European Food Safety Authority

EFSA's assessment of relationships between nutrition and health:

1. **dietary reference values**,
2. **food based dietary guidelines**,
3. **health claims**.

Hildegard Przyrembel, Vice-Chair of the EFSA-Panel on Dietetic Products, Nutrition and Allergies (NDA)

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

(33) *„The establishment of a European Food Safety Authority should reinforce the present system of scientific and technical support".*

(35) „The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence…."

(46) „In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure."

Scientific Panel for dietetic products, nutrition and allergies (NDA)

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- 21 members from 11 countries (UK:4; F:3; D:3; NL 2; SF:2; 1 each from DK, E, GR, IRL, I, N), last appointed 2009 for 3 years
- Tasks: assessment of risks and (increasingly) benefits

  Human nutrition,

  Food allergies/allergens,

  Safety of novel foods and ingredients

  Dietary reference values

  Health claims
- Working groups: Claims; Food allergy; Novel foods;

  Population reference intakes; Infant nutrition

1. Dietary reference values (DRV)

Relevant opinions

- Scientific Opinion on principles for deriving and applying Dietary Reference Values
- Scientific Opinion on Dietary Reference Values for water
- Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, *trans* fatty acids, and cholesterol
- Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre
- all published 25.03.2010 after public consultation
- *http:// www.efsa.europa.eu/en/scdocs/doc/1458.pdf or 1459.pdf or 1461.pdf or 1462.pdf*

DRV for protein and energy are presently being discussed

Terms of reference

In accordance with Article 29 (1)(a) and Article 31 of Regulation (EC) No. 178/2002, the Commission requests EFSA to review the existing advice of the Scientific Committee for Food on population reference intakes ……...

In the first instance the EFSA is asked to provide advice on energy, macronutrients and dietary fibre. Specifically advice is requested on the following dietary components:

- **Carbohydrates**, including sugars;
- **Fats**, including saturated fatty acids, poly-unsaturated fatty acids and mono-unsaturated fatty acids, *trans* fatty acids*;*
- **Protein;**
- **Dietary fibre**.

Following on from the first part of the task, the EFSA is asked to advise on Population Reference Intakes of micronutrients in the diet and, **if considered appropriate, other essential substances with a nutritional or physiological effect …..**

What are DRV and which DRV are proposed ?

Quantitative reference values of nutrient intake of healthy individuals and population groups which can be used for assessment and planning of diets:

population reference intake (PRI),

average requirement (AR),

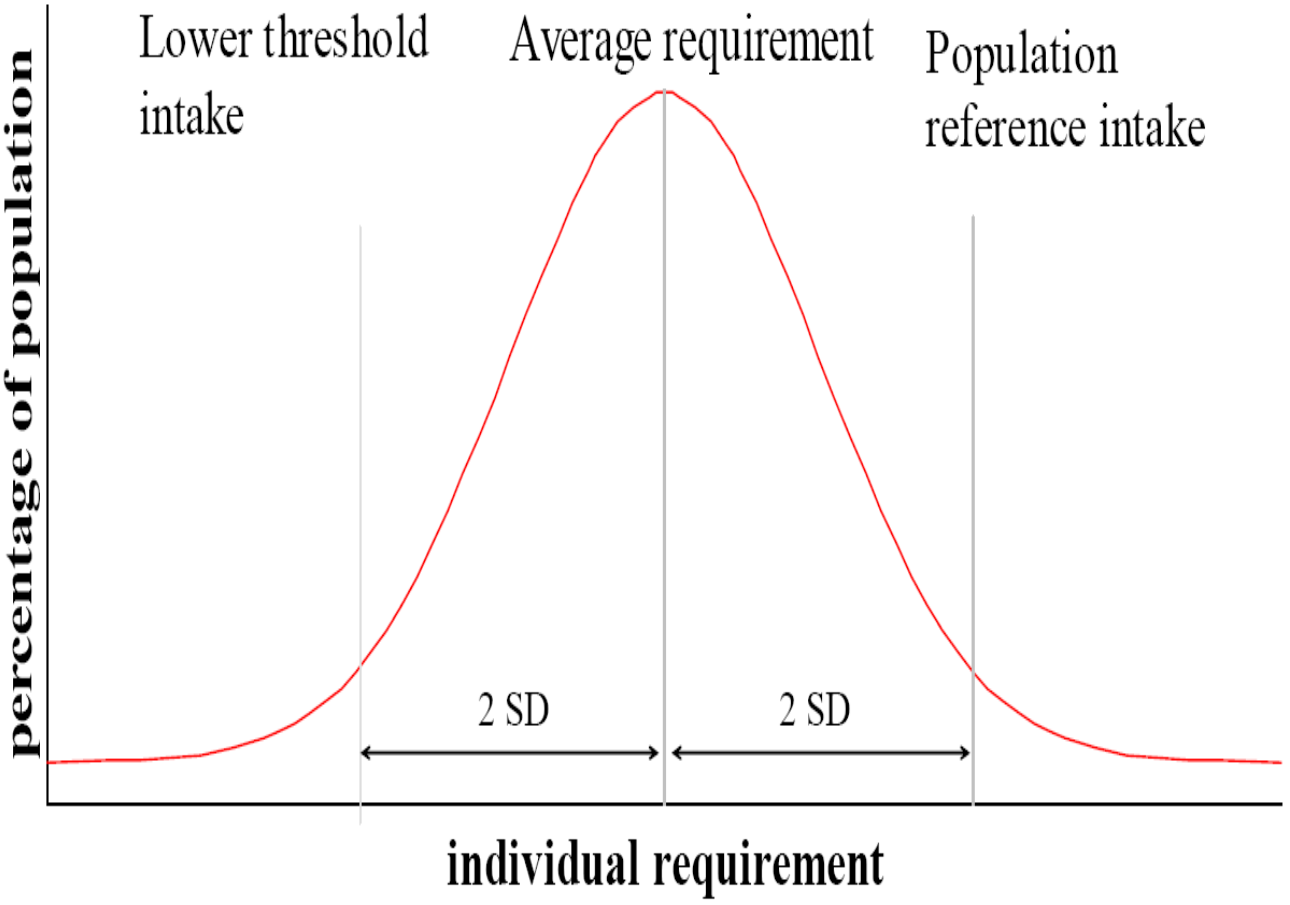
lower threshold intake (LTI),

adequate intake (AI),

reference intake range for macronutrients (RI)

Tolerable upper intake levels (UL) were published in 2006 *(http://www.efsa.europa.eu/en/science/nda/nda_opinions.html).*

Derivation of LTI, AR, PRI



Derivation and definition of DRV

1. AR=*average requirement* = the level of (nutrient) intake that is adequate for half of the people in a population group, given a normal distribution of requirement.

The average requirement is the level of intake of a defined group of individuals estimated to satisfy the physiological requirement or metabolic demand, as defined by the specified criterion for adequacy for that nutrient, in half of the healthy individuals in a life stage or sex group, on the assumption that the supply of other nutrients and energy is adequate.

For energy, the average requirement is generally the only reference value provided, because of the very large variations in requirements due to variations in anthropometric characteristics and in the levels of physical activity.

Derivation and definition of DRV

2. LTI= *lower threshold intake* = the level of intake below which, on the basis of current knowledge, almost all individuals will be unable to maintain "metabolic integrity", according to the criterion chosen for each nutrient.

   The LTI is the lowest estimate of the requirement from the normal distribution curve, and is generally calculated on the basis of the AR minus twice its SD. This will meet the requirements of only 2.5% of the individuals in the population. When the distribution of the requirement among individuals is not normal, data may be transformed to normality.

Derivation and definition of DRV

3. PRI=*population reference intake* = the level of (nutrient) intake that is adequate for virtually all people in a population group.

By convention and on the assumption that the individual requirements for a nutrient are normally distributed within a population and the inter-individual variation is known, the PRI is calculated on the basis of the AR plus twice its standard deviation (SD). This will meet the requirements of 97.5% of the individuals in the population. The magnitude of the PRI in relation to the AR depends on the estimated variation between individuals. For nutrients for which the variation in requirement is unknown, a default coefficient of variation (CV) of 10% to 20% is used assuming a normal distribution. Depending on the CV used the PRI is calculated as [AR x (100+2CV)] /100. EFSA will decide on the coefficient of variation case by case. PRI are expressed on a daily basis, but are applied to usual intakes averaged over longer periods of time.

Derivation and definition of DRV

4. AI = *adequate intake* = is the value estimated when a PRI cannot be established because an average requirement cannot be determined.

An AI is the average (median) daily level of intake based on observed, or experimentally determined approximations or estimates of nutrient intake, by a group (or groups) of apparently healthy people that is assumed to be adequate. The practical implication of an AI is similar to that of a PRI, i.e. to describe the level of intake that is considered adequate for health reasons. The terminological distinction relates to the different way in which these values are derived and to the resultant difference in the „firmness“ of the value.

Derivation and definition of DRV

5. RI = *recommended intake ranges for macronutrients* = the reference intake range for macronutrients, expressed as % of the daily energy intake, defined by a lower and an upper bound.

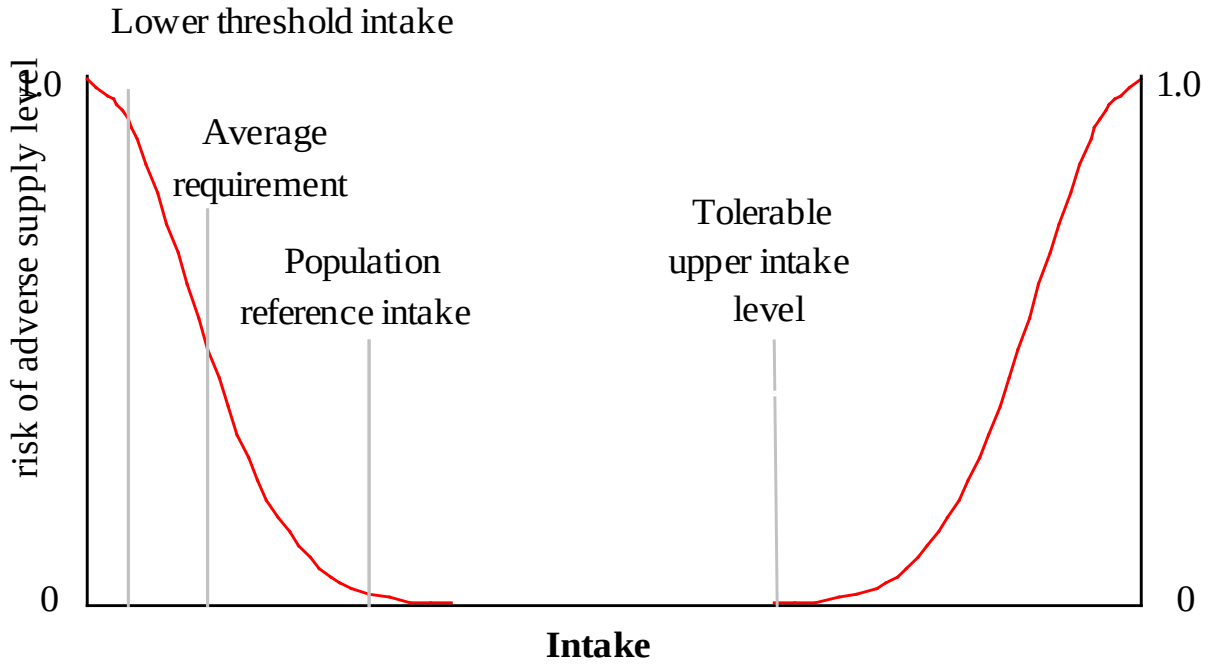
For some energy-yielding macronutrients, reference intake ranges are expressed as the proportion (percentage) of energy derived from that macronutrient. These are usually derived from data on intake in healthy populations and on data on risk of chronic disease and apply to ranges of intakes that are adequate for maintaining health and that are associated with a low risk of selected chronic diseases.

Derivation and definition of DRV

6. UL= *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

EFSA has published in 2006 ULs for vitamins and minerals determined by the Scientific Committee on Food and by the EFSA.

Relationship between different DRVs



From: Health and Welfare, Canada, 1983; as adapted by Netherlands Health Council , 2000

Derivation and definition of DRV

Necessary steps and decisions

- Criteria for adequate nutrient status (prevention of deficiency, optimalisation of body stores and function)
- Consideration of variability in absorption, metabolism and growth depending on age and status
- Choice of age groups and anthropometric reference values (same as SCF, 1993),
- Exclusion of the first six months of life
- Choice of the method of interpolation/extrapolation between different age groups on the basis of body weight, surface or "metabolic weight" on a case-by-case basis
- Choice of the presentation method, point estimates and/or distribution of estimates

PRI - Example water

Sources of water for the body

The Panel differentiates between „**total water**“ intake, i.e. water from beverages, including drinking water, and solid foods,

and „**total available water**“ intake, i.e. water from beverages, including drinking water, solid foods and oxidative water.

„**Total water**“ intake is the subject of DRVs, „**total available water**“ intake is relevant for water balance estimation.

Water requirement

There is an absolute requirement to replace all losses of water. A water intake that covers the need of everybody in any population group cannot be defined, because the individual need for water is related to caloric consumption, to insensible water losses and to the concentrating/diluting capacity of the kidney.

"The **minimum water requirement** for any individual in a defined condition is the amount of water that equals losses and prevents adverse effects of insufficient water, such as hypohydration. Adding up the losses via urine, skin, lung and faeces, total water intakes of between 1400 ml in a sedentary adult and up to 12,000 ml in an active adult at high temperature, eating a diet providing an osmotic solute load of >1500 mosm, and with reduced capacity to concentrate urine above 400 mosmol/L water would be needed to balance losses".

Therefore, it was not possible to determine average requirements (AR) for water in population groups from the available data obtained under non-standardised conditions, consequently also not population refererence intakes (PRI)

DRVs for water

Adequate intakes (AI), *applicable in moderate temperature environments and under moderate physical activity*

- **Infants 0-6 m**: intake of water from breast-milk
- **Infants 7-12 m**: intake of water from breast-milk and from complementary food and beverages
- **Children 1-2 y**: by interpolation between infants and toddlers
- **Children 2-3 y, 4-8 y and boys and girls 9-13 y**: observed intakes, corrected for water-energy relationship
- **Adolescents and adults including elderly**: observed intakes and achievable/desirable urine osmolarity
- **Pregnancy**: adult values plus increase in proportion to increased energy consumption
- **Lactation**: adult values plus compensation for water loss due to milk production

No UL or LTI

DRVs for total water intake

Adequate intakes (AI),

- **Infants 0-6 m**: 100-190 ml/kg b.w./d
- **Infants 7-12 m**: 800-1000 ml/d
- **Children 1-2 y**: 1100-1200 ml/d
- **Children 2-3 y:** 1300 ml/d
- **Children 4-8 y:** 1600 ml/d
- **Boys 9-13 y:** 2100 ml/d **and girls 9-13 y**: 1900 ml/d
- **Female adolescents and adults including elderly**: 2.0 L/d (P 95 3.1 L/d)
- **Male adolescents and adults including elderly**: : 2.5 l/d (P 95 4.0 L/d)
- **Pregnancy**: adult values plus 300 ml/d
- **Lactation**: adult values plus 700 ml/d

The individual maximum tolerable water intake is determined by the renal capacity for urine dilution.

2. Food based dietary guidelines (FBDG)

Relevant publication:

Scientific Opinion on establishing food-based dietary guidelines

published 25.03.2010 after public consultation

http://www.efsa.europa.eu/en/scdocs/doc/1460.pdf

Terms of Reference – Food based dietary guidelines (FBDG)

☞ ***To provide guidance on the translation of nutrient based recommendations (dietary reference values, DRV) into guidance on contribution of different foods to the overall diet (into food-based dietary guidelines)***

Rationale for FBDG

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- Unfavourable dietary habits in the EC contribute to health problems.
- Nutrition means a combination of different foods which together cover the needs for energy and nutrients.
- Nutrition is not only characterised by the content of nutrients and the bioavailability and effects of nutrients are dependent both on properties of foods and on their processing and preparation.
- Certain dietary patterns appear to be associated with a reduced risk for some diseases although the responsible substances or mechanisms are often not (yet) known.
- Dietary habits have a cultural, ethnic, social and/or family background.

General principles for FBDG

Combining the knowledge on nutrients, food constituents and foods in guidelines for *„healthy eating“*,

taking into account epidemiological and experimental research on nutrition dependent diseases (*e.g. cardiovascular disease, hypertension, dyslpidaemia, type 2 diabetes mellitus, obesity, osteoporosis, constipation, diverticulosis, iron deficiency anaemia, dental caries and malnutrition*),

the prevalence and importance of which can vary in different European countries because of different dietary habits.

EFSA's approach in developing guidance for FBDG

1. Review and evaluation of existing FBDG taking particularly into account goals and fields of application
2. Review and evaluation of recent literature on nutrition dependent health problems and nutrition patterns in Europe
3. Consideration of the results of the 5th Scientific Colloquium of EFSA (2006) on scientific approaches and the advantages and disadvantages of different approaches to the development of FBDG
4. Questioning of 20/25 Member States of the EC on the existence of (national) FBDG, their origin, target groups, data bases, food groups included, statements on health and representation

Approach in Setting FBDG (1)

☞ **Identification of general diet-health relationships**

Convincing evidence: energy balance, fatty acid pattern, fruit and vegetables, water, fibre, sugar, certain vitamins and minerals, alcohol consumption

Important for individual countries:

to collect recent international and national expert reviews on diet-health relationships and to complete the review if additional country-specific health and dietary issues have to be considered

Approach in Setting FBDG (2)

☞ **Identification of country-specific diet-related health problems**

Public health issues in most MS: cardiovascular diseases, cancer, hypertension, dyslipidaemia, type 2 diabetes, overweight, obesity, osteoporosis

Important for individual countries:

to review diet health patterns, diseases and mortality in their area, to identify the nutrition problems of public significance and to try to rank the different problems according to their potential impact on health

Approach in Setting FBDG (3)

☞ **Identification of critical nutrients**

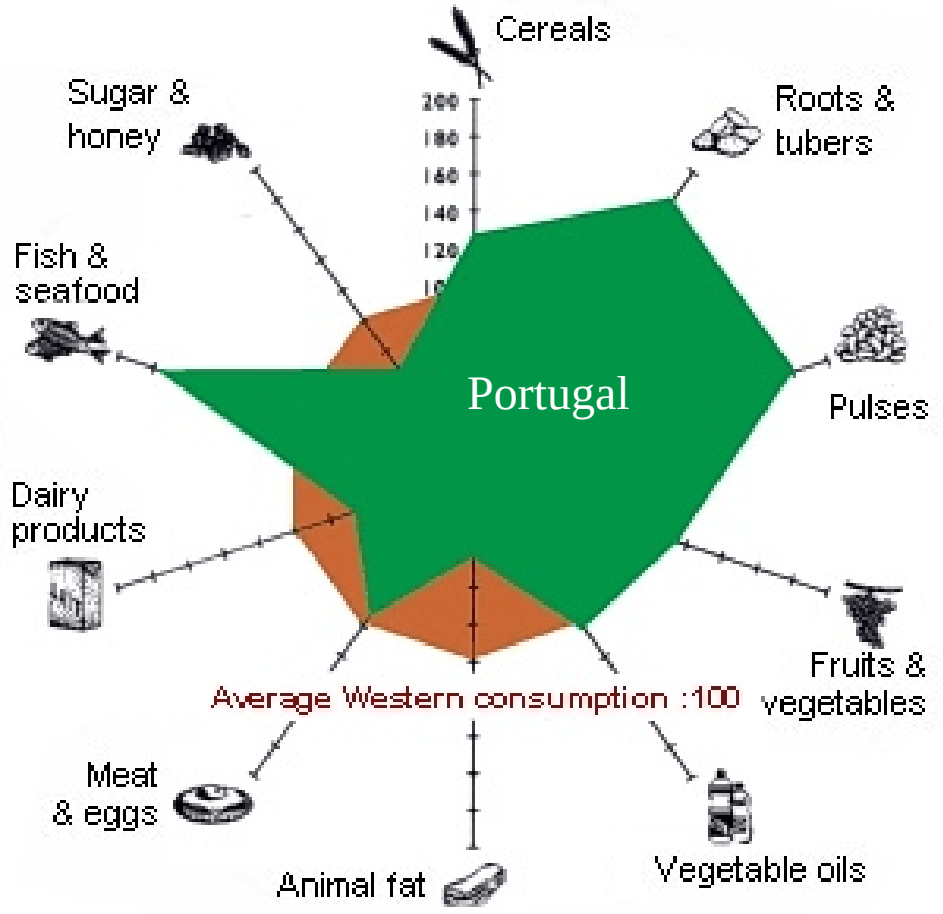
comparing habitual intake from dietary surveys to DRV

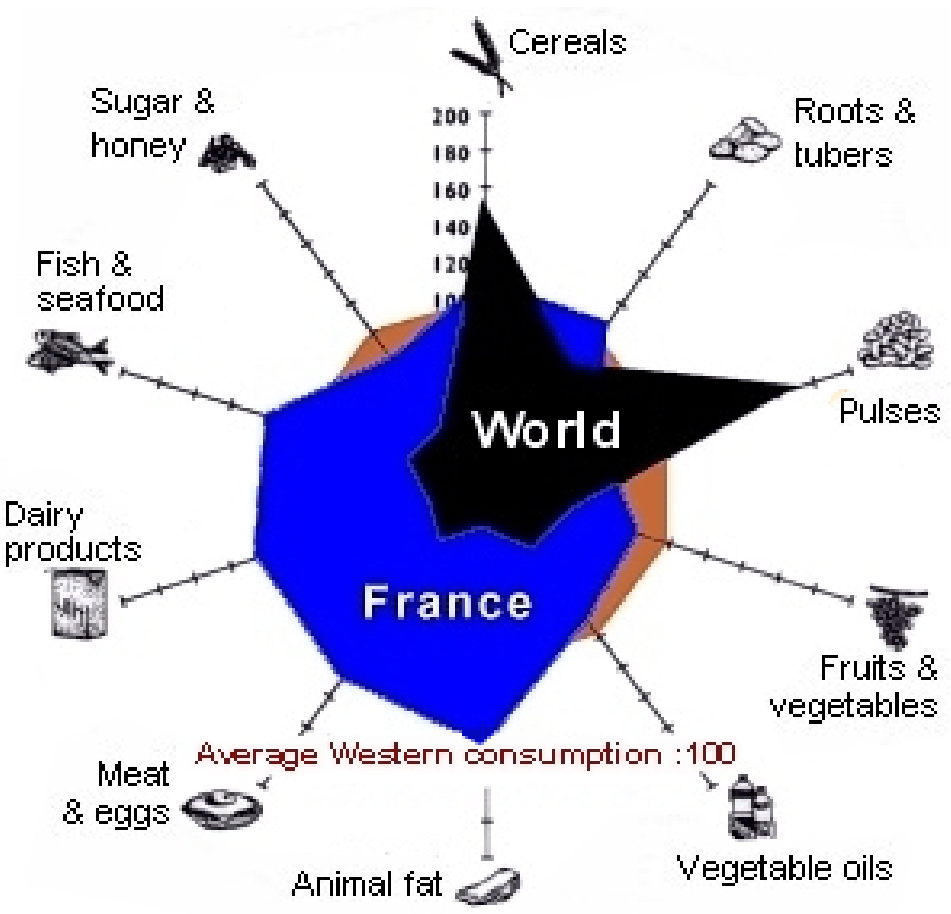
comparing anthropometry and available biochemical indicators to reference values

Important for individual countries:

to prioritise those nutrients consumed at levels not in accordance with DRV and for which there is evidence of an important health relationship in their specific country/region

Comparison of the pattern of available foods of Portugal and France with the food pattern of all western countries (brown circle) and of the world (black)





Approach in Setting FBDG (5)

☞ **Identification of critical food consumption patterns**

relationship of health with the overall diet rather than with single nutrients

Important for individual countries:

to identify main food consumption patterns in the population, to identify those patterns which are likely associated to better health, to identify foods characteristic for more favourable or less favourable patterns and the characteristics of the population for each consumption pattern for targeting recommendations and actions

Approach in Setting FBDG (6)

☞ **Testing and optimising FBDG**

to confirm the coherence and ability of FBDG to achieve the recommendations, to avoid unwanted side effects

Important for individual countries:

To model effectiveness and potentially undesirable effects on overall dietary balance and to modify and adapt FBDG according to the results of modelling and in accordance with conditions prevailing in the country

Approach in Setting FBDG (7)

☞Graphical translation of FBDG

Important for individual countries:

to develop geographical representations of FBDG in order to facilitate communication to consumers and to adapt and validate existing tools for the country-specific FBDG or to develop country-specific graphical tools

3. Health claims

Relevant publications by EFSA

Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim. The EFSA Journal (2007) 530, 1-44.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm

Frequently Asked Questions (FAQ) related to the EFSA assessment of Article 14 and 13.5 health claims applications. EFSA Journal 2009; 7(9):1339. [18 pp.]. doi:10.2903/j.efsa.2009.1339.

Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims. EFSA Journal 2009; 7(11):1386. [10 pp.]. doi:10.2903/j.efsa.2009.1386.

Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (issued for public consultation). 01.06.2010. Available online: www.efsa.europa.eu

Regulation (EC) 1924/2006 …on nutrition and health claims made on foods

Goal: to *complement the general principles in Directive 2000/13/EC in prohibiting the use of information that would mislead the purchaser or attribute medicinal properties to food.*

Claims must be truthful

- Entered into force 19 January 2007
- Applicable from 1 July 2007

Regulation (EC) 1924/2006 …on nutrition and health claims made on foods

- **Claim** *means any message or representation, which is not mandatory.., including pictorial, graphic or symbolic representation,…which states, suggests or implies that a food has particular characteristics.*
- **Nutrition claim** *means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to a) the energy it provides; provides at a reduced or increased rate; or does not provide and/or b) the nutrients or other substances it contains; contains in reduced or increased proportions; or does not contain.*
- **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** *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.*

How are claims regulated in the EU?

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Article 13

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

1. role of a nutrient in growth, development and the functions of the body
2. psychological+behavioural functions
3. slimming, weight control, hunger, satiety, reduced energy

Community list adopted by the Commission after consulting EFSA on compilation of claims from Member States by 31 December 2011 (**Register**)

Article 14

Reduction of disease risk claims and claims referring to children's development and health

Must be accompanied by a statement that diseases have multiple risk factors and that altering one of these may or may not have a beneficial effect.

Application for authorisation (dossier) via Member State to EFSA, information of other Member States and the Commission and of the public; EFSA's opinion within 5 months; decision draft by Commission after 2 months; decision with Member States after 3 months;

(**Register,** public, contains also rejected claims and reasons for rejection)

Regulation (EC) 1924/2006 …on nutrition and health claims made on foods

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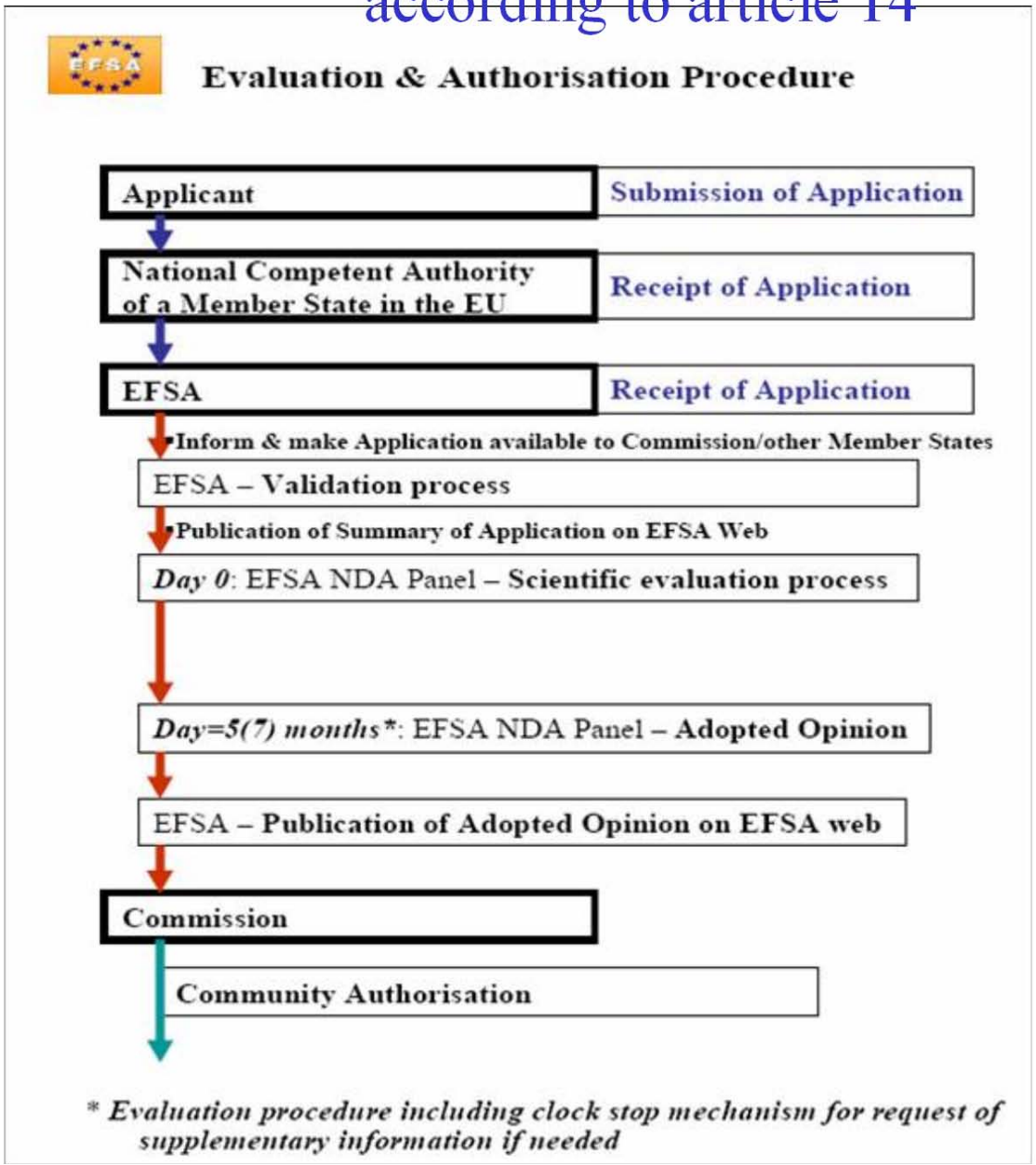
Health claims ***shall not*** (art. 3):

- *"give rise to doubt about the safety and/or the nutritional adequacy of other foods"*
- *"encourage or condone excess consumption of a food"*
- *"state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general"*
- *"exploit fear in the consumer"*
- *"be false, ambiguous or misleading"*

Terms of Reference given to EFSA for the evaluation of §14 claims

"EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No.1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to Product X and Effect Y".

Schedule for evaluation of an application for a health claim according to article 14



Within 14 days

Immediately

Immediately

5 Months

30 days for comments

60 days for decision

EFSA‘s procedure in the evaluation of article 14 and 13.5 claims

1.Characterisation of the food/ constituent: Food, nutrient, combination; product or substance specific claim; source,composition, stability, variability; plant: name, parts used, processing; bacterium: strain identity; conditions of use

2. Claimed effect:

Which effect is claimed? Meaning of proposed wording

Relevance of the claimed effect to human health: is it a beneficial physiological effect ? Is there an effect on a risk factor for a disease? Can it be measured? Is it a relevant and validated risk factor ? Does the change in the risk factor constitute a beneficial physiological effect ? What is the target group of the claimed effect ?

3. Scientific substantiation:

Literature provided and search criteria; Literature pertinent? Study types, numbers, quality, reliability; Study description and results; Conclusion on studies individually and in total; Human studies central, supported by animal and/or *in vitro* studies

Result: a) characterisation yes/no; b) beneficial physiological effect yes/no; c) cause and effect relationship between consumption and effect yes/no; d) wording scientifically correct; e) conditions of use

Beneficial effects

The claimed effect must be clearly defined.

It must be testable or measurable.

The chosen outcome measure(s) must be appropriate to allow an assessment if (and to what extent) the effect has occurred.

Not every demonstrated statistically significant effect is BENEFICIAL !

The NDA Panel makes a scientific judgement on whether the claimed effect is considered to be a beneficial nutritional or physiological effect

"Function claims" (as in article 13, No. 1) may relate to "maintenance" or "improvement" of a function.

When the definition of the claimed effect is unclear in the consolidated list, the NDA Panel uses its best judgement to identify the intended message from the health relationship and the proposed wordings provided.

Risk factors

- - serve as **predictors** for the development of a human disease.

There are non-modifiable risk factors, like sex, age, genetics and modifiable risk factors, like life-style habits (diet, physical activity, smoking, body mass.

- A (bio)marker (or symptom) can serve as a surrogate risk factor.

A biomarker is any substance, structure or process that can be measured in the body or its products and influences or predicts the incidence or outcome of diseases.

- Risk factors need to be relevant and valid.
- Relevance refers to the appropriateness of the risk factor to denote a plausible mechanism for or predict the development of a disease.
- Validity is a function of both the methodology of measurement and the established relationship to health.

Regulation (EC) 1924/2006 – EFSA's assessment

If a cause and effect relationship is considered to be established, EFSA considers whether:

- the quantity of food/pattern of consumption required to obtain the claimed effect can be consumed within a balanced diet
- the proposed wording reflects the scientific evidence
- the proposed wording complies with the criteria for the use of claims specified in the Regulation
- the proposed conditions of use are appropriate
- substantiation was dependent on data claimed as proprietary by the applicant

Regulation (EC) 1924/2006 – EFSA's assessment

Possible outcomes of EFSA's assessment:

- A cause and effect relationship **is** established between the consumption of the food/constituent and the claimed effect
- A cause and effect relationship **is not** established between the consumption of the food/constituent and the claimed effect

OR

- The evidence provided is **not sufficient** to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect

Terms of reference for the evaluation of list of § 13 claims dd 24 July 2008

EFSA should consider and advise particularly on

- *adequate characteristics of the food pertinent to the beneficial effect*
- *the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence*
- *specific importance of the food for the claimed effect*
- *extent to which the claimed effect of the food is beneficial*
- *extent to which a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.*
- *could this quantity reasonably be consumed as part of a balanced diet*
- *the representativity of the study group(s) in which the evidence was obtained for the target population for which the claim is intended .*
- *the wordings used reflect the scientific evidence and comply with the criteria laid down in the Regulation*
- *additional labelling requirements*

Commission Rules for Art. 13 *Health Claims*

Evidence on the role of a food in a nutritional or physiological function is insufficient for the justification of a *Claim* without demonstrating a significant beneficial effect of the consumption of that food on functions of the body which have an impact on HEALTH.

Regulation (EC) 1924/2006 – Article 13

- **31 January 2008** - Member States submitted national lists – (44.000 entries)
- **End 2008** - Consolidated list submitted to EFSA together with ToR
  - (4185 main entry claims / around 10.000 similar health relationships)
- **January 2009** – EFSA publishes database
- **2009** - Clarification process
  - 2145 health claims sent back to the MS for further information or clarification (6 criteria)
- **March 2010** - Submission of an addendum to EFSA (452 main entry claims)
- **May 2010** – EFSA publishes consolidated database (4637 main entry claims)
  - Incorporates amendments to January 2009 database (missing and misplaced claims)
- **Approx 300 claims withdrawn so far**

Example § 14 claim (reduction of disease risk)

Product: Food supplement with cranberry extract and D-mannose

Claimed effect: "*prevents adhesion of bacteria (mostly E. coli) to the cell surface, a risk factor for urinary tract infections.*"

Proposed wording: "*eliminates the adhesion of harmful bacteria to the bladder wall. The adhesion of harmful bacteria to the bladder wall is the main risk factor in the development of urinary tract infections*".

Accepted health relationship by EFSA: reducing the risk of urinary tract infection by inhibiting the adhesion of certain bacteria in the urinary tract is beneficial to human health.

Wording proposed by EFSA: none

Example functional § 14 claim (children)

Product/substance: a) Iron b) Iodine

Claimed effect:

a) „Iron is n*ecessary for the cognitive development of children"*.

b) *„Iodine is "necessary for the growth of children"*.

Proposed wording:

a)*"Iron is necessary for the cognitive development of children"*

b)"Iodine is necessary for the growth of children"

Accepted health relationship by EFSA:

a) Normal cognitive development is beneficial to children's health.

b) Normal growth is beneficial for children's health.

Wording proposed by EFSA:

a) Iron contributes to normal cognitive development of children.

b) Iodine contributes to normal growth of children

Example § 13 (5) claim

Product: Dietary supplement with concentrated wild fish oil

Claimed effect: *"Management of vasomotor symptoms, particularly hot flushes".*

Proposed wording: *"Contributes to the reduction in the number of hot flushes".*

Accepted health relationship by EFSA: Reduction in the frequency of episodes of hot flushes is beneficial to the health of peri- and post-menopausal women.

Wording proposed by EFSA: none

Example § 13(1) claim

Substance: Thiamin

Claimed effects:

a)*"Energy metabolism"* and *"macronutrient metabolism"*

b)"Normal cardiac function".

Proposed wordings:

a)*"Thiamin is needed to release the energy from foods; from protein and carbohydrates".*

b*)"Thiamin is needed to keep the heart working properly; for normal cardiac function; for the normal function of the heart".*

Health relationship accepted by EFSA:

a) Normal energy-yielding metabolism is beneficial to human health

b) Normal cardiac function is beneficial to human health

Wordings proposed by EFSA:

a) Thiamine contributes to normal energy metabolism.

b) Thiamine contributes to the normal function of the heart

Example § 13(1) claim continued

Substance: Thiamine

Claimed effects:

c) *"Neurological function/neurological systems"*

d-h) "Bone/teeth/hair/skin and nail health"

Proposed wordings:

c) "*Thiamin is necessary for normal neurological and cardiac function; helps keeping the nervous system working properly*".

d-h) *"Necessary for healthy teeth, bones, hair, skin and nails"*.

Health relationship accepted by EFSA:

c) Normal function of the nervous system is beneficial to human health.

d-h) Maintenance of normal bone/teeth/hair/skin and nails is beneficial to human health.

Wordings proposed by EFSA:

c) "Thiamin contributes to the normal function of the nervous system".

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30 April 2010: Overview Article 13.5 und 14 *Claims-Assessment by* EFSA

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Claim type	Received	Withdrawn	Adopted	In progress
Children (Article 14)	210	32	48 Opinions covering 55 Applications	2*
Disease risk Reduction (Article 14)	48	7	15	7**
New science/ Proprietary (Article 13.5)	36	8	22	5
Total applications	303	47	85 Covering 92 applications	19
Article 13 list of health claims	4637	298	1080 (937 published)	3259

Regulation (EC) 1924/2006 – Article 13

- **EFSA published opinions in series**
  - First series: October 2009
  - Second series: February 2010
  - Finalisation of the assessment: end of 2011
- **Breakdown of EFSA's first two series:**
  - Substantiated claims: 182 + 10 = **192**
  - Insufficient evidence: 20 + 6 **= 26**
  - Insufficient characterisation of micro-organisms: 171 + 92 = **263**

Thank you for your attention