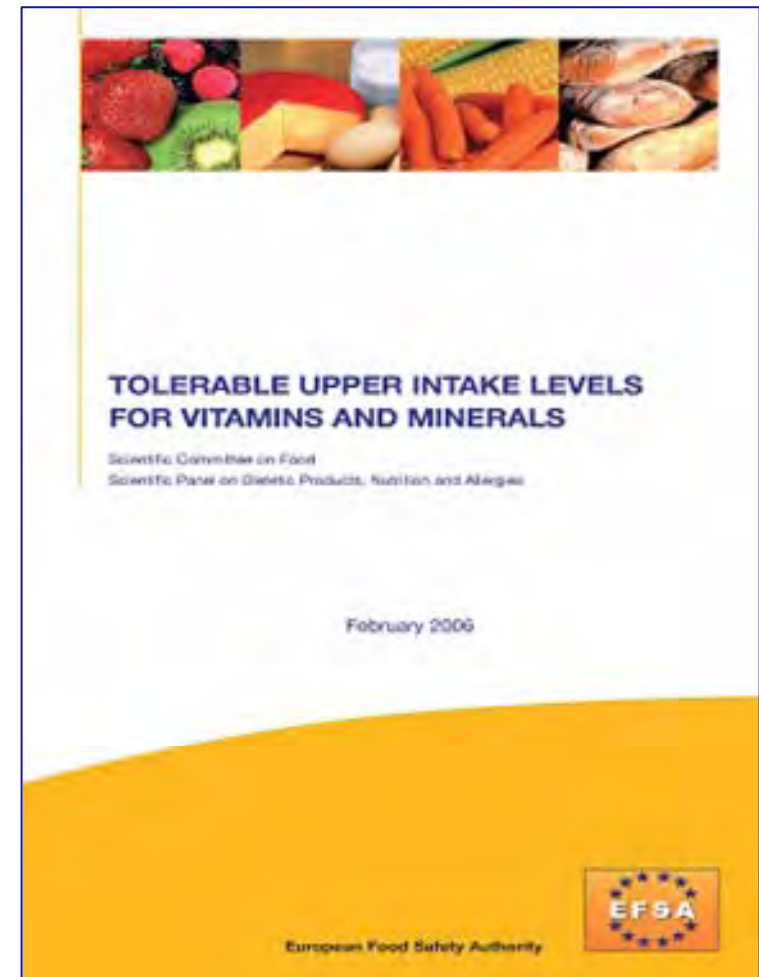
1. Tolerable Upper Intake Levels

...for Vitamins and Minerals

Tolerable upper intake level

...the maximum level of total chronic daily intake of a nutrient from all sources – judged to be unlikely to pose a risk of adverse health effects to humans.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753824_1178633962601.htm



2. Dietetic Foods

= foods for particular nutritional use

EFSA: assessment of safety & suitability of

- Fructooligosaccharides for particular nutritional use by infants
- Goats' milk protein as protein source
- Whey protein hydrolysate as protein source
- "Fungal oil" as a safe source for arachidonic acid

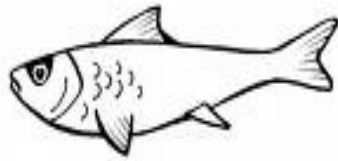


3. Allergenic Foods

Labeling Directive* Annex III a: Labeling requirement for a list of ingredients known to trigger allergic reactions or intolerances:

- Cereals containing gluten
- Crustaceans
- Eggs
- Fish
- Peanuts
- Soybeans
- Milk (including lactose)
- Nuts
- Celery
- Mustard
- Sesame seeds
- Sulphites (>10 mg/kg)
- Molluscs
- Lupin

...and products thereof



DIRECTIVE: provisions for granting labeling exemptions;

Applications from industry



EFSA: risk assessment & opinion

E.g: Finning of wine & beer



* Directive 2003/89/EC as amended by Directive 2006/142

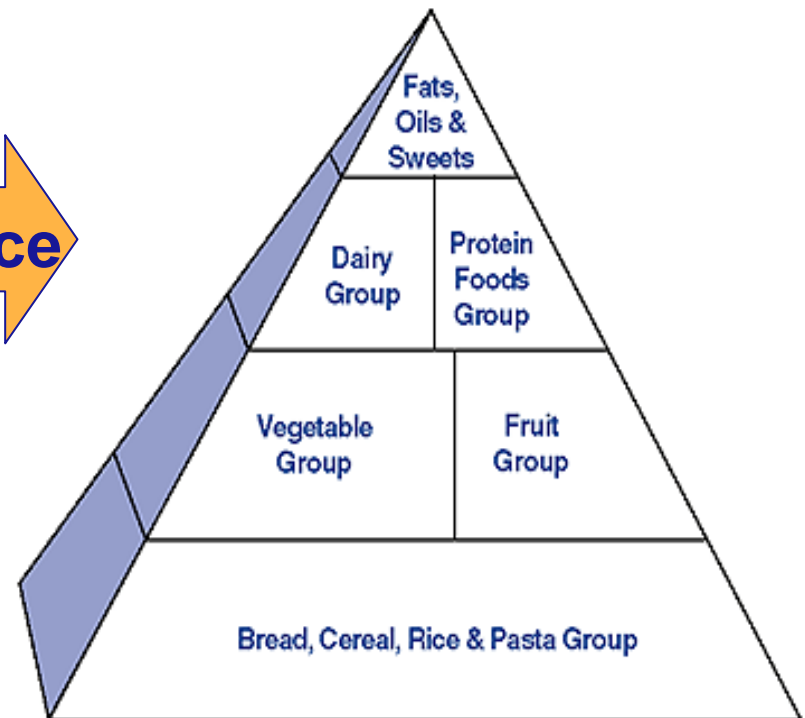
4. Population Reference Intakes

Establishment of nutrient based recommendations for the European population: Population Reference Intakes (PRI) for energy, macronutrients, dietary fibre, water & micronutrients

Guidance on translation of nutrient-based recommendations into

food-based recommendations

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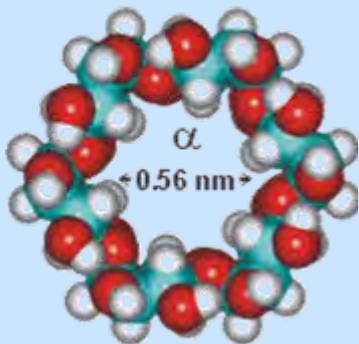


4. Novel Foods

Foods/food ingredients which have not been used for human consumption to a significant degree within the EU before 15 May 1997.

Novel Foods Regulation (EC) N° 258/97

α -Cyclodextrin



Noni juice / leaves



Lycopene: - Blakeslea trispora
- tomato oleoresin
- synthetic



Application Procedure*

⇒ EU Member State (MS): Initial assessment (3 mon)
IF Comments/objections from other MS (60 d)



⇒ EFSA: safety assessment & scientific opinion

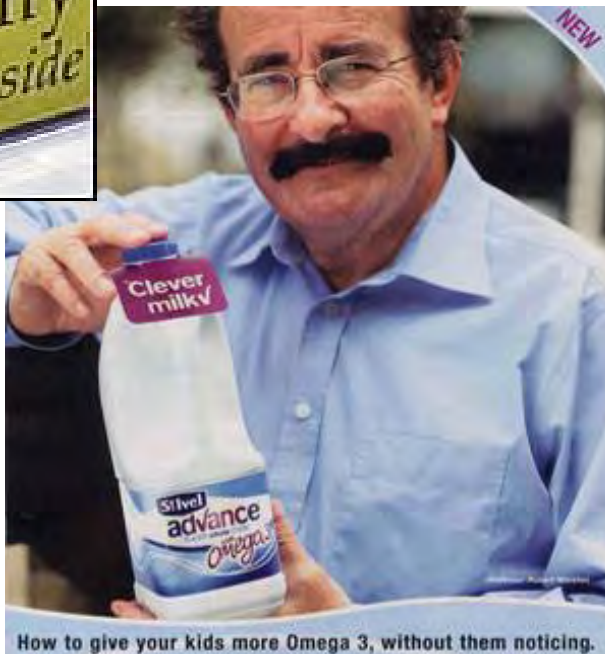
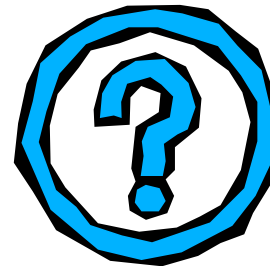


⇒ Commission & MS: Authorisation decision

* *Novel Food Regulation under revision*

6. Nutrition and Health Claims

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods



The Need for the "Claim Regulation"

Consumer protection:

- Claims should be scientifically substantiated to avoid false or misleading information.

Food industry:

- Different national provisions; harmonizing rules required to facilitate free movement of goods within EU market.
- To promote innovation.

a) "Nutrition Claim"

= claim which states or suggests that a food has particular beneficial nutritional properties due to the content of energy, nutrient(s) or other substances

Art 8: only be permitted if they are listed in the Annex and are in conformity with this Regulation.



Art 28: Nutrition claims which are not included in the Annex shall be communicated by MS to the EC (31 Jan 08). EC/MS to decide.
(EFSA consultation if appropriate).



b) “Function Claim” (Art. 13 Claims)

...**claims other than those** referring to the reduction of disease risk and to children's development & health

a) growth, development and the functions of the body

b) psychological and behavioral functions

c) claims related to slimming, bodyweight control



Calcium: good for bones

Calorie Reduction



Art 13 (2) List of claims (31/01/2008) based on “generally accepted scientific evidence” Member States ⇒ EC ⇒ **Consultation of EFSA** ⇒ Final list by EC/MS (31/01/2010)

Art 13 (5) Any additions if based on newly developed scientific evidence and/or proprietary data (Art. 18) ⇒ **Assessment by EFSA**

c) "Reduction of Disease Risk Claims" (Art. 14)

& claims on children's development & health

that state or imply 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



Applicant ⇒ Member State
⇒ EFSA: assessment + opinion
⇒ EC/MS ⇒ decision on authorization
⇒ community list of claims.



EFSA's Tasks on Claims

- 1) SCIENTIFIC AND TECHNICAL GUIDANCE for applications
- 2) SCIENTIFIC EVALUATION of submitted claim dossiers
- 3) "NUTRIENT PROFILES": to provide scientific advice

...for the PREPARATION and PRESENTATION of the application for authorisation of a health claim (Art. 14 Claims)

Objectives:

To indicate a common format for a well-structured application and to give advice on:

- **type of data** which should be included in the application
- **hierarchy** of different study designs
- **aspects** related to design, outcome & quality of the study
- to indicate **other key issues** to substantiate a health claim

- All pertinent scientific data **in favour** + **not in favour** to substantiate the claim by the **totality of the scientific data** and by weighing the evidence.
- Information on the characteristics of the food: manufacturing, composition, physical/chemical characterisation, stability...
- **Claimed effect** of the food shall be relevant for human health.
- Causal relationship food consumption - health outcome in humans; quantity & pattern of consumption required to obtain the claimed effect can reasonably be achieved as part of a balanced diet.
- Animals & in vitro models cannot substitute for human data, but may be included only as supporting evidence, e.g. to explain the mechanism underlying the claimed effect of the food/constituent.
- Study group(s) must be representative for the target population.

Nutrient Profiles (Art. 4)

Nutrient Profiling: "science of categorizing foods according to their nutritional composition" (Rayner et al., 2004).
... for specific purposes (Tetens et al., 2007).

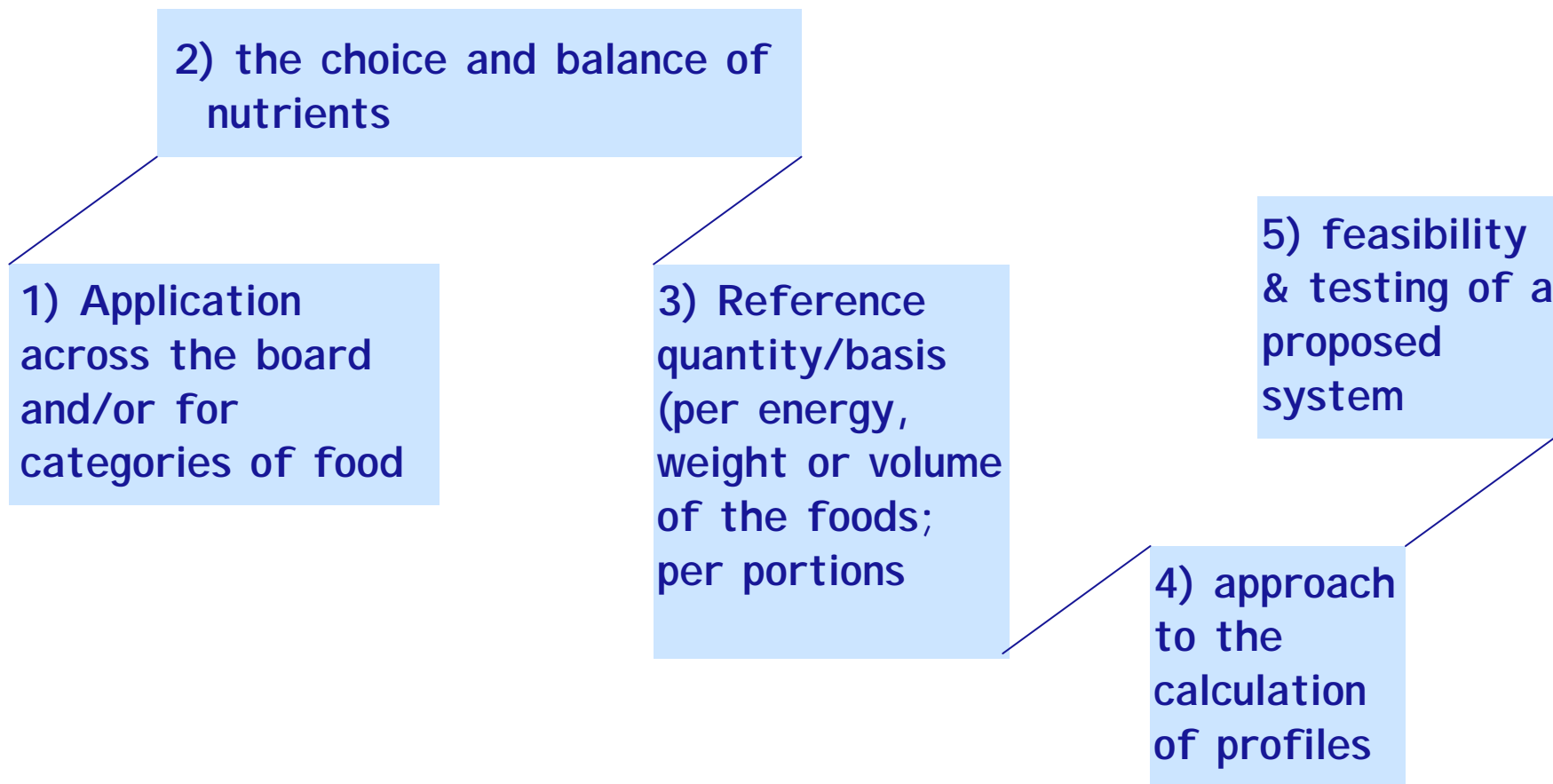
Claim Regulation: The nutrient profiles shall be based on **scientific knowledge** (human nutrition).

Application of nutrient profiles should avoid that health claims **mask** the overall nutritional status of a food product and **mislead** consumers when trying to make healthy choices.

Profiles should also allow for product **innovation** and should take into account the variability of dietary habits and traditions.



EFSA's Task on Nutrient Profiles



EFSA NDA in the Spot Light

...now and in the next future



Claims: EFSA Opinions on claim dossiers such as on antioxidants, prebiotics/probiotics, food supplements & botanicals and others; 'Nanoclaims' ?

Novel Foods:

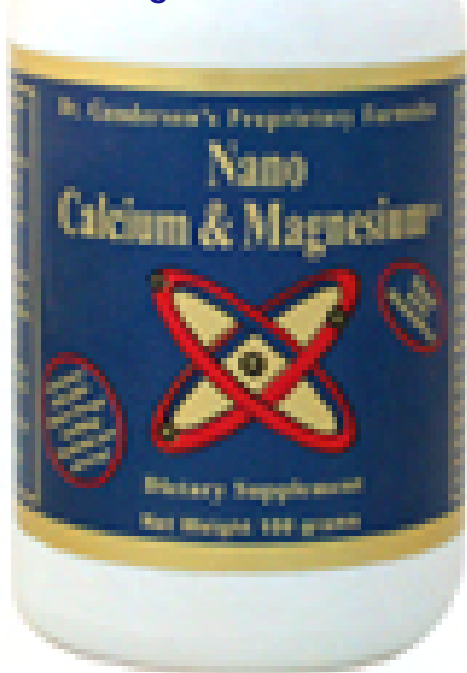
- new production process (e.g. synthetic lycopene), Nano(Novel)food?
- world trade will introduce more 'new' foods such as tropical fruits, nuts, oils (e.g. Allanblackia oil), teas (e.g. Noni tea), botanicals
- Revision of the Novel Food Regul. (Guidance Document by EFSA)

Polulation Reference Intake: Opinions consider endpoints of lifestyle related chronic disease such as obesity, diabetes, cardiovascular diseases, metabolic sysndrom, (colon) cancers, osteoporosis, other dieseases.

Further tasks on the safety of allergenic and dietetic foods
...and other questions related to human diet and nutrition.

"Nano-Claims" in the Future?

NEW Nano Cal/Mag supplement begins to be absorbed directly into the bodies cells the moment it enters your mouth. This allows for fast effective absorption and high utilization...



Nanotea "Prepared with nano-technology, Nano-tea can boost the adsorption of free radicals, cholesterol and blood fat; annihilation of viruses through penetration; a good supplement of selenium can be achieved and the selenium function can be increased by 10 times."



Artichoke Nanoclusters Internal cleansing and detoxing with Artichoke NanoClusters promotes proper liver function and radiant skin. Powerful bioflavonoids known for their detoxifying properties work to cleanse your liver...



Buon appetito

Pilar Rodríguez Iglesias (Head of Unit)

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