

European Food Safety Regulations

Muss, C.

Assoc. Prof.Dr.habil.Dr.med.Claus Muss Ph.D.
St. Elisabeth University Public Health & Preventive Medicine Bratislava, SK (EU) profmuss@gmail.com

European Experts for food quality



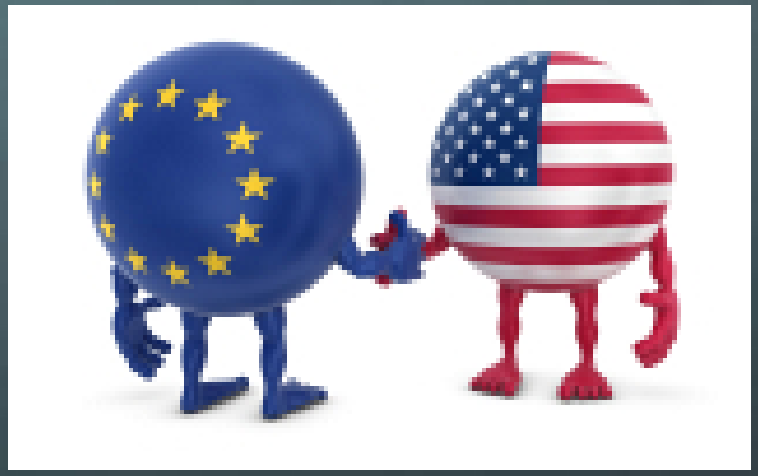


St. Elisabeth University University
Bratislava Slovakia Instutute for Public Health



Head Quater I-GAP

Comparison of Food Safety regulations bewteen US and Europe



Fit for European Market?



Neutraceuticals in Europe

Dietary supplement

- Products contains nutrients derived from food products that are concentrated in liquid or capsule form

Novel food

- Foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997.

Functional food

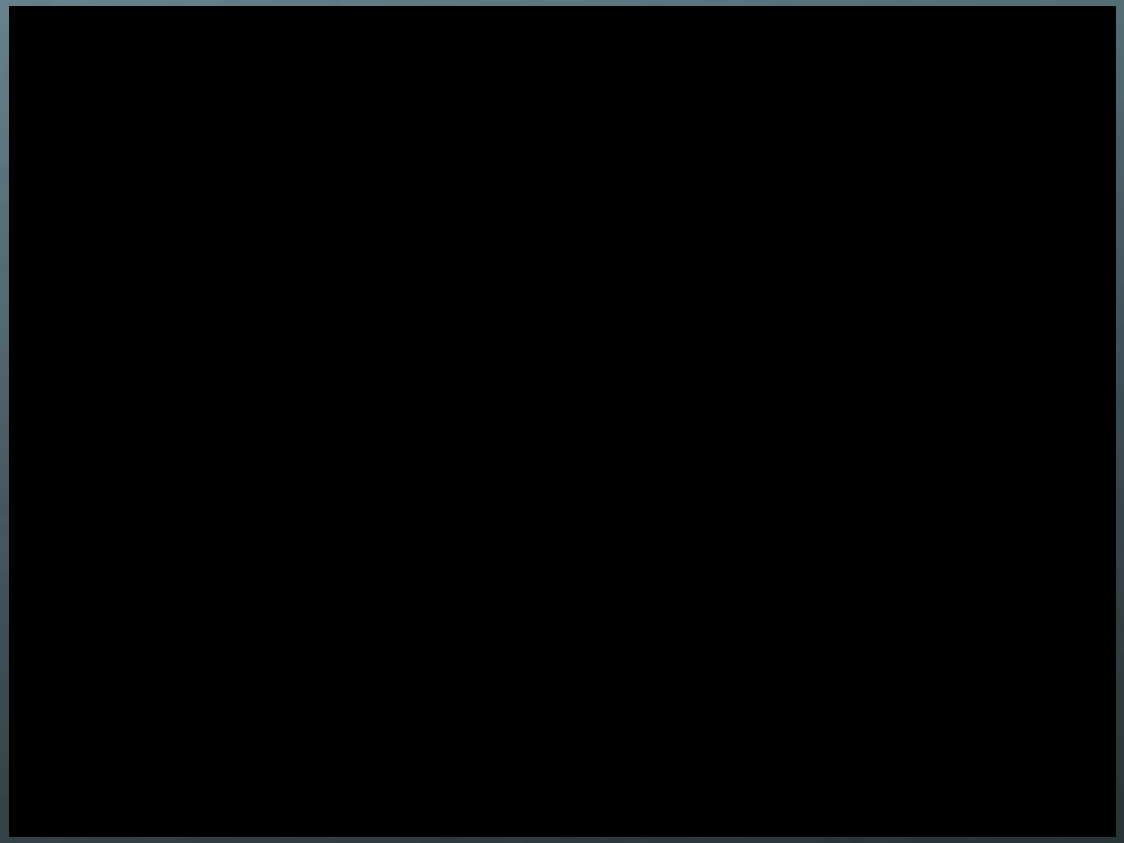
- Functional foods have been either enriched or fortified, a process called nutrification

efsa
European Food Safety Authority

European Food Safety Authority (since 2002)

- In the European Union the European Food Safety Authority (EFSA) is the keystone of risk assessment regarding food.
- Independent source of scientific advice and communication on risks associated with the food chain.
- Funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States
- Goal: To improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply.
- Produces scientific opinions and advice to provide a sound foundation for European policies and legislation and supports the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions.

Food Assessment in Europe by EFSA



Neutraceuticals

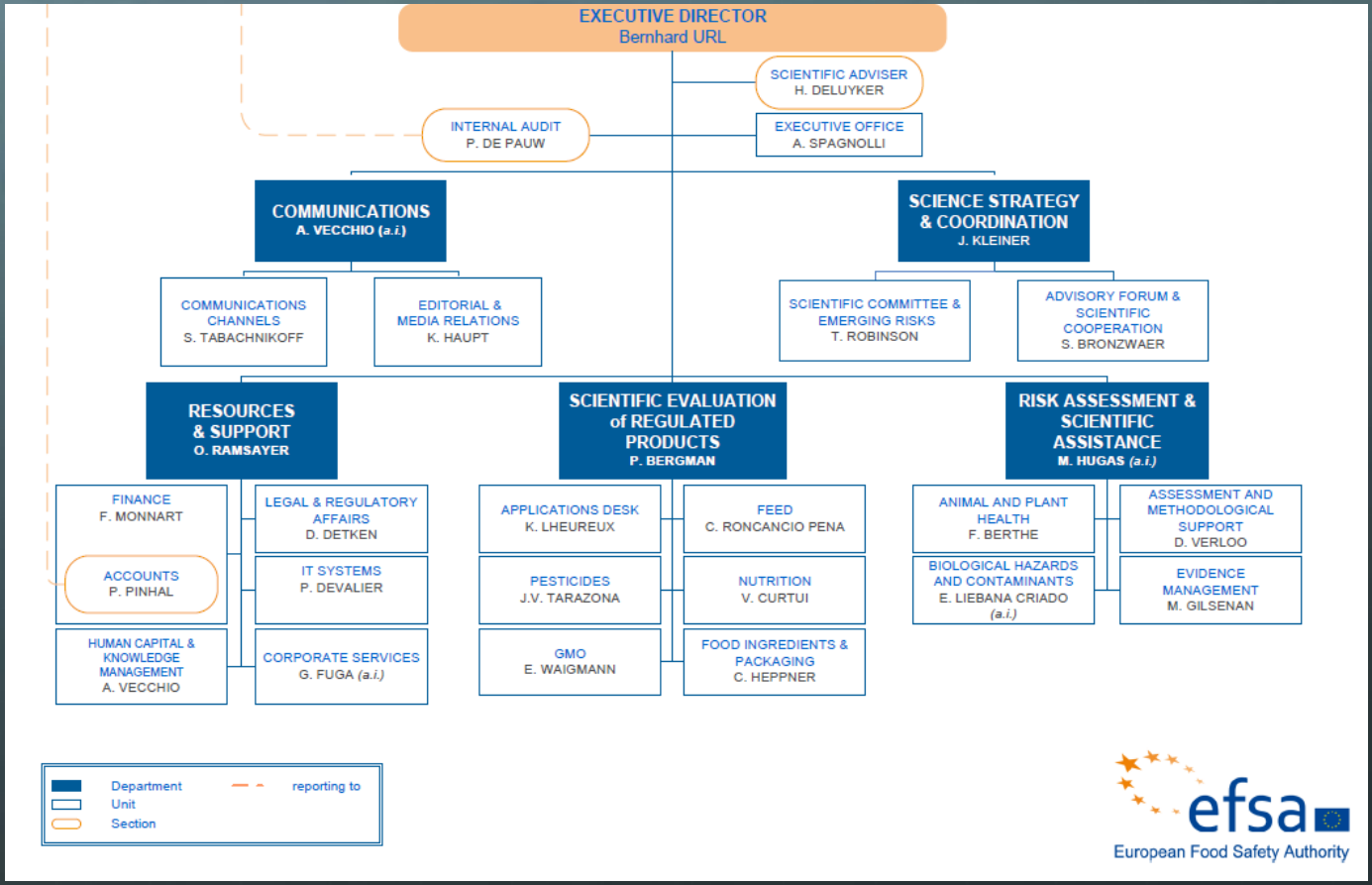
- Nutraceuticals are products derived from food sources that are purported to provide extra health benefits, in addition to the basic nutritional value found in foods.
- Neutraceuticals claim to prevent chronic diseases, improve health, delay the aging process, increase life expectancy, or support the structure or function of the body.

Pathak, Y.V. (2010). *Handbook of Nutraceuticals(vol. 1): Ingredients, Formulations, and Applications*. CRC Press

EFSA TASKS

- EFSA provides objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge.
- EFSA's Scientific Panels are composed of highly qualified, independent scientific experts with a thorough knowledge of risk assessment.

EFSA organisational structure



Novel food

- **Foods and food ingredients**
  - with a new or intentionally modified primary molecular structure (eg, fat substitutes);
  - consisting of microorganisms, fungi or algae, or can be isolated from this (for example, microalgae oil);
  - consisting of plants or isolated (eg phytosterols), and isolated from animals food ingredients.

Novel food legislation in Europe

- Any food or food ingredient that falls within this definition must be authorized according to the Novel Food legislation, Regulation (EC) No 258/97 of the European Parliament and of the Council.
- To market a novel food or ingredient, companies must apply to a EU country authority for authorisation, presenting the scientific information and safety assessment report.
- The competent authority decides if additional assessment is necessary.
- It allows the marketing of the product if no additional assessment is necessary, and if the Commission and EU countries do not object.
- Before approving, the Commission asks the Standing Committee on Food Chain and Animal Health for an opinion.

Novel food authorisation

Authorisation covers:

- Conditions of use,
- Designation of novel food or novel food ingredient,
- Specification and labelling requirements.

Safeguard measures of Novel food

- If a EU country considers a novel food or ingredient a risk to human or environmental health because of new information, it may suspend or temporarily restrict the marketing and use of any novel food or ingredient on their territory.
- The country informs the Commission which either extends the national measures to all EU countries or asks that they are repealed.

Regulation EC 258/97 – Article 12

Novel Food Catalogue

- Lists products of plant and animal origin and other substances subject to the Novel Food Regulation, after EU countries and the Commission agree in the Novel Food Working Group.
- It is non-exhaustive, and serves as orientation on whether a product will need authorisation under the Novel Food Regulation. EU countries may restrict the marketing of a product through specific legislation. For information, businesses should address their national authorities.
- If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorisation under the Novel Food Regulation.

Novel food notification

- A novel food or ingredient may be marketed through a simplified procedure called "notification".
- The company notifies the Commission about their marketing a novel food or ingredient based on the opinion of a food assessment body that has established "substantial equivalence".
- The Commission sends decisions on a novel food or ingredient likely to affect public health to the Scientific Committee for Food.

Labeling of novel foods

Requirements for labelling of novel food and ingredients are additional to the general EU requirements on food labelling. Where necessary, labelling of novel food and novel food ingredients may mention:

- Characteristics - composition, nutritional value, intended use;
- Materials which may affect the health of some individuals;
- Materials that give rise to ethical concerns.

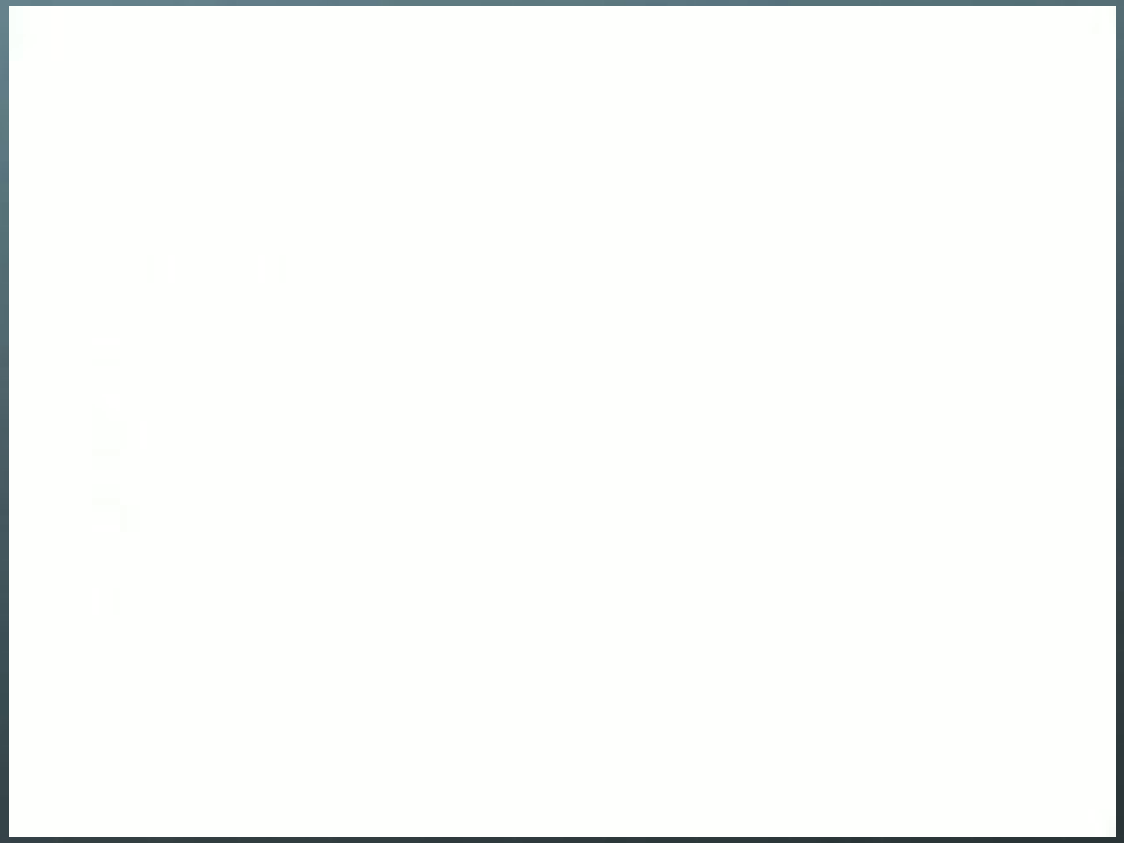
Novel food regulation (EU)

- Originally also foods derived from genetically modified organisms, the so-called genetically modified foods, under the NF Regulation were under Novel food regulation.
- Since April 2004, there now are own regulations for genetically modified organisms.
- Even foods that have been produced using nanotechnology and cloned meat are considered to be novel and must be approved by the NFVO.
- Additives and flavorings are not covered by the NFVO

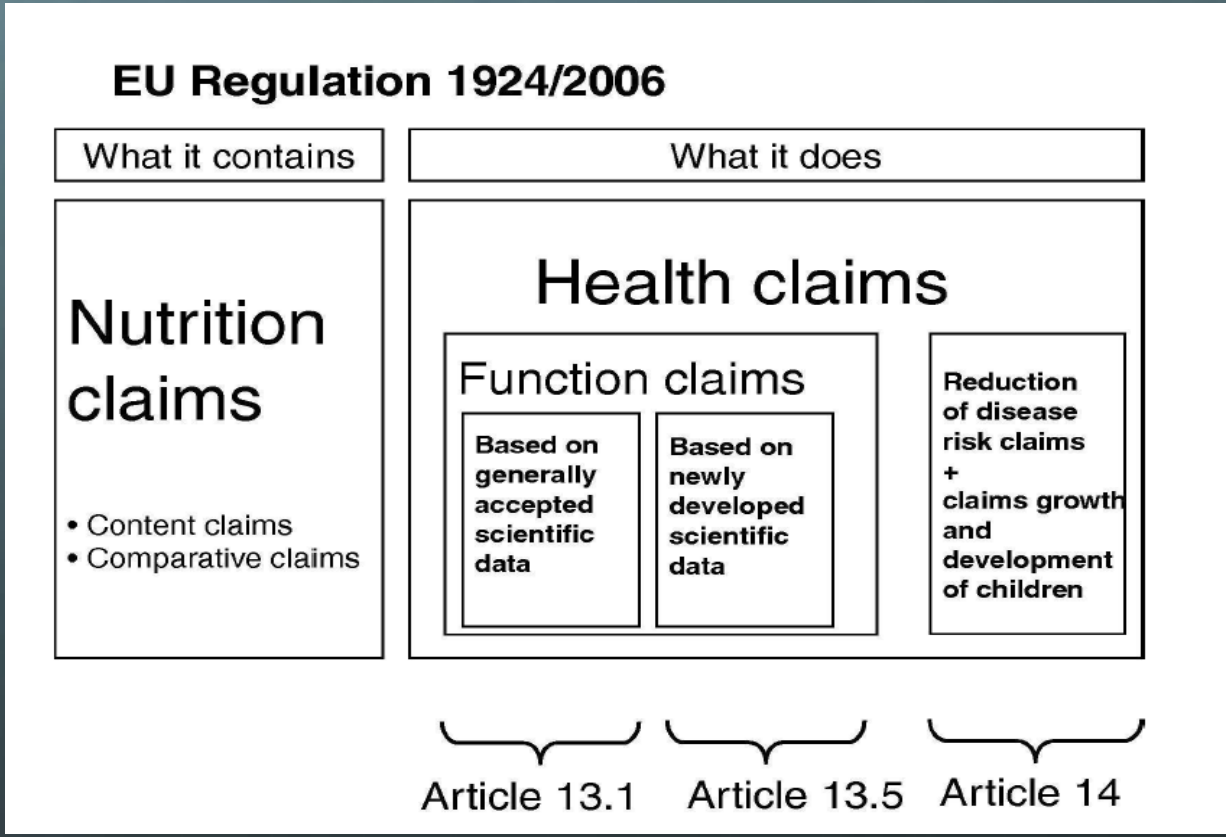
Nutritional & Health Claim

- A **nutrition claim** states or suggests that a food has beneficial nutritional properties, such as “low fat”, “no added sugar” and “high in fibre”.
- A **health claim** is any statement on labels, advertising or other marketing products that health benefits can result from consuming a given food, for instance that a food can help reinforce the body’s natural defences or enhance learning ability

Health claims controlled by EFSA



EU Regulation 1924/2006



Classifications of claims

Nutrition claims	**Health claims**	
Claims describing the beneficial nutritional properties of foodstuffs	Claims that suggest that a relationship exists between a food category, a food or one of its constituents and health	
Only nutritional claims listed in the regulation are authorised	Article 13 = functional claims	Article 14
The energy (calorific value) that it: • provides • provides at a reduced or increased rate, or • does not provide	(1)(a) Claims related to growth, development and functions of the body	(1)(a) Reduction of disease risk claims
The nutrient or other substance it: • contains • contains in reduced or increased proportions • does not contain	(1)(b) Claims related to psychological and behavioural functions	(1)(b) Claims referring to children's development and health
	(1)(c) Claims related to slimming, weight-control, etc.	
	(5) Claims based on newly developed scientific evidence or in cases where proprietary data is to be protected	

Nutritional claims

Specific composition

- Low energy, energy reduced, energy free
- Low fat, low saturated fat
- Low sugar
- High fiber, high protein

Specific content

- ω3 FA, mono unsaturated FA.....

Nutritional claim

source of vitamins and minerals

In accordance with the Regulation, a food may be referred to as a source of vitamins or minerals, provided that the product contains at least a significant amount of the vitamin or mineral in question as defined in Directive 90/496/EEC. Directive 90/496/EEC is amended by Commission Directive 2008/100/EC and Regulation (EC) No 1137/2008 of the European Parliament and of the Council. At the national level, these have been enforced with the nutrition labelling decree (588/2009).

The product must contain 15% of the recommended daily allowance as defined in the nutrition labelling decree in order for the product to be considered as containing a significant amount of the nutrient in question and allowing it to be labelled as a "source of" the nutrient in question. Correspondingly, the claim "high in vitamins and/or minerals" can be used, provided that the product contains 30% of the recommended daily allowance of the nutrient in question as defined in the nutrition labelling decree annex.

According to Section 9 of the Food Act, "In food packaging, presentation and advertising, or in some other way in connection with marketing... information given about food must be truthful and it must be sufficient..." "...information given about food must not be misleading;"

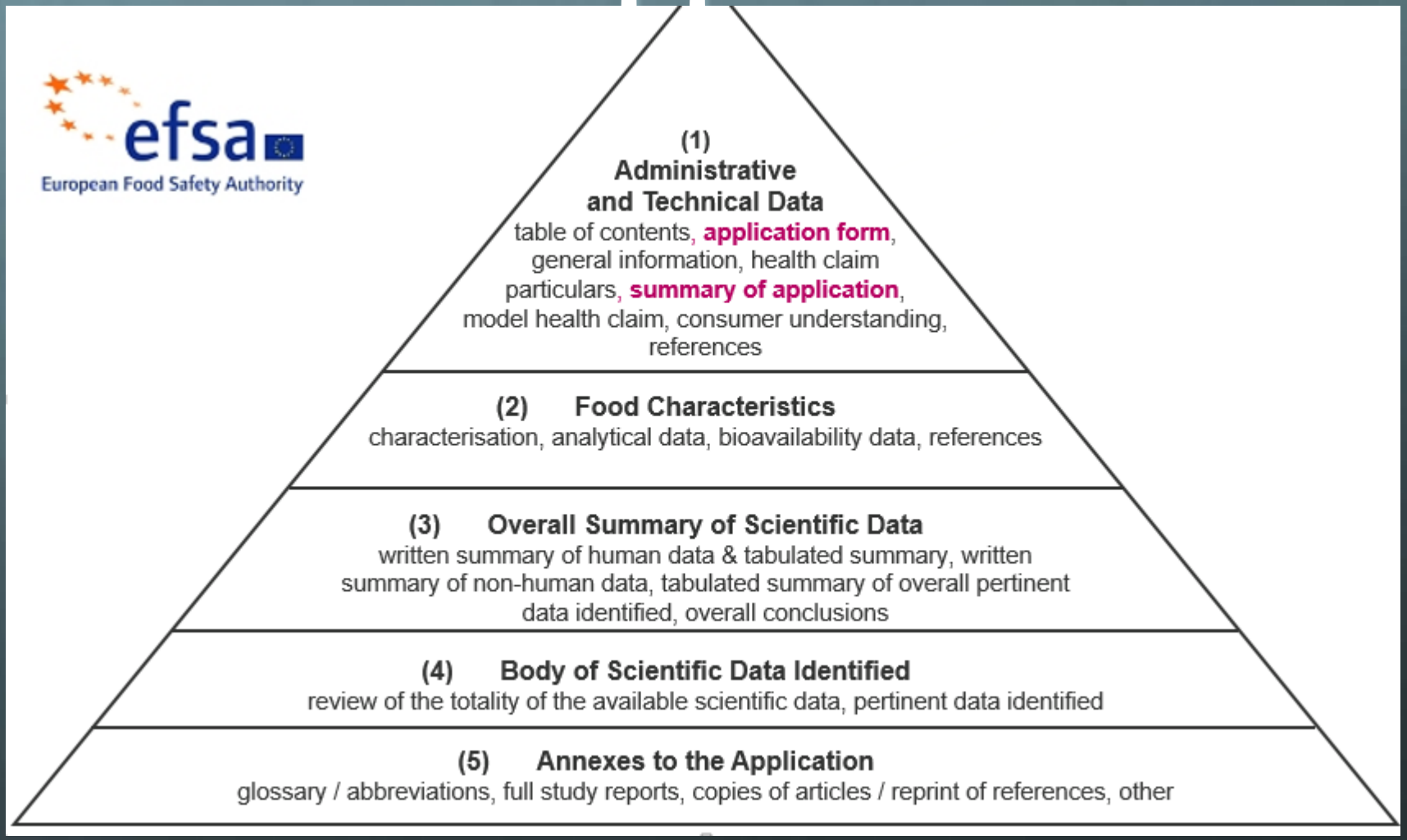
"...food must not be presented as having properties related to prevention, treatment or curing of human diseases or refer to such information, unless otherwise provided elsewhere in the law."

Regarding the use of nutrition and health claims, attention should be given to the following points, which are also taken into consideration in the oversight of claims:

- Only authorised nutrition claims may be used.
- Only authorised health claims or health claims subject to transition period measures may be used. These include health claims compliant with Article 13(1) that are under consideration as well as rejected health claims given a 6-month transition period.
- The conditions of claim use must be met.
- Nutrition labelling must be in order.
- The general principles of using claims must be met.
- Health claims must include the required additional labelling.
- Additional labelling specified in Article 14 must be included with claims concerning the reduction of disease risk factors.
- Ensuring the accuracy of nutrition and health claims used must be a part of self-monitoring.

Annex 2 depicts a decision tree, which is intended as an aid in checking the correct use of claims.

Claim application




Truth or
Consequences
ELEPHANT
BUTTE LAKE
STATE PARK
CITY OF
ELEPHANT
BUTTE

Health Claims reviewed since 2008 by EFSA

- Since 2008 the Panel has assessed 2,758 food-related general function health claims to determine whether they were supported by sound scientific evidence, thereby assisting the European Commission and Member States in establishing a list of claims authorised for food.

Claims not considered nutritional claims

Information on the quality or quantity of a nutrient, which is required elsewhere in legislation, is not considered a nutrition claim.

Furthermore, the listing of ingredients used or not used in the manufacture of the food item or that describe the ingredient properties, are not deemed nutrition claims:

- with added sugar (N.B. conversely, " sugar-free" , " no added sugars" and " without added sugar" are considered to be nutrition claims)
- unsweetened
- sweetened with Xylitol/fructose
- no fats used in manufacture
- does not contain any milk components
- milk-free
- additive-free
- preservative-free

"Lactose-free", "low-lactose", " gluten-free" and "very low gluten" are not nutrition claims, but rather are regulated by legislation concerning foods for particular nutritional uses.

Rejected nutritional claims

Nutrition claims that are not authorised in accordance with the Regulation and that may not be used include the following:

- cholesterol-free, low-cholesterol
- does not contain trans fatty acids, 0% trans fats
- super-light, ultralight
- "equal to" comparisons
- low-carbohydrate

Rejected Health claims

-lack of scientific evidence-

According to Article 12 of the Regulation, the following health claims are considered rejected:

- claims which suggest that health could be affected by not consuming the food
- claims which make reference to the rate or amount of weight loss
  Evira also considers references to, for example, a reduction in waist size or clothing size to be prohibited.
- claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

The Commission expert working group has outlined a policy, wherein the decision on who is considered a health professional must be made on a case-by-case basis. The decision is based largely on the impression made and message content.

For example, the following can be considered rejected health claims:

- a health professional talks about how a food item affects the health or about their own experiences
- a health care student talks about how a food item affects the health or about their own experiences
- actors portraying health professionals talk about how a food item affects the health or about their experiences

According to Article 6 of the Regulation, claims made concerning foodstuffs must be based on generally accepted scientific evidence. Marketing the user experience of an individual consumer can be seen as misleading, because an individual experience cannot be considered as meeting the legal requirements for presenting health claims. Individual consumer experiences may not even make reference to intended medical uses or make other claims rejected in the Regulation.

Positive and neagtive Evaluation of Health Claims by EFSA

- A positive list shows which health claims are permitted for which foods.
- All health claims that do not appear in this list, may also not be used i.t. everything that is not allowed is forbidden.
- A negative list outlines those health claims that have been requested by food manufacturers for special foods, but were rejected. Since these lists were completed and published until January 1, 2012, was the regulation does not - as planned - January 31, 2010, but until this year to be implemented with two-year delay Comprehensively into action.

Approved EFSA Health Claims

(1 in 5 claims reviewed)

- vitamins and minerals;
- specific dietary fibres related to blood glucose control, blood cholesterol, or weight management;
- live yoghurt cultures and lactose digestion;
- antioxidant effects of polyphenols in olive oil;
- walnuts and improved function of blood vessels;
- meal replacement and weight control;
- fatty acids and function of the heart;
- the role of a range of sugar replacers (such as xylitol and sorbitol) in maintaining tooth mineralisation or lowering the increase of blood glucose levels after meals;
- carbohydrate-electrolyte drinks/creatine and sports performance.

Reasons for disfavorable opinions by EFSA

- lack of information to identify the substance on which the claim is based (for example, claims on “probiotics”, or on “dietary fibre” without specifying the particular fibre);
- lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of the functions of the body (for example, food with “antioxidant properties” and claims on renal “water elimination”);
- lack of precision regarding the health claim being made (for example, claims referring to terms such as “energy” and “vitality”, or claims on women’s health or mental energy);
- lack of human studies with reliable measures of the claimed health benefit;
- claims referring to food categories which were considered to be too broad, such as “fruits and vegetables” and “dairy products” to be linked to specific effects.

All are equal

-some are more equal-

- Originally the Health Claims Regulation poclaimes the paragraph that a food is at least no longer assessed as healthy if it contained more than 1.3 grams of salt per 100 grams of flour.
- However German bread contains up to 2.2 grams of salt per 100 grams of flour. According to this opinon German bread would not according to Health Claims Regulation be considered a healthy food. This was not in accordance and excetance of German bakers and they protested.
- EU politicians turned out to be flexible. The EU Commission announced (due to the apparent threatening of the German Bakers' Guild), that bread was excluded from the scheme above.

International scientific Group of Applied Preventive Medicine, Vienna



Networking for nutritional evidence



Food safety assessemnt

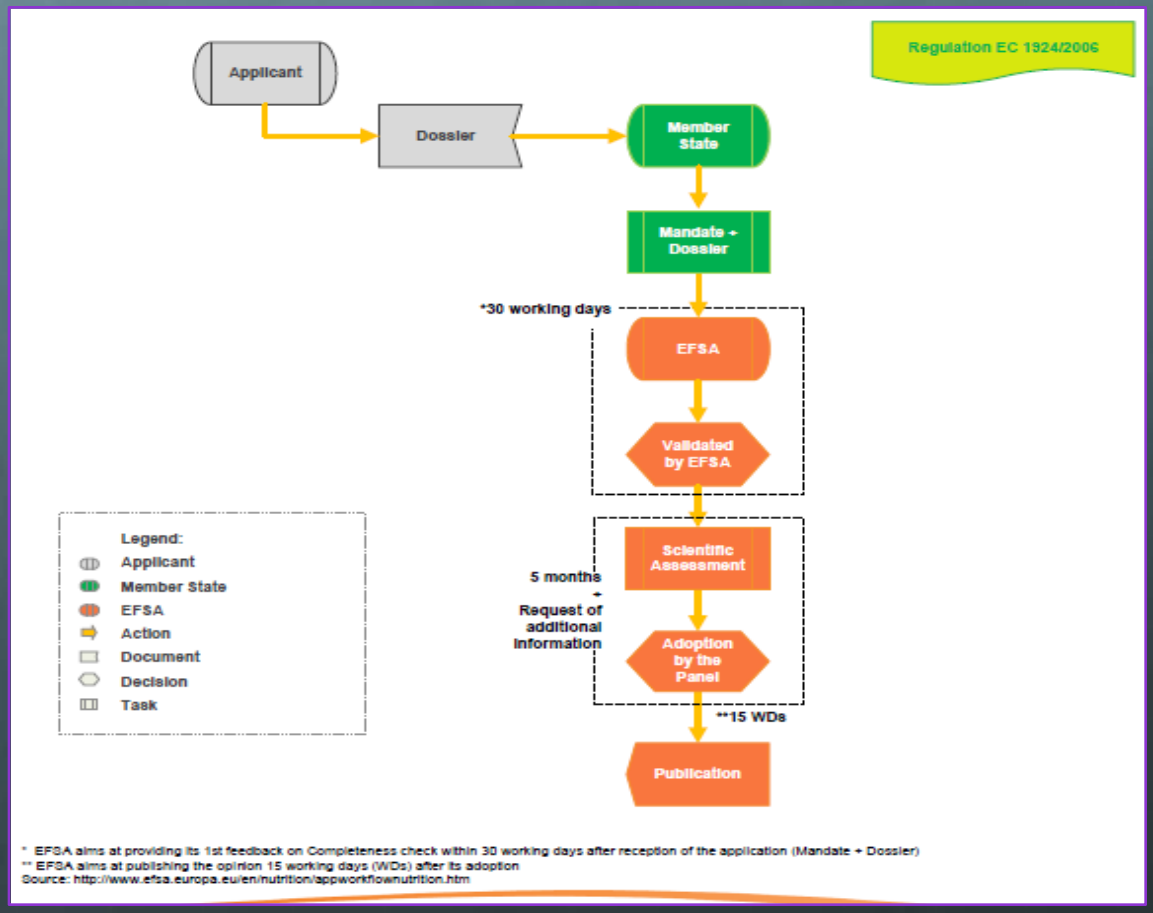
The work of I-GAP

- In this frame work of European Food safety assessment I-GAP supports manufactures' and food industry to profile their products under scientific criteria for a health claim approval .
- I-GAP provides the full range of clinical experience to prepare EFSA proposals and to conduct clinical human trials as well as to document the results in an approvable manner.
- For this reason our organization is closely linked with highly cited and pub med listed scientific journals.

Yes, we can



Health Claim Dossiers



Authorization requirements in the EU:

- Food additives with technological purpose
- Flavorings and enzymes
- New vitamin and mineral compounds
- Novel foods and food ingredients
- Nutrition and health claims (claims)

Dossiers also available for:

- Dietetic foods (eg, balanced diets)
- Dietary supplements
- Fortified foods

Individual Health Claim application now available

- ✓ Characterization of the food, take into account all relevant designated ingredients
- ✓ Effects must be relevant to human health
- ✓ Intake must be realistic
- ✓ Request for Human studies at the highest level: the "gold standard" double-blind randomized controlled-
  (in vitro and animal studies: considered not enough evidence)

- ✓ Studies with the proposed product (matrix effects)

- ✓ Study population must match the target group of the food

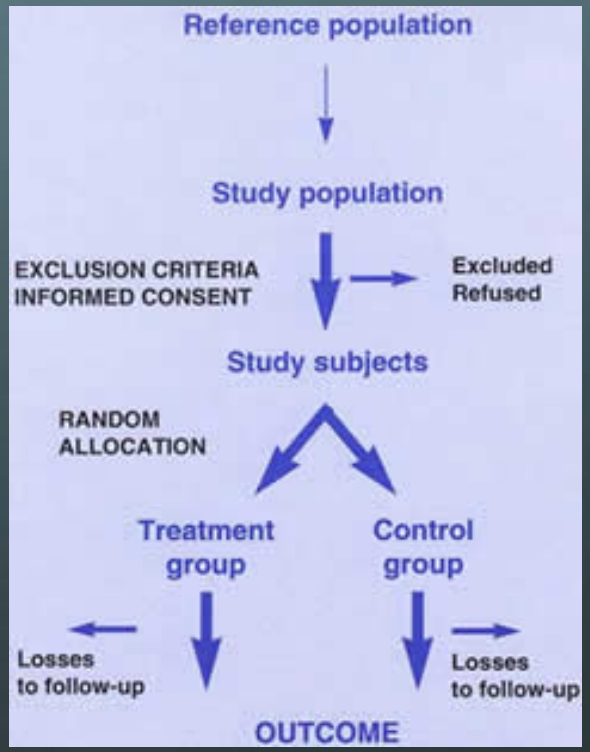
- ✓ Define target audience clearly, consider all the targeted age groups

Pitfalls of study design

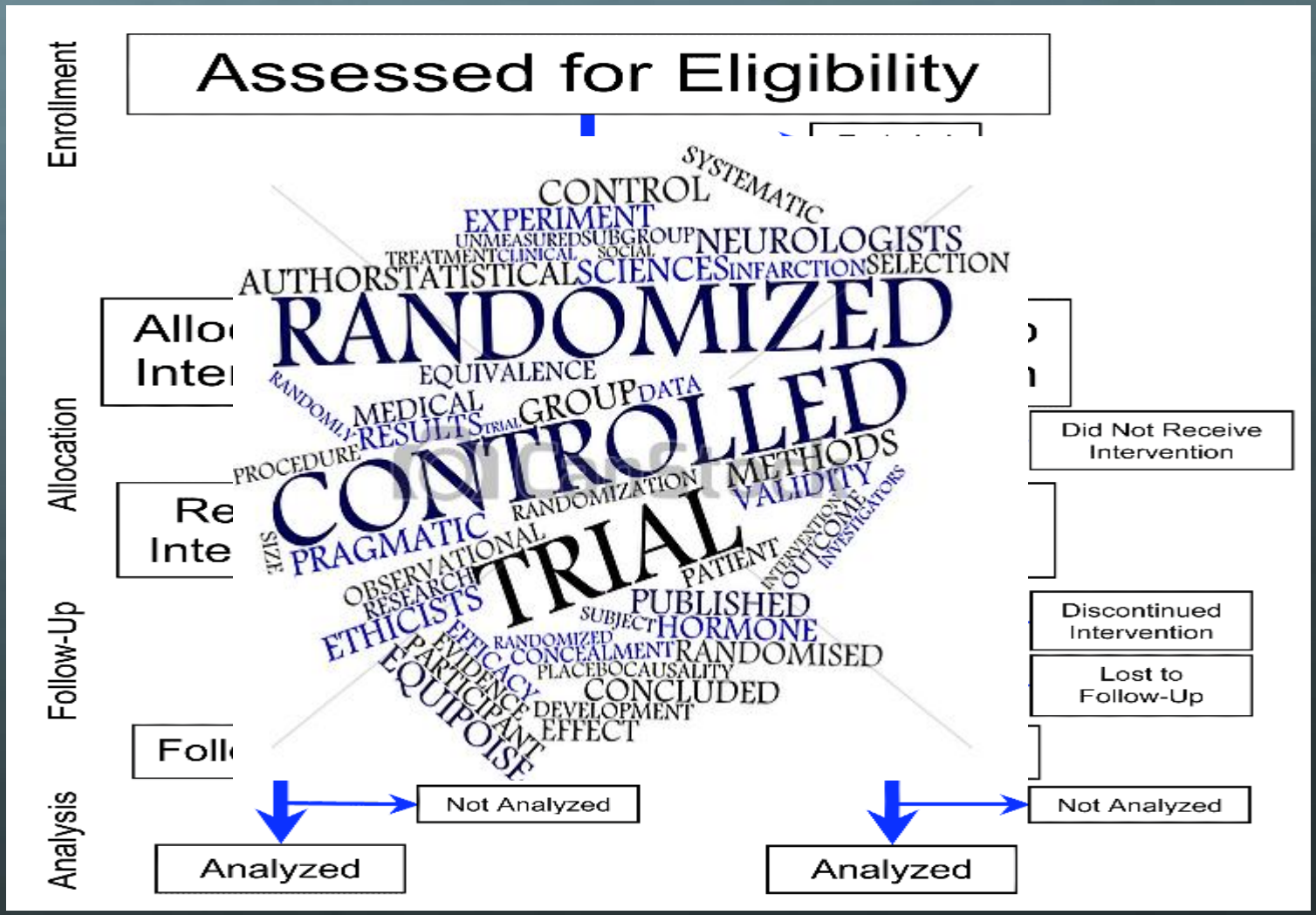
- Significant results alone are not even relevant
  (Placebo often is also significant)
- Study design and statistical quantities required
  Background: dietary habits, lifestyle, physical activity
- Long-term monitoring: Does the effect of (significant only at a time when results are not sufficient)
- Consider recent literature, in addition to the application
  Comprehensive literature needs to review the pros and cons

Study set

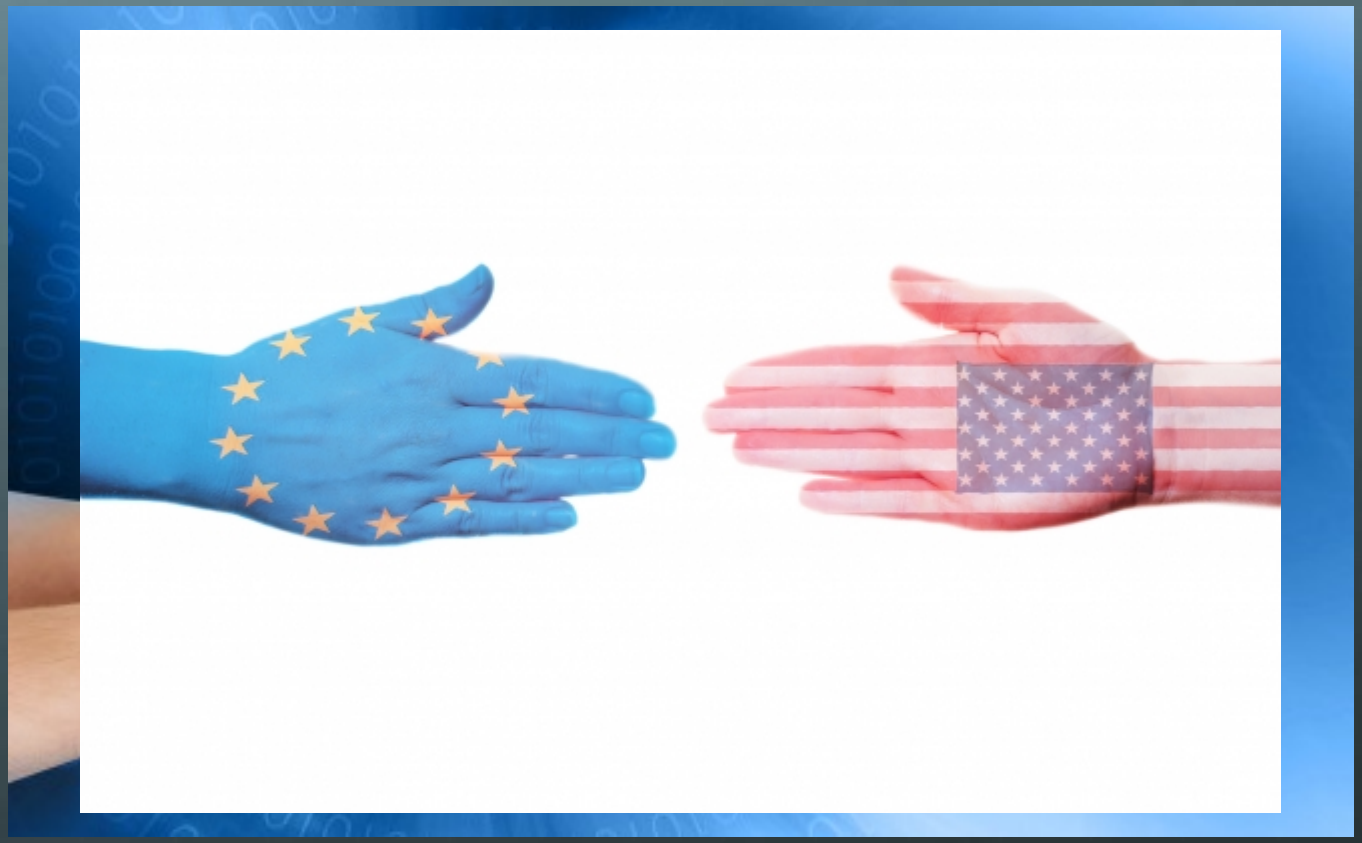
- Intervention: what, how much, where, to whom, when, how often?
- Select appropriate target variable and clearly define: effect on health
- Choose Methodologically valid analytical parameters: endpoint or marker
- Take into account intra-and inter-individual differences
  Hypothesis should already take into account the amount of the effect
- Statistics: Number of cases calculation (primary / secondary), evaluation, dealing with drop-outs external conditions: season, multi-centric?



RCT


Enrollment
Assessed for Eligibility
Allocation
Follow-Up
Analysis
Did Not Receive Intervention
Discontinued Intervention
Lost to Follow-Up
Not Analyzed
Not Analyzed
Analyzed
Analyzed
RANDOMIZED
CONTROLLED
TRIAL
CONTROL
EXPERIMENT
NEUROLOGISTS
SCIENCES
AUTHORS
STATISTICAL
INFARCTION
SELECTION
EQUIVALENCE
MEDICAL
RESULTS
GROUP
DATA
METHODS
VALIDITY
PRAGMATIC
RANDOMIZATION
OBSERVATIONAL
RESEARCH
PATIENT
PUBLISHED
HORMONE
ETHICISTS
RANDOMISED
CONCEALMENT
PLACEBO
CAUSALITY
CONCLUDED
DEVELOPMENT
EFFECT
EQUIPOISE
SYSTEMATIC
UNMEASURED
SUBGROUP
TREATMENT
CLINICAL
SOCIAL
PROCEDURE
RANDOMLY
TRIAL
SIZE
OUTCOME
INVESTIGATORS
SUBJECT
EFFICACY
PARTICIPANT

Let´s cooperate



Thank you for your final attention

Claus Muss MD.Ph.D



Internationale Gesellschaft für angewandte Präventionsmedizin e.V.

www.i-gap.org

St. Elisabeth University for Research and Social Science