Eur J Nutr (2007) 46[Suppl 2]:4–14
DOI 10.1007/s00394-007-2003-6

SUPPLEMENT

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Nutritional characterisation of foods: Science-based approach to nutrient profiling

Summary report of an ILSI Europe workshop held in April 2006

Abstract The background of the workshop was the proposed EU legislation to regulate nutrition and health claims for foods in Europe. This regulation will require the development of a science-based nutrient profiling system in order to determine which foods or categories of foods will be permitted to make nutrition or health claims. Nutrient profiling can also be used to categorize foods, based on an assessment of their nutrient composition according to scientific principles. Today, various nutrient profiling schemes are available to classify foods based on their nutritional characteristics. The aim of the workshop was to discuss the work developed by ILSI Europe's expert group and to explore wider scientific aspects of nutrient profiling, including their relative effectiveness, strengths and weaknesses. In particular, the focus of the workshop was on scientific approaches to the development of nutrient profiles for the purpose of regulating nutrition and health claims. The 76 workshop participants were scientists from European academic institutions, research institutes, food standards agencies, food industry and other interested parties, all of whom contributed their thinking on this topic. The workshop reached a degree of agreement on several central points. Most participants favored a food category approach rather than an 'across the board' system for nutrient profiling. Most also felt that nutrient profiling schemes should focus on disqualifying nutrients, while taking into due account relevant qualifying nutrients. Levels of each nutrient should be clearly defined for all food categories to be profiled. Reference amounts selected for further considerations were: (1) per 100 g/100 ml, (2) legislated reference amounts, and (3) per 100 kcal. The majority of workshop participants agreed that nutrient profiling schemes should allow for a two-step decision process; step (1) identify which nutrients to take into account, and step (2) define the thresholds for these nutrients. All participants agreed that an objective validation should be conducted before implementation of nutrient profiling. This would include determination of sensitivity and specificity using "indicator foods" selected on their potential to affect major health issues. The management of any adopted system needs to allow it to be dynamic over time and revise the system when new scientific knowledge emerges. The majority of participants favored a food category approach rather than an 'across the board' system. Further work is required to identify the final list of qualifying and disqualifying nutrients for any food category that may be identified and for the selection of optimal reference amounts. It is essential that key stakeholders continue to communicate and work together on the complex issues of nutrient profiling.

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EJN 2003

Key words nutrient profiling – health claims – food category – across the board – validation

Glossary and abbreviations

'Across the board' system: Generic benchmarks for all food products
BMI: Body Mass Index
CIAA: Confederation of the Food and Drink Industries of the EU (http://www.ciaa.be/)
Codex Alimentarius: Literally: 'Food Code'. An organization that creates and compiles food standards, codes of practice and recommendations. Membership is open to all countries associated with the Food and Agricultural Organization of the United Nations and with the World Health Organization. Also non-governmental organizations. (http://www.codexalimentarius. net)
DAFNE: Data Food Networking (http://www.dafne.uk.com/)
DALYs: Disability Adjusted Life Years
Disqualifying nutrient: a nutrient that, when present in a food, potentially disqualifies the food for bearing a nutrition and/or health claim
EFG: European Food Grouping
EPIC: European Prospective Investigation into Cancer and Nutrition (http://www.iarc.fr/epic/)
EUROCODE: Eurocode2, Food Coding System (http://www.eurocode2.info/)
EURODIET: Nutrition and Diet for Healthy Lifestyles in Europe (http://www.eurodiet.com/)
Food category system: Benchmarks for specific food groups
FSA: Food Standards Agency. The UK Food Standards Agency is an independent Government department set up by an Act of Parliament in 2000 to protect the public's health and consumer interests in relation to food (http://www.fsa.gov.uk/)
GDA: Guideline Daily Amounts. A guide to the daily amount of e.g. calories, fat and salt that the average adult should have in their diet. Enable the consumer to see the nutritional contribution a product makes to the diet. These do not apply to children
GI: Glycemic Index
Good nutrient: qualifying nutrient
HEI: Healthy Eating Index
Negative nutrient: disqualifying nutrient
Nutrient profiling: Nutritional evaluation systems for foods to categorize foods according to their nutritional composition
PARNUT: Foodstuffs for particular nutritional purposes Qualifying nutrient: a nutrient that, when present in a food, potentially qualifies the food for bearing a nutrition and/or health claim
Sensitivity: the proportion of true positives of all positive cases in the population
Specificity: the probability of a true negative being correctly identified in a statistical test
VAT: Value Added Tax

Introduction

An ILSI Europe Workshop "Nutritional Characterisation of Foods: Science-based Approach to Nutrient Profiling was held in Mallorca, 25–27 April 2006 and was attended by 76 stakeholders involved in nutrient profiling. The list of workshop participants is shown in annex A.

At the time of the workshop the European Commission's proposal on the use of nutrition and health claims on foods was awaiting the 2nd reading by the European Parliament. In the draft proposal it states the following requirement that "…general principles applicable to all claims made on foods should be established in order to ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry" [1].

The proposal laid down strict conditions for the use of health claims. Among these conditions were nutrient profiles. Article 4 of the draft regulation required the Commission to "*...establish specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles*".

The nutrient profiles for food and/or certain categories of food shall be established taking into account in particular:

- The quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;
- The role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;
- The overall nutritional composition of the food and the presence of nutrients that have been scientifically recognized as having an effect on health.

The nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.

Objectives of the workshop

The aim of the workshop was to provide a forum for discussion of the complex issues surrounding the task of

developing a scientifically valid nutrient profiling system. In particular, the focus of the workshop was on scientific approaches to the development of nutrient profiles for the purpose of regulating nutrition and health claims. The approach of the workshop was to present, discuss and develop the recent evaluation of nutrient profiling schemes developed by the ILSI Europe "Expert Group on Nutritional Characteristics of Foods" (the main body of this work is published separately in this supplement) and to explore the wider complex scientific aspects of nutrient profiling, including their relative effectiveness, strengths and weaknesses. This was done by in depth consideration of specific questions previously posed to interested parties by the Commission in the context of this challenging task.

Prior to the workshop, the ILSI Europe "Expert Group on Nutritional Characteristics of Foods" had prepared a draft overview of existing nutrient profiling schemes and a comparison of five selected nutrient profiling models (published within this supplement issue) as well as a draft of an evaluation of nutrient profiling schemes based on dietary food intakes from five European countries (published within this supplement issue). Details of this work were sent to the workshop participants prior to the workshop.

The main discussions of the workshop took place in four working groups focusing on specific issues related to the setting of nutrient profiles, each intended to address one or more question posed by the Commission as part of its consultation on this subject. Each working group was asked a set of specific questions. The working groups were:

Working group 1: Nutrient profiling of foods
Working group 2: Choice and balance of nutrients
Working group 3: Calculation of profiles
Working group 4: Testing/validation of profiling

The outcome of the working group discussions was reported back and discussed in plenary sessions. The intention was not to reach a consensus at the meeting, but rather to review, discuss, and where possible to consolidate, the different views of the academic, governmental and industrial scientists present. In particular, the following issues were going to be discussed:

- Strengths and weaknesses of the existing nutrient profiling systems and the methodology used to evaluate their effectiveness;
- The diversity of the modeling approaches and the rationale for selecting one approach over another.
- Validation methods based on statistical quantitative assessment of indicator foods;
- Gaps in the existing research and methods that could be used to overcome them.

In addition, at the outset of the workshop, the stakeholders were given the opportunity to present their views on the perceived benefits and limitations, as well as the potential implications of nutrient profiling.

In the opinion of the regulators, nutrient profiles were viewed as a risk management tool for the legislator rather than a risk assessment tool. It was highlighted that the main objectives of the proposed regulation are to achieve a high level of consumer protection, as well as to increase legal security for economic operators, ensure fair competition in the area of foods and promote and protect innovation in the area of foods. The purpose of including nutrient profiles in the regulation was to prevent inappropriately positive claims being made on foods.

The industry perspective was that a nutrient profiling scheme should be based on scientific knowledge, food categories, be non-discriminatory, simple and applicable by all food-operators. Further, as required in the regulation, a nutrient profiling scheme should be set at the community level rather than at a regional or national level; it should not inhibit innovation and it should be applicable to every-day-food/ready-to-eat food.

From the consumer perspective, a nutrient profiling scheme should be rapidly applied, should reach the goals, be consistent with national nutritional recommendations, and should make evolutions possible. The long-term objectives of the nutrient profiling scheme should be to ensure optimal health and reduction in the risk of food related diseases, including curbing the rise of obesity and preventing the risk of cardiovascular diseases. Nutrient profiling should be science-based and be widely applicable in the whole of EU. Refinement of profiling schemes to reflect changing eating habits should be made possible.

Working group discussions and conclusions

Working group 1: Nutrient profiling of foods

Two main questions were addressed in relation to nutrient profiling of foods. First, should nutrient profiling be set for foods in general or should separate standards apply for different food groups? The group discussed the strengths and weaknesses analysis on food categories v. 'across the board' approaches. The strengths and weaknesses identified by the working group are shown in Table 1.

Second, several possibilities of categorizing foods were identified and are summarized in Table 2. There was a general agreement that the setting and use of food categories should avoid misleading consumers,

Table 1 Strengths/weaknesses analysis of 'food category' and 'across the board' approaches to nutrient profiling

Food Category System	'Across the Board' System
Strengths	
• Helps the consumer to make choices within food categories • Does not, in principle, exclude any food categories from making claims • Addresses intrinsic differences between food products • Drives reformulation and innovation within a food category e.g. incentive to reduce fat in a food product • Keeps with the principle of nutrition and dietetics that all foods can be part of a balanced diet • Addresses to some extent the issue of serving size/consumption making comparisons between foods more reasonable	• Simple to establish and execute • Does not require judgment for categorization • Some food categories considered to be less healthy would be excluded from claims • Could theoretically drive people to choose healthier alternatives from different food categories
Weaknesses	
• Complex to define food categories, regional differences, etc. • Difficult to manage food categories over time • Difficult to deal with borderline products	• Could hypothetically lead to a situation where some foods are excluded from claims (e.g. cheese, oil, bread, low fat spread, etc.) • Does not give incentive to producers to reformulate "negative" nutrients as goals may not be reachable • Could hypothetically lead to a situation where all foods have similar composition • Uses the same measure for products which are intrinsically different

should be easy to use, and applicable to ready to use foods/convenience foods. Further, food categorizations should be based on average consumption patterns. Other prerequisites for a food category system, which is applicable to the whole of Europe, were: identification of descriptors for each category (e.g. fried, fatty, fortified, frozen); and identification of categories applicable to different needs (e.g. children, elderly). Different suggestions for multiple step procedures for a common food categorization system were discussed, among others a matrix structure and a hierarchical tree structure. The conclusion was, however, that food categories should be adequately defined taking into account foods/food groups central for a healthy diet and eating culture, thus avoiding a lot of subcategories with their own set of thresholds.

The third main question dealt with how should the reference standards for nutrient profiling be defined? The Pros and Cons of using different reference amounts were discussed in the working group and are summarized in Table 3.

Table 2 Suggestions for possible food categories

Possible Food Categories
• Biological basis (e.g. meat, cereals, milk etc.) • Food guide, pyramid or vitamin/mineral/trace element rich etc. • Natural vs. processed or at specific stages along the food chain. Simple for agricultural level, but gets more complex with processing • Target group/user group defined (i.e. children, adults, athletes) • Meal types or preferred use (e.g. snack food, breakfast food, spreads) • Meal situation (e.g. social context) or eating occasion • According to claim (e.g. nutrient content, health claims, disease risk reduction such as reducing the risk of osteoporosis etc.) • According to consumer understanding (e.g. role of diet and individual foods for well-being and health) • Simple foods (e.g. sugar) vs. complex foods

During the compilation of the lists of Pros and Cons for the legislative reference amount, foods in small portions were compared to staple foods. It was discussed how e.g. 5 g sweets might have an advantage in making claims, as compared to portions of potatoes which are traditionally eaten in much larger quantities.

The working group discussed the potential use of the following combinations of reference amounts: either/or combinations; daily intake and calories; Serving size and 100 kcal; 100 g, calories per serving and reference amount for foods; and 100 g and nutrient density – feeling for quality of food.

The prevailing opinion was that a simple approach with one reference amount should be chosen initially and if this does not work in practice, various combinations should be taken into account. It was favored by the majority of the working group participants that a food category approach should be used. Furthermore, existing category systems such as the Codex Alimentarius, EPIC and the CIAA system should be used when applicable. The following reference amounts were recommended for further consideration:

- per 100 g or 100 ml;
- per 100 kcal;
- Legislated reference amounts.

Working group 2: Choice and balance of nutrients

The main question raised in relation to the choice and balance of nutrients was: How can the choice and balance of food properties be taken into account when profiling foods? The group addressed the choice/balance of nutrients with regard to food categorization or

Table 3 Pro's and Con's of the use of different reference amounts

Reference amount	PROs	CONs
100 g/100 ml	• Easy comparison for foods of same food category • Consistency with existing legislation for labeling and claims • Simplicity for regulator and industry • Real comparison for industry • 100 g is internationally accepted basis for claims 'across the board' by Codex Alimentarius, but in USA the reference value is per serving	• Foods can be consumed in (very) different amounts (How important is this for claims and on a food category basis or 'across the board'?) • Difficult to understand for consumers • Does not take into account energy content • Does not take into account health recommendations
100 kcal/kJ	• Relates to some nutrition recommendations, e.g. for dietary fiber • 'Across the board', applies to all products (except low calorie products) • PARNUTS legislation • Reference daily energy needed for different age groups, gender, individuals etc.	• Difficult to understand for consumer and regulator
Legislative reference amount – standard serving size	• Consistency across different countries • Easier for regulator than serving size • Less open to manipulation • Can apply to non-pre-packed foods (e.g. Gov't claims that fruit and veg are good for you)	• Does not take account of frequency of consumption • Challenge of coming up with amounts which apply across all EU countries for different food categories • Not related to eating habits

across the board system; the balancing and weighting of nutrients and the required level of evidence.

The working group discussed which nutrients to take into account based on scientific evidence, and what advantages and disadvantages this would entail for a food category system and 'across the board' system respectively (Tables 4 and 5).

With the focus on disqualifying nutrients, the working group suggested that total fat, saturated fatty acids, trans fatty acid, sodium and sugar(s) should be taken into account. However, no consensus could be reached regarding sugar(s) and total fat and it was suggested that the amount of energy should be taken into account instead in a modeling system.

The working group agreed that a food category system would be preferable for all the suggested disqualifying nutrients. Food categories will allow for reasonable and 'healthy' competition within the category, whereas an 'across the board' system would lead to a discriminatory system for many foods. Some examples of these disadvantages are mentioned in Table 4.

Further, the majority of the working group participants were in favor of the food category approach because of its simplicity compared to the rather complex judgements required in the 'across the board' systems (scoring systems).

During the discussion on disqualifying nutrients no general approach was identified for the compen-

Table 4 Comparison of disqualifying nutrients in the Food Category System and 'Across the Board' System

Disqualifying nutrients		
Nutrients/aspects	Food category system	'Across the Board' System
Total Fat	Disadvantage: No separation between "good" and bad fatty acids Advantage: Possibility to set different criteria for high fat and no-fat products	Disadvantages: No separation between "good" and bad fatty acids High fat products will 'per definition' be penalized
Saturated fatty acids	To be included	To be included
Trans fatty acids	To be included	To be included
Sodium	To be included Advantage: Relevant and applicable criteria for savory products	To be included Disadvantage: Savory products may 'per definition' be penalized
Sugar(s)	?	?
Energy	?	?

Table 5 Potential qualifying nutrients in the Food Category System and the 'Across the Board' System

Potential qualifying nutrients	Comments
Beneficial fatty acids	
Minerals	E.g. minerals for which population is deficient
Vitamins	E.g. vitamins for which population is deficient
Protein	
Dietary fibre/prebiotics	
Phytonutrients	

sation of disqualifying nutrients by a qualifying nutrient. It was recommended that this issue should be assessed on a case-by-case basis.

Considering the choice of nutrients, the working group expressed the opinion that the focus should be on the disqualifying nutrients. The list containing the qualifying elements was seen as a complete list whereas the list containing the disqualifying elements is open for incorporation of other negative properties of food components. However, both lists should be dynamic and revisited on the basis of new available scientific knowledge. It was felt to be easier to incorporate qualifying nutrients in a food category profiling system than in an 'across the board' system.

The working group recommended that the choice and levels of nutrients should be defined clearly and be relevant for food categories. Additionally, consumption data/contribution to the diet of each food category should be taken into account when setting the cut-off levels.

After discussions on the balancing and weighting of foods and nutrients, the working group recommended that foods should be considered in the form they are eaten by the consumer (fresh food vs. reconstituted food) taking into consideration the overall dietary composition. The water content of the food product is also important and could be taken into account in an evaluation system that includes an energy factor. Food items should be considered individually, although, correlations exist between some foods, as for instance 'breakfast cereals and milk' and 'bread and jam'.

If the reference basis and the food category are adequately defined, the contribution of foods to the overall diet should be taken into account. The question remains whether the amount of the nutrients considered for qualification or disqualification should be the amount of nutrients brought about by the considered food in the usual diet? It was clearly stated that no 'a priori' exclusion of a whole category should be employed. The setting of categories in a food category based system should be sufficiently specific to avoid unjust comparison between different foods.

For micronutrients it is important to take into account those for which there is a significant difference between actual intake and recommended intake, as well as the balance of scientific evidence for possible health effects. Foods should be considered before fortification to distinguish between intrinsic and extrinsic nutrients (vitamins, minerals, phytochemicals, etc).

A qualifying nutrient does not compensate for a disqualifying one. The overall nutritional quality of a food is important. A first approach to the balancing of disqualifying against qualifying nutrients could be to set levels for disqualifying nutrients and then consider which are the qualifying nutrients. Finally, it is important to know if the food makes a significant contribution to the overall intake of the specific disqualifying or qualifying nutrients.

With respect to the choice of nutrients the working group participants recommended a two-step procedure based on (1) a review of available studies, and (2) a ranking of the strengths of the evidence. The group agreed that the choice of qualifying and disqualifying nutrients should follow for example the WHO Technical Report on Diet, Nutrition and the Prevention of Chronic Diseases, 2003. The working group identified a possible preliminary list of disqualifying nutrients to include saturated fatty acids, trans fatty acids, salt, and a list of qualifying nutrients to include dietary fiber, calcium, iron, and folate. The opinion was expressed that for total fat and added sugars a thorough evaluation is needed before it can be decided whether these nutrients should be added to the list of disqualifying nutrients.

For the choice of levels of nutrients, the most important parameters to be taken into account are: portion size, nutrient intake data, consumption data, dose response assessment (risk and benefits) and usual consumption levels. It is not considered necessary to have different nutrient profiling for different types of claims (nutrient content, nutrient function, disease risk reduction). In the case of disease risk reduction claims, which are supported by strong evidence (RCT, validated biomarkers) nutrient profiles could become superfluous.

The majority of participants favored the implementation of a food category system. Focus should be on the disqualifying nutrients and the levels of each nutrient of concern should be clearly defined for each food category.

Working group 3: Calculation of profiles

The main question in relation to the calculation of profiles was: How should the calculation of profiles be carried out? This question includes the following is-

Table 6 The strengths and weaknesses identified in the Threshold and the Scoring System

Threshold system	Scoring system
Strengths	
• Seems to be simple	• More sensitive (permits avoidance of borderline effects; e.g. a product can be "less healthy" with 10 g of added sugars/100 g but "healthier" with 9.99 g of added sugars/100 g)
• Can be combined with other tools (possibility to combine scoring and threshold methods)	• Flexible
• Allows more than one qualifying option (with several thresholds, it is possible to define several categories; e.g. less healthy, intermediate, healthier)	• Qualifying and disqualifying contributions
• Already in use	• Allows "more complex" weighting of nutrients
• Thresholds can be for both qualifying and disqualifying nutrients	• Already in use
Weaknesses	
• Long list of exemptions only in case of 'across the board' system	• Seems to be difficult/complex (e.g. communicate to users)
	• Seems to be difficult to have a scientific justification for the final "nutrient" score
	• Seems to be difficult to scientifically justify the compensation of disqualifying criteria with qualifying ones

sues: the choice of reference nutrients and reference amounts, the choice between a threshold-based or a score approach for each nutrient; and the choice of an algorithm or a decision tree method as the optimal way to calculate nutrient profiles.

The working group participants agreed that the most relevant reference data were nutrients and nutrient recommendations rather than dietary guidelines. Nutrient recommendations are scientifically based and are independent of dietary habits, variability in consumption and availability of foods. The prerequisite for such approach would be common European nutrient recommendations, for instance set down by the European Food Safety Authority (EFSA).

Concerning the choice of nutrients, the discussion focused on the use of either: (1) both disqualifying and qualifying elements, or (2) only disqualifying elements. Finally, the group emphasized that also qualifying elements of the food need to be taken into account, as it is not possible to qualify a food only by defaults or based on only disqualifying nutrients.

The discussions on the rationale for the calculation of nutrient profiling supported a food category approach.

Firstly, it was recommended to define specific levels of nutrients from the corresponding guideline daily amounts (GDA). Secondly, two important points were raised concerning the definition of criteria in the rationale for the calculation: (1) to take into account the market value of the foods (in order to define realistic values), and (2) to take into account the role of the considered nutrient in the diet. The working group highlighted the importance of calculating criteria that are realistic and which could be an incentive for the food industry to make nutritional improvements to their food products.

The working group discussed the strengths and weaknesses of the threshold and scoring system in a nutrient profiling system of foods. The outcome is summarized in Table 6.

Concerning the question "should the threshold or score approach be applied for each nutrient?", the working group made two observations:

- Based on the final objective of the nutrient profiling scheme, which needs to have a two-step conclusion (e.g. OK/Not OK; Qualified/disqualified), the approach applied must permit such types of conclusions. In that sense, the group felt that the threshold approach was more appropriate as it allows for a distinction between OK/not OK or qualified/disqualified. As such the objective could be met by indicating the borders. However, this needs to be discussed further.
- Following a long discussion on scoring versus threshold approach, it was concluded that these approaches were similar since the threshold system is a scoring system with an infinite number of variables with zero as weighting factor. This means that for every nutrient included, a threshold can be indicated. All nutrients and their respective values and weighting factors can be summed up in a final nutrient profile; albeit the weighting factor can be zero (0) for some nutrients. In fact nutrients with a zero weighting factor, do not contribute to the overall nutrient profile of a scoring system.

Finally, it was concluded that the most important point was to apply an approach with a two-step decision process; step (1) identify which nutrients to take into account, and step (2) define the thresholds for these nutrients.

The working group agreed that the scientific rationale to justify the use of weighing factors was lacking, but the question was not analyzed in enough detail to suggest an alternative.

Overall, the working group recommended initially placing more importance to the disqualifying nutrients, but no final recommendation as to whether the outcome for the disqualifying and qualifying nutrients should be combined or on the other hand, stay as two separate statements after the profiling exercise was made.

Further, the working group was in favor of a dynamic system, flexible enough to adapt and incorporate issues from new research in the nutrition and health area.

The last point raised was concerning whether an algorithm or a decision tree would be the best way to calculate nutrient profiles. Following some discussion on the more appropriate way of calculating nutrient profiles, the working group agreed on a decision tree approach starting with the results for the disqualifying nutrients added to build a final statement (combined by an "AND" operator) and to combine this conclusion with the single results for the qualifying nutrients (combined by an "AND" or "OR" operator). The qualifying nutrients to be taken into account should be those dealt with in the existing claims framework. However, this issue needs more in-depth analysis.

The working group discussed if a different method should be used for the calculation of profiles according to the type of food or the considered nutrient. It was concluded that the type of food is already taken into account if the profiling is carried out by food category. This is not the case, however, for 'across the board' systems. An alternative method at the nutrient-level could be to define nutrients on the basis of the energy content of foods. This approach will pose a special case for low-calorie products and this option needs to be discussed in more detail.

It was suggested that nutrient recommendations should be used as reference data because their potential impact on public health issues is based on scientific evidence. The working group favored the use of a two-step decision system that includes which nutrients to take into account and a definition of thresholds for these nutrients. This recommendation means that even if a scoring system is used, a threshold approach will be applied as the final step. Finally, the use of a decision tree approach was recommended, but this needs further analysis.

Working group 4: Testing/validation of profiling

The main questions raised in relation to the validation of nutrient profiling of foods with respect to other measures of a healthy diet were methodological ones. The group defined four main topics for consideration and for further discussion. These were the selection of a scientifically sound framework of key parameters for the evaluation tool; new ways to optimize the validation tool; exploration of alternative approaches, and the selection of additional criteria for model validation. In practical terms, favorable nutrient profiles should be based on indicator foods for a healthy diet. This approach requires the selection of a healthy diet from which to identify indicator foods; the positive identification of indicator foods and the adaptation of the validation tool to a food category specific nutrient profiling model.

There is no one healthy diet across Europe that can be used as an evaluation tool and opinions of what constitute a healthy diet vary somewhat throughout Europe. Ideally, a European dietary intake data set should be used to define the healthy EU diet, but the surveys available are not perfect since they were not set up for this reason. To start in this area, for instance the dataset from the EPIC study could be of value although it was judged as not being representative. Hence it was suggested to choose healthy diets from so called 'indicator countries, regions or dietary patterns'. For example, the healthy diets in Northern Europe, the Mediterranean region or a fish-based vs. a meat-based diet.

In general, one should start with the general population, but further analysis is necessary to assess if this approach is also valid for high-risk groups such as specific age groups, genders, socio-economic groups, and for certain lifestyle habits.

To select indicator foods from the pre-defined healthy diet(s) several approaches were identified. The criteria of EURODIET could be used. Secondly top/bottom quintiles or tertiles of nutrient intakes could be chosen. Another possibility would be to apply Healthy Eating Indices (HEI); although no EU harmonized index is currently available. It was concluded that there is a need for a new systematically developed and tested HEI. It was recommended to include diet diversity in a new index. Furthermore, a new index with defined end-points should be considered, however, not necessarily only endpoints such as "chronic disease", but also other health indicators should be investigated.

In order to adapt the evaluation tool presented by the ILSI Europe 'Expert Group on Nutritional Characteristics of Foods', to be used with category based profiling systems, it will initially be necessary to define food categories that can be agreed and accepted across EU. Among the suggested approaches were the food coding systems used in Food Composition Tables; EUROCODE, DAFNE & EFG (European Food Grouping already used by EFSA),

the VAT (Value Added Tax) Approach, or Consumer perceptions.

The next step in adapting the evaluation tool is to identify the qualifying and disqualifying food indicators and to place these indicators in the category groups identified.

The most important component identified was the weighting of nutrients/compounds making up the HEI. This could be done by estimating the relative impact on health of the different nutrients using a common metric like disability adjusted life years (DALYs). Further, the level of evidence for links between each health effect and nutrient/component (e.g. total fat vs. saturated fat) should be included.

For this evaluation tool, those eating a healthy diet were identified by using a scoring approach. Healthy eating individuals were defined as those achieving most of the nutrient intake recommendations. An alternative approach could be to use data from large population studies in order to identify sufficient numbers of individuals meeting all the targets for a healthy diet.

It was agreed that sensitivity of any validation tool is important to avoid the use of health claims on less "healthy" foods. Specificity is an equally important factor in the validation process to avoid that "healthy" foods are excluded from bearing a scientifically justified health claim.

The fact that the quality of a validation tool depends on the proportion of misclassified foods was discussed. Two sets of misclassifications were identified: (1) Misclassification during compilation of the reference or indicator foods list; and (2) Misclassification in the setting of a minimum sensitivity and specificity for the profiling model. Further, attention should be paid to the possible wider consequences and implications of misclassifying given foods.

Finally, the problem of circularity, which is inherent in a validation process, was discussed. Circularity can be minimized by using indicator foods different from those used in the conception of the model. The best approach is to establish the validation tool at a different time and use criteria, which are independent from those of the nutrient profiling scheme, to avoid any adaptation of the tool to accommodate the profiling scheme. On the other side, circularity can be used positively, for the continuous improvement of modeling methods.

The working group identified four different approaches for the evaluation of nutrient profiling models in the future: nutritionist panel, nutrition survey, mathematical modeling of nutrition survey data and stakeholder-related validation tools (Table 7).

It was agreed that an evaluation tool can be developed by using all four approaches. In the final evaluation it might be helpful to use a multidisciplinary panel consisting of nutritionists, dieticians, physicians, the stakeholders from industry and consumer associations, statisticians and experts from quality assurance.

Table 7 Different approaches to a nutrient profiling evaluation tool

Nutritionist panel
- Evaluates by discussion how foods are classified by the nutrient profiling model
- Can be used to fine-tune the nutrient profiling model
- Simple and inexpensive
- Not systematic
- Not transparent
- Discussion bias
- Potential intellectual conflict of interest: experts may have been involved in nutrient profiling model design

Nutrition survey
- Use the real diet consumed by European consumers
- Evaluates food classification by conducted survey
- Provides quantitative data
- Outcome depends on how questions are asked
- Bias, e.g. take-away food scored too low
- For EU application, should be done at EU level

Mathematical modeling of nutrition survey data
- Needs to be tailored to Nutrient Profiling model; both AB* and FC* possible
- Transparent (for mathematicians)
- Complex to establish
- Data intensive

Stakeholder-related validation tools
- Does not evaluate food classification but other aspects: consumers, market research, feasibility for stakeholders
- Consumer research could help choose between AB and FC, FC category definition, portion size/100 g/100 kcal

* AB = Across the Board; FC = Food Category

The robustness of the final evaluation tool should be checked by changing assumptions and measuring the effect of the change or could also be carried out in a more objective way by statistical tests (e.g. on nutritionist survey and mathematical models).

Two alternative approaches were identified for the evaluation of profiling models in the future: Clinical outcome related validation and consumer related validation (Table 8).

Additional criteria for the validation of nutrient profiling models were discussed including the range (limits) of applicability of a nutrient profiling scheme and the possibility of including other criteria. Further, different models under consideration could be validated with selected "fake" (virtual, hypothetical) indicator foods that could be considered universally as positive or negative contributors to healthy eating. This validation would result in a ranking by the different profiling schemes.

It was recommended that an optimum framework of key parameters in a nutrient profiling evaluation tool comprised a healthy diet or selected indicator

Table 8 Alternative approaches for the evaluation of nutrient profiling models

Clinical outcome related validation
- Validation tool should detect when a clinical effect is beyond the detection capacity of the model e.g. margarine with same classical nutrient profile but with different health outcome
- Biological (clinical) validation: whether differences identified by any profiling scheme end up in different health outcomes (epidemiology and intervention) to validate the profiling scheme
- Step-by-step build-up
- Reality check by using human intervention trials (used for claim substantiation) and include additional markers e.g. BMI, cholesterol, GI, blood pressure… to assure that:
  - An eligible product does not have an undesirable side effect
  - A non-eligible product does not have an overall "good" effect

Consumer related validation
- Nutrient profiling schemes should be aligned with nutrition policies
- Nutrient profiling scheme should take into account potential changes in consumption behavior (based on consumer research/knowledge)
- Profiling may promote over-consumption of certain foods

foods, recognizing that the choice was difficult. The majority of the group recommended that the approach of food categories was applied in the evaluation process and that several parameters like sensitivity and specificity were considered. The group discussed pros and cons for selected approaches to evaluate the nutrient profiling, including the use of nutritionist panels, nutrition surveys, mathematical modeling of nutrition survey data and stakeholder-related validation tools.

Wider considerations on nutrient profiling

The development of *universal* as opposed to *targeted* profiling is a central issue. The former assumes that an all-embracing model for nutrients applied to foods will be feasible. The less demanding targeted approach can also help modify nutrient profiles within a food category by creating a competitive standard for a given category. Participants expressed a need to allow the food industry to claim for nutrient improvements of their products and this could also be an incentive for product innovation.

The EU favors units per 100 g above portion sizes. However, no research is available on which measure is the most appropriate in communicating nutritional information to consumers. The continued use of units per 100 g as opposed to *portion size* may not help in improving consumer understanding of food labels. There is a need for research accompanying the implementation of the claims regulation and other measures of information on food labels to assess consumer understanding and eventual consequences on consumer behavior.

Foods with a *high population nutritional impact* must clearly be seen differently from those with a narrow population impact; and these population characteristics must also apply to age and sex *subgroups*. Currently individual foods are the base unit of analysis in food consumption studies. However, newer approaches to food coding, e.g. *meal coding*, allow associations of foods typically consumed together to be identified.

Summary of key points and conclusions from the workshop

The majority of the workshop participants favored the use of a food category approach rather than an 'across the board' system and a focus on disqualifying nutrients. However, some disparity arose between the working groups regarding the choice of nutrients. One working group recommended a selection procedure based on available data and a ranking of evidence whereas another group felt that such ranking was not possible due to lack of scientific evidence.

It was recommended that further work should to be carried out on methods of defining the qualifying and disqualifying nutrients for each food category and optimal reference amounts. Finally, the adopted system will need to be dynamic over time and be readapted with the evolution of knowledge. Further, it was recommended that evaluation tools should be developed based on selected indicator foods and extrapolation from nutrients to foods should be further addressed.

A final conclusion from the ILSI Europe workshop, is that even though this is early times in the multifaceted process of nutrient profiling, the majority of workshop participants reached agreement on central issues highlighting the importance of all stakeholders continuing to work together on the complex issues of nutrient profiling.

Acknowledgments The authors would like to thank the participants of the Workshop 'Nutritional Characterisation of Foods: Science-based Approach to Nutrient Profiling', 25-27 April 2006, Spain for their useful comments and discussions.

This publication was coordinated by Carina Madsen, Scientific Project Manager at ILSI Europe. This work was commissioned by the Functional Foods Task Force of the European branch of the International Life Sciences Institute (ILSI Europe). Industry members of this task force are Ajinomoto Europe, Barilla G. & R. Fratelli, BASF, Bayer CropScience BioScience, Beneo-Orafti, Beverage Partners Worldwide, Campina, Coca-Cola European Union Group, Colloïdes Naturels International, CSM, Danisco, Dow Europe, Friesland Foods, Frutarom, GlaxoSmithKline, Groupe Danone, Kellogg, Kraft Foods, Mars, McNeil Nutritionals, Monsanto Europe-Africa, Nestlé, PepsiCo International, Procter & Gamble, Raisio, Red Bull, Royal Cosun, Südzucker, Tate & Lyle Speciality Sweeteners, Unilever, Valio, Wild Flavors, Wimm-Bill-Dann Foods, Yakult Europe. For further information about ILSI Europe, please call + 32 2 771.00.14 or email info@ilsieurope.be. The opinions expressed herein are those of the authors and do not necessarily represent the views of ILSI Europe.

Disclosure J. de Vries works for the company CSM. The other authors have no conflict of interest to declare.

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