BREAKOUT SESSION 1

CHAIR: ***A. Martin***

RAPPORTEUR: ***B. Sundberg***

BREAKOUT SESSIONS

QUESTION N. 1

What are the essential elements/criteria that should be included in the process of scientific substantiation of claims? How to define and identify claims that are based on generally accepted/well-established scientific data/evidence? How to define and identify claims that are based on newly developed/emerging scientific data/evidence

Question 1

What are the essential elements/criteria that should be included in the process of scientific substantiation of claims? How to define and identify claims that are based on generally accepted/well-established scientific data/evidence? How to define and identify claims that are based on newly developed/emerging scientific data/evidence

- Generic claims; Close relation to recommendations, PRI as far as taking into account risk reduction
- General agreement on scientific principles, but there is a need to develop objective ways for the weighing of evidence
- Also a need, especially for plant products, to develop criteria for “traditional knowledge”

Continuing question 1

- No need for a new process where there are general agreements upon the substantiation between MS – but a need to make sure that MS agree with the list of transmitted claims.
- Emerging evidence for new claims could be accepted if there is no risk and a possibility of benefit(s).

BREAKOUT SESSIONS

QUESTION N. 2

Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

Question 2

Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

- The same quality of science should be used: only the nature of this science is depending on the kind of claim
- Extrapolation of data from studies done in countries having different nutritional habits: no "a priori" rejection, but need to examine the relevance to the European context
- The same is true for traditional knowledge (i.e. plants)

BREAKOUT SESSIONS

QUESTION N. 3

What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

Question 3

What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

- Clarify the boundary between foods and supplements, exclude the latter from the profiles?
- Public health use and consumers use
- Not misleading the consumer

BREAKOUT SESSIONS

QUESTION N. 4

What endpoints/public health indicators should be considered when establishing nutrient profiles?

Question 4
What endpoints/public health indicators should be considered when establishing nutrient profiles?

- Claims for “anything” but profiles based on major public health concerns including; wellbeing, diseases, disease related biomarkers.
- The same science quality for disqualifying or qualifying nutrients
- Specific national or regional health problems (e.g. iodin insufficiency), addressed by other means than nutrient profiles
- Consideration for food before fortification

BREAKOUT SESSIONS

QUESTION N. 5

How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?

Question 5

How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population

- Only one profile system for the whole population, but….
- Suggestion of specific reference values for labelling for specific sub groups (children, elderly,…)
- Particular attention to vulnarable sub groups, during the modelisation and validation of profiles.

BREAKOUT SESSIONS

QUESTION N. 6

Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

Question 6

Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

- Agreement upon the need and diffilculty to assess the impact of claims and profiles
- Agreement on positive effect if included in more general nutrition and education policies
- Interpretation problems with symbols without words i.e. heart, smiling face

General comments from group 1

- Guidelines for implementation of the regulation (EU)
- Guidelines for applicants how to apply, build the dossier (EFSA)

BREAKOUT SESSION 2

CHAIR: ***M. Heinonen***

RAPPORTEUR: ***J. Ruprich***

BREAKOUT SESSIONS

QUESTION N. 1

What are the essential elements/criteria that should be included in the process of scientific substantiation of claims? How to define and identify claims that are based on generally accepted/well-established scientific data/evidence? How to define and identify claims that are based on newly developed/emerging scientific data/evidence

Question N.1

1. *What are the essential elements/criteria that should be included in the process of scientific substantiation of claims?*
   - *There are good examples (PASSCLAIM, JHCI …)*

   In addition to think about:
   - *biological relevance*
   - *mechanism of action*
   - *botanical preparations with medicinal claims*
   - *food technology (stability)*

2. *How to define and identify claims that are based on generally accepted/well-established scientific data/evidence?*
   - *Totality of the evidence*
   - *Practicalities concerning of authorization of claims:*
     - *Generally accepted claims – quickly proceed*
     - *Claims based on nutritional recommendations (already approved)*

   It was also discussed that following are needed:
     - *Guidance from EFSA is a critical element for the work on the national level*
     - *Coordination of the work between EFSA and national FSA*
     - *EFSA model examples can help SMEs*
     - *Reasons for failure to make a claim to be conveyed to the applicant*

3. *How to define and identify claims that are based on newly developed/emerging scientific data/evidence*
   - *Totality of evidence*
   - *Importance of the quality of studies when number of studies is limited*
   - *Case by case approach is needed*
   - *Science is a continuous process: need for update*

BREAKOUT SESSIONS

QUESTION N. 2

Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

Question N.2

1. *Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?*
    - *Confusion about a need of scientific substantiation for nutrition claims*
    - *Nutritional and health claims need same level of scientific substantiation*
    - *Distinguish between nutrients in annex and new nutrition claims (e.g. omega -3 FA)?*

BREAKOUT SESSIONS

QUESTION N. 3

What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

Question N.3

1. *What would be the aim and scope of establishing nutrient profiles for foods bearing claims?*
    - *Scientifically based on internationally accepted dietary guidelines*
    - *Keep it simple*
    - *Dealing by food categories*
    - *Cross category definitions with exceptions*
    - *Should start from a market analysis (Swedish example)*
    - *Frequency, dietary pattern and regional variation*
    - *Scoring system?*

BREAKOUT SESSIONS

QUESTION N. 4

What endpoints/public health indicators should be considered when establishing nutrient profiles?

Question N.4

1. *<u>What endpoints/public health indicators</u> should be considered when establishing nutrient profiles?*
    - *There was some confusion about understanding the question*
    - *Initial list can be used from WHO (2003) publication*
    - *How to include other health messages e.g. fruit and vegetable consumption*
    - *It is applied only to small part of the foods on the market (?)*

BREAKOUT SESSIONS

QUESTION N. 5

How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?

Question N.5

1. *How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?*
    - *Is it an ethical question? Differences are covered by scientific substantiation*
    - *For nutrient profiles specific requirements need to be considered (vit.B12 for elderly, folate for pregnant women, Fe for young children)*
    - *Scientific substantiation should take into account target population and then labeling should indicate target population if applicable*

BREAKOUT SESSIONS

QUESTION N. 6

Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

Question N.6

1. *Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?*

   - *Taste, price, health are possible determinants of food choice, order can differ between countries*

   Other determinants:

   - *Trademarks, sign posting such as keyhole*
   - *Tradition-trust, convenience*
   - *Advertising; campaigns*

   - *Should it be included into EFSA task?*

BREAKOUT SESSION 3

CHAIR: ***H. Przyrembel***

RAPPORTEUR: ***V. Azais-Braesco***

1a: What are the essential elements/criteria that should be included in the process of scientific substantiation of claims?

- The guidance provided by the PASSCLAIM[1] project is a good basis:
  - Strict criteria needed, but application on a case by case basis is necessary, as appropriate [no a priori disqualification of certain type of studies]
  - Totality of the relevant evidence : description of methodology for literature search (exclusion/inclusion criteria)
  - Weighing of the evidence remains to be better specified
- Need for Commission (advised by EFSA) to provide practical guidance on how to build a dossier on this basis.

1.Richardson et al. EJCN 2003, 42 S1, 96-111

1b: ***How to define and identify claims that are based on generally accepted/well-established scientific data/evidence?***

- Generally accepted does not always mean well-established
- Definition of relevance according to the grading of evidence as in WHO report (2003) : levels should be “convincing” or “probable”

1c: How to define and identify claims that are based on newly developed/emerging scientific data/evidence

- Use of WHO terminology : “possible”

2-Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

- Truthfulness of the claims should be the same
- Nature of the evidence will, by necessity, be different
  - Nutrition claim : strain and number of probiotic bacteria
  - Health claim : a validated biomarker

3-What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

- Aims:
  - Categorisation of foods
  - Preventing claims on “undesirable” foods
  - Incentive for innovation and improvement of nutritional quality of foods
  - Hopefully, positive impact on Public Health. However, claim regulation cannot substitute for nutrition education of the public.
- Scope
  - No a priori exclusion of any food
  - Restricted application to foods for special dietary purposes, none for food supplements

4. What endpoints/public health indicators should be considered when establishing nutrient profiles?

- Recommended procedure
  - Identification the diet/disease relationships (e.g. WHO report) with relevance for Public Health.
  - Assessment of actual nutrient intake of populations
  - Comparison with recommended diets
  - Develop strategies to fill the gaps: NP can be part of these strategies
- Endpoints
  - Changes in dietary habits and intakes of critical nutrients
  - Increase the consumption of more healthy foods
  - …

5-How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?

- Existing legislation is already covering most of these issues
- When evaluating an application for a general claim, a systematic assessment of its impact on the health of special population groups is needed
  - The outcome can be specific warnings or recommendations
- Special attention should be given to the nutritional needs of the elderly (energy density, nutrient density, water). This can result in targeted claims.
- No specific labelling reference values for pregnant or lactating women are necessary, which does not prevent they can be specifically targeted

6-Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

- Claims have an impact on consumer behaviour, particularly on the purchase of food
- However, claims are not the only determinant (product, presentation, pricing, advertisement, …)
- Claims may also have a negative impact (eg substitution of desirable food)
- Because of the uncertainty of the overall impact, article 27 (evaluation) is strongly supported
  - Evolution of the market, Consumer understanding, Impact on dietary choices, Potential impact on non-communicable disease
  - To be added : post-marketing monitoring, including consumption by target population (mainly for disease reduction claims)

BREAKOUT SESSION 4

CHAIR: ***Prof S. Salminen, University of Turku, Finland***

RAPPORTEUR: ***Prof J. Buttriss, British Nutrition Foundation UK***

QUESTION N. 1a

What are the essential elements/criteria that should be included in the process of scientific substantiation of claims?

- Need to separate articles 13 and 14
- Need human studies (supporting mechanistic studies helpful); Totality of the evidence needs to be taken into account
- Conditions of use e.g. amount needed for effect, matrix, bioavailability
- Work has already identified some of the key issues that need to be addressed (e.g. CIAA, JHCI, Swedish and Dutch approaches)
- For article 13, JHCI experience (well established health statements for vitamins and minerals) could be a useful starting point
- **Above all guidance is needed from EFSA and EU on what exactly is required**
- Need to take a pragmatic scenario based approach to setting a realistic hurdle for inclusion & exclusion of article 13 claims – different approaches need to be tested

BREAKOUT SESSIONS

QUESTION N. 1b

How to define and identify claims that are based on generally accepted/well-established scientific data/evidence?

- **Again, guidance needed from EFSA**
- lots of good examples already developed that can be considered – different strengths and weaknesses – need guidance from EFSA

BREAKOUT SESSIONS

QUESTION N. 1c

How to define and identify claims that are based on newly developed/emerging scientific data/evidence

- Much more challenging area, particularly from a risk assessment perspective
- Above all, guidance is needed from EFSA
- We can learn from experience with medicinal products, proportional approach used by JHCI (e.g wholegrains)
- Probably will need a case by case approach

QUESTION N. 2

Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

- *No,*
- *Emerging science needs particularly careful analysis of pros and cons (in case evidence changes)*
- *Context of claim important e.g. amount of the active ingredient that needs to be in the food*
- *Need to get this right, otherwise we risk food innovation dying in the EU*
- *can learn from PASSCLAIM*
    - *Useful guidance on biomarkers but perhaps too strict, need more pragmatic approach*

BREAKOUT SESSIONS

QUESTION N. 3

What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

- Nutrient profiles have a **supporting** role to ensure that health claims do not mask the actual nutrient contribution of the food
- But need a balance - so that positive attributes are also evident to consumers for foods with a mix of nutrients, e.g. cheese, oily fish

What endpoints/public health indicators should be considered when establishing nutrient profiles?

- Overarching context is improvement in diet (public health goals)
- Need to understand the impact of claims: will they result in larger consumption of individual foods that carry claims? Changes in dietary patterns?
- Price and taste are likely to remain key drivers
- Unavoidable that once profiles are set they may be used for other purposes: this needs to be taken into consideration
- Some models we heard about included national consumption data ? extrapolation
- Request that EFSA develops models for detailed consultation.

QUESTION N. 5

How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?

- [Not sure what was meant!]
- In general claims should be relevant for the whole population
- But if claim relates to a subgroup, it needs to stipulate the target audience (and relevant evidence be available)
- PARNUTS will be of relevance in some cases
- Non-nutrients – levels for different age groups do not exist

QUESTION N. 6

Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

- Taste, price are recognised as higher priorities than health (in most cases, possible exceptions e.g. sports people)
- Need to establish who uses health claims (and the effect on dietary patterns and ?? health – is this across the board, healthy groups, others??)
- Need to establish what research needs to be place to assess this at 6 years.
- This topic will be evaluated 6 years after introduction of the Regulation. (Need to consider impact in terms of different socio-economic groups)
- Incentives for products that successfully go through substantiation process, to help ensure wider access to healthier products

BREAKOUT SESSION 5

CHAIR: ***H. Verhagen***

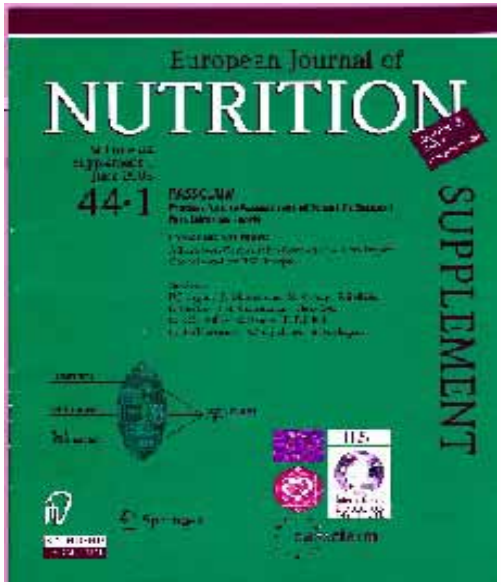
RAPPORTEUR: ***N. Ilback***

Good working group. Consensus on all points, even across stakeholders from industry, science, government etc.

BREAKOUT SESSIONS

QUESTION N. 1a

What are the essential elements/criteria that should be included in the process of scientific substantiation of claims?



passclaim

PROCESS FOR THE ASSESSMENT OF SCIENTIFIC SUPPORT FOR CLAIMS ON FOODS

Consensus on Criteria

Authors:

P. J. Aggett[1], J.-M. Antoine[2], N.-G. Asp[3], F. Bellisle[4], L. Contor[5], J. H. Cummings[6], J. Howlett[7], D. J. G. Müller[8], C. Persin[9], L. T. J. Pijls[5], G. Rechkemmer[10], S. Tuijtelaars[5] and H. Verhagen[11]

BREAKOUT SESSIONS

QUESTION N. 1b

How to define and identify claims that are based on generally accepted/well-established scientific data/evidence?

- *Apply a high scientific standard and transparency*
- *Avoid criticism not having applied scientific rigor even for obvious health claims*
- *Even ancient knowledge has to be re-evaluated by current scientific standards*
- *Redo evaluation after some years (in the light of emerging science and possible deletion from list)*

BREAKOUT SESSIONS

QUESTION N. 1c

How to define and identify claims that are based on newly developed/emerging scientific data/evidence

- *Grading of evidence is neccesary in the process of scientific evaluation*
- *Grading of evidence is not for consumer information. Participants had consensus that qualified health claims are not desirable. Even in the USA qualified health claims are not appreciated by scientists nor by industry.*
- *Passclaim has also expressed an opinion against qualified health claims.*

BREAKOUT SESSIONS

QUESTION N. 2

Should the same criteria be used for the substantiation of both nutrition and health claims as well as for the different type of health claims, i.e. functional claims, disease-risk reduction claims, claims on children's development and health, etc?

- *Nutrition claims are straigth forward: "contains, light, rich in etc."*
- *All health claims have to be evaluated to the same scientific standard.*

BREAKOUT SESSIONS

QUESTION N. 3

What would be the aim and scope of establishing nutrient profiles for foods bearing claims?

- *Aim and scope were already identified years ago as they are now an integral part of the Regulation.*
- *In the light of the Regulation a binairy system (yes /no) is sufficient.*
- *Nutrient profiles are for allowing health claims, NOT for consumer education and communication.*
- *A category-based approach is preferred because:*
  - *This drives industry innovation*
  - *Is better from a public health perspective (stimulates better options even within 'bad food' categories)*

BREAKOUT SESSIONS

QUESTION N. 4

What endpoints/public health indicators should be considered when establishing nutrient profiles?

- *Identify public health indicators from common diseases (e.g. obesity, cardiovascular disease, …)*
- *Select nutrients from epidemiology studies for negative / positive nutrient profiling evaluation*

BREAKOUT SESSIONS

QUESTION N. 5

How to deal with the different nutritional requirements of different subgroups of the population, such as pregnant women, lactating women, children and elderly, concerning health claims in general as well as claims directed at these specific groups of the population?

Population reference values are already defined for subgroups; this is an issue outside the scope of the health claims Regulation

- *Claims are already aimed at subgroups in the populations; a subgroup may comprise a large part of the population*
- *Nutrient profiles are already so complicated that setting NP's for subgroups would be essentially impractical*

BREAKOUT SESSIONS

QUESTION N. 6

Determinants of food choice and dietary behaviour: evaluation of food choices/dietary behaviours (what information is needed, what are the means for assessment, what are the main components for characterization); which determinants have positive effects and which ones have negative effects?

- *Wording of a claim can be judged by EFSA, but not the consumer understanding of its meaning. Need for guidance from Commission.*
- *Consumer understanding of a health claim should be included in the dossier (not for article 13.1 claims); manufacturers will anyway do studies on consumer understanding prior to marketing.*
- *Need for knowledge of consumer understanding of nutrient function claims in article 13.1 list.*