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Nutrition and Health Claims

Briefing Note

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Executive summary

A balanced diet is a prerequisite for health, well-being and good performance, particularly in childhood. Therefore, it is of importance for the promotion of public health and the creation of wealth in the European Community to promote balanced dietary choices in adults and especially in children.

Consumers and particularly parents of young children are increasingly aware of the importance of dietary choices for health. Their food choices are markedly influenced by information on nutritional and health properties of foods. There has been a considerable proliferation of soft claims related to food products intended for use by children, which often do not follow agreed criteria for claims and/or are not based on agreed scientific evidence. Therefore, it is important to reach agreed conditions and rules for the use of nutrition and health claims in the EU which also apply to foodstuffs intended to be consumed by children and adolescents.

Within the scope of this briefing note, nutrition and health claims are considered for the age groups of preschool and school age children and of adolescents, but not for infants for whom age specific dietetic foods are offered for which specific community legislation applies.

Nutrition claims for dietary products intended to be consumed by children may help to promote healthy dietary choices. The physiological and dietary concepts underlying nutrition claims are similar for adults and for children and adolescents from the age of about 3 years onwards. Therefore, nutrition claims with dietary and public health relevance that are addressed to adults can often be helpful also for food products consumed by children and adolescents. There are no indications that nutrition claims directed exclusively to children and adolescents would be necessary, but there is concern that nutrition claims directed exclusively to children may lead to misunderstanding and misinterpretation. Thus it is recommended that nutrition claims directed exclusively to children should not be introduced, even though specific conditions for establishing a certain claim for a food for children may be defined.

A limited and selective use of enhanced function claims directed to children is conceivable if they are based on agreed scientific evidence, the products for which the claims are made are intended to be consumed as part of a balanced diet, and such products are also appropriate as components of a balanced diet. However, currently there is no compelling argument for the introduction of specific enhanced target function claims that would address specifically children only.

While diet in childhood has the potential to contribute to long term disease risk reduction, there are no specific diseases related only to the diet of children for which specific health claims directed to children should be established.

The use of reduction of disease risk claims directed specifically to children might raise inappropriate fears among parents and caregivers of young children and lead to inappropriate dietary choices. Therefore, reduction of disease risk claims directed specifically to children should not be established.

While nutrient profiles for foods intended to be consumed by children can be based on the food contents of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium, it appears preferable to use scoring systems that also take into account the food contents of desirable food components (e.g. fibre, calcium, certain other minerals, trace elements, and vitamins), which will better reflect the nutritional value that a foodstuff contributes to dietary intake.

Variables to be considered in developing nutrient profiles for children include the age range and possibly gender of children of the target group, the choices of nutrients and food components used in the score, the choice of food unit to which the score refers (e.g. 100 g, 100 kcal, or an average portion size), the choice of the model used, and the desirable quantity of nutrient intake for the target group. Given that these factors are defined, the development of nutritional profiling of foods for children based on scores considering nutrient contents is feasible.

Appropriate and easily understandable nutrition claims have the potential to provide a relevant contribution to improving food choices for children. Nutrition claims may contribute to enhancing dietary quality and health, but they appear not to reach lower socioeconomic segments of the population to a similar degree. In contrast to nutrition claims, there are no indications of benefits of the use of reduction of disease risk claims directed specifically to children.

While tempting nutrition and health claims may help consumers to choose healthier food alternatives for themselves and for their children, the use of claims may also lead to undesirable effects. If products with a less than desirable nutrient composition, such as sweet foods and snacks with high energy density but low contents of valuable and essential nutrients, can be labelled and advertised with positive claims, parents may consider such products as more healthy and desirable choices while there actual nutritional composition would not support such a conclusion. A further concern is that health claims are usually made for industrially processed foods, whereas they are not applied to products that are presented and sold loose, for example bread, vegetables and fruits which are recommended to be consumed in large amounts as basic components of a healthy diet. Health conscious parents might be mislead to consider bread, vegetables and fruits less valuable and desirable components of their children's diets than processed foods with some added nutrients which might allow positive claims. Therefore, it appears preferable to link the use of claims for children's foods to a certain nutritional profile score, and to avoid specific health claims for children's foods.

Proposed claims should be evaluated by a science based approach, on a case by case basis, considering criteria that have been developed and agreed by EU supported collaborative research projects. Such evaluations should be performed by an independent scientific expert body, such as the European Food Safety Authority (EFSA). Since there no agreed concepts on criteria for health claims addressing specifically children, it is recommended to refrain from establishing specific health claims for children's foods at the present time.

Contents

1 Background

A varied, balanced diet is an essential prerequisite for health, well-being and good performance. There is no other time in life when diet is of greater importance than during childhood, in particular during the first years of life. In young children the nutrient requirements per unit bodyweight are very high due to the additional substrate needs for growth, while endogenous body reserves are limited and some gastrointestinal, metabolic and renal body functions are not yet fully matured. In addition to immediate effects, diet in childhood also modulates the development of growing tissues and thus has long term implications for health and well-being that extend well into adulthood and old age (Koletzko B, Aggett PJ, Bindels JG, Bung P, Ferre P, Gil A, Lentze MJ, Roberfroid M, Strobel S. Growth, development and differentiation: a functional food science approach. Brit J Nutr 1998;80, Suppl. 1:S5-S45). Furthermore, dietary habits that are adopted in childhood tend to influence food preferences throughout life. Therefore, it is of considerable importance for the promotion of public health and the creation of wealth in the European Community to promote balanced dietary choices in childhood.

Consumers and particularly parents of young children are increasingly aware of the importance of dietary choices for health, and their food choices are markedly influenced by information on nutritional and health properties of food products. In response to this consumer demand, there has been a considerable proliferation of soft claims related to food products intended for use by children, which often do not follow agreed criteria for claims and in many cases also are not based on sufficient and agreed scientific evidence. Therefore, it is considered important to reach agreed conditions and rules for the use of nutrition and health claims in the EU which also apply to foodstuffs intended to be consumed by children and adolescents.

Scope and type of claims considered

Within the scope of this briefing note, nutrition and health claims are considered here for the age groups of preschool and school age children and of adolescents, but not for infants. Infancy is characterized by very specific physiological and dietary conditions, and infants are fed predominantly age specific foods, including breast milk, infant formulae and follow-on formulae, and complementary foods. Compositional requirements and conditions of marketing for infant formulae and follow-on formulae and for complementary foods are detailed by specific community legislation, which also details the conditions of marketing and of claims to be made for such dietetic products for infants and young children. Therefore, the considerations on nutrient content and health claims for children discussed in this briefing note do not apply to those specific dietetic foods for infants and young children, but refer to food products intended to be fed to preschool and school age children and to adolescents.

2 Types of claims

2.1 Nutrient content claims (nutrition claims)

Information on nutrient content of foods is a prerequisite to enable consumers to choose a diet according to their preferences, to promote healthy dietary choices and to encourage producers to improve the nutrient composition of products. Nutrient content claims can refer to the levels of nutrient contents and can describe them, for example, as "low", "high" or "contains" and "does not contain". Comparative nutrient content claims can describe contents as "lower", "reduced" or "higher" relative to a standard product that is easily identified by a major proportion of consumers. Examples that are relevant to the diet of children and their biological implications are shown in Table 1 and illustrate that nutrition claims may be useful also with respect to dietary products consumed by children..

The physiological and dietary concepts related to nutrient content claims such as shown in Table 1 are generally rather similar for adults and for children and adolescents from the age of about 3 years onwards. Therefore, nutrition claims with dietary and public health relevance that are addressed to adults can often be also useful for the choice of food products of children and adolescents.

In contrast, there are no indications that nutrition claims directed exclusively to children and adolescents would be necessary, but there is concern that nutrition claims directed exclusively to children may lead to misunderstanding and misinterpretation. Thus it is recommended that nutrition claims directed exclusively to children should not be introduced.

Table 1: Examples of nutrient content claims with possible relevance for child health

Nutrient content claim	Biological and health relevance
Low fat, fat free, reduced fat content	Lower fat and energy intake, contribution to reduced risk of overweight and obesity
Low saturated fat, saturated fat free, reduced fat	Improved blood lipids/lipoproteins
Low/reduced trans-fatty acids	Improved blood lipids/lipoproteins
Low or very low sodium/salt, sodium/salt free	Reduced salt intake, contribution to reduced risk of high blood pressure
Low sugars, sugars-free, with no added sugar	Reduced sugar intake, contribution to reduced glycaemic load, may contribute to reduced risk of dental caries and to reduced risk of overweight and obesity
Good source of calcium	May contribute to bone health
Good source of fibre	May contribute to gut health

2.2 *Health claims*

Health claims relate to effects of foods or dietary components that enhance specific target functions or biological responses, or that can contribute to a reduced risk of defined target diseases. The EU DG XII Concerted Action "Functional Food Science in Europe" (FUFOSE) thus proposed two respective types of health claims, i.e. Enhanced target function claims and Reduction of disease risk claims (Fig.

Therefore, one might want to discuss the option of accepting a limited and selective use of enhanced function claims directed to children, if such claims are based on solid and agreed scientific evidence, the products for which the claims are made are intended to be consumed as part of a balanced diet, and such products are also appropriate as components of a balanced diet. However, this and other diet effects on specific functions that are currently discussed are not specific to children only, and thus at the present time there is no compelling argument for the need to introduce specific enhanced target function claims that would address specifically children only.

ii Reduction of disease risk claims

Dietary effects on reduction of disease risk are generally based on long term effects of dietary exposure and tend to relate to chronic diseases that usually manifest in late adulthood and in the elderly, such as cardiovascular disease, stroke, type II diabetes, dementia or certain types of cancer. While diet in childhood also has the potential to contribute to long term disease risk reduction, there are no specific diseases related to the diet of children only for which specific health claims directed to children could or should be established. Rather, reduction of disease risk claims should target primarily the general adult population. Given the considerable consciousness of many parents with respect to protecting the health of their children, the use of reduction of disease risk claims directed specifically to children might raise major and inappropriate fears among parents and caregivers of young children, and thereby lead to inappropriate reactions with respect to dietary choices. Therefore, it is strongly recommended that reduction of disease risk claims that are directed specifically to children should not be established.

3 Comments on the questions raised

3.1 What are the ideal children's nutritional profiles?

According to the Proposal for a Regulation of the European Parliament and of the Council in nutrition and health claims made on foods [2003/0165 (COD)], nutrient profiles shall be established with reference to the amounts of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium. These nutrients, if consumed in inappropriately high amounts, are also of considerable concern with regard to children's diets and associated health consequences, including overweight and obesity.

The prevalence of childhood overweight and obesity is increasing at alarming rates across Europe. Data collected by the International Obesity Task Force (www.iotf.org) indicate that the prevalence of overweight in children aged 7-11 years is in the range of 10-20 % in most European countries, reaches some 27 % of the population in the UK and even exceeds 30 % in Southern European countries (Fig. 2).

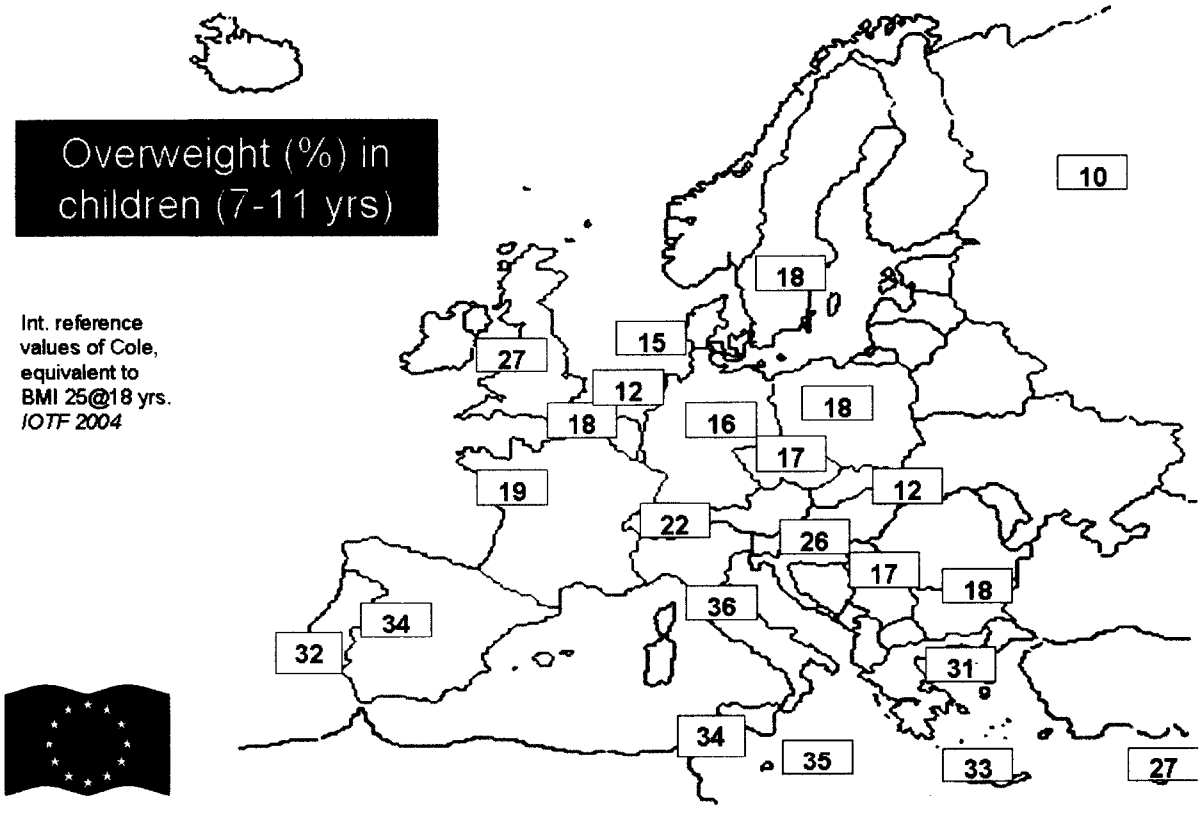

Figure 2: Percentage of overweight children aged 7-11 years across Europe (IOTF)

This alarming increase of childhood overweight is related to low levels of physical activity and to high dietary intakes of energy with foods and drinks. Total dietary energy intake is correlated to the energy density of the diet consumed in several studies in adults and in children (Fig. 3).

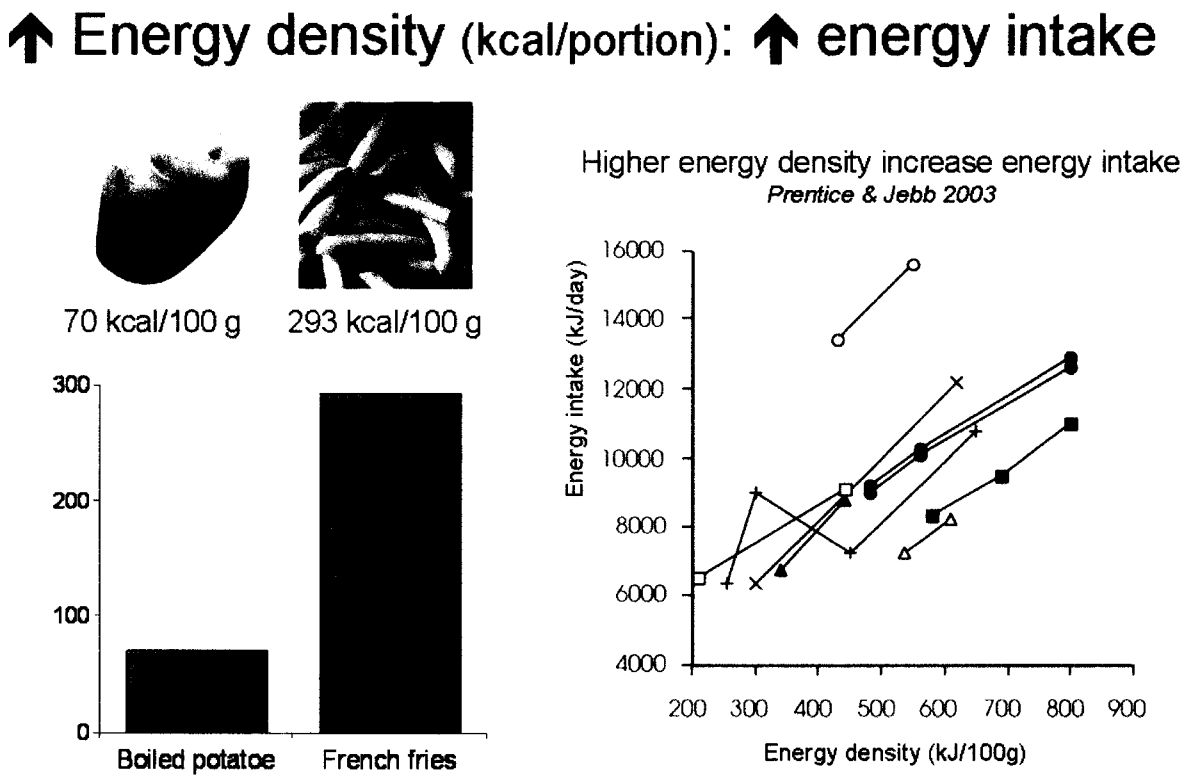

Figure 3: The energy density of foods are a major predictor of total energy intake. While the energy density of boiled potatoes is less than ¼ of that of French fries, consumers will not eat 4 times as much boiled potatoes than French fries with meals and thus consume less total energy with boiled potatoes.

The major determinant of dietary energy density is the fat content of foods. Scientific studies have demonstrated that the regular and frequent consumption of diets with high energy density, with high fat contents, and with the addition of large amounts of sugar are associated with an increased risk of overweight and obesity (Fig. 4) and their adverse metabolic consequences.

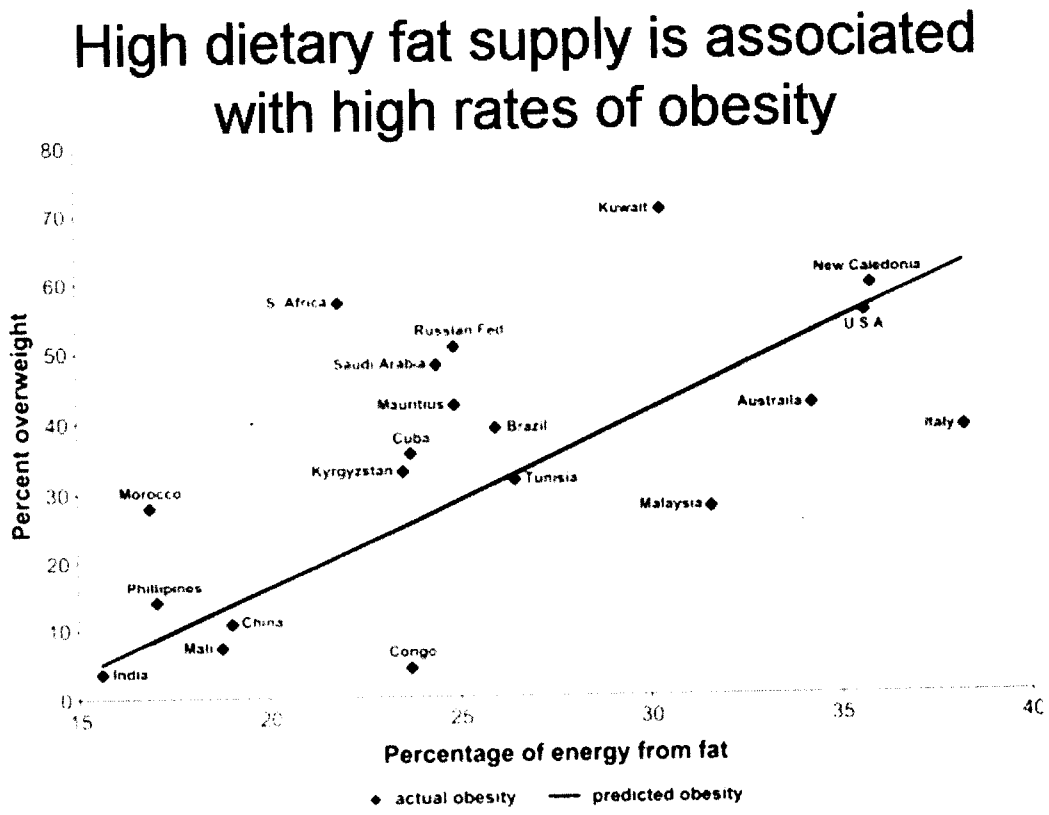

Figure 4: Populations with a high dietary fat intake (expressed as percentage of dietary energy intake comprised by fat), which is the major determinant of dietary energy density, have a higher prevalence of overweight (from Bray GA, Paeratakul S, Popkin BM. Dietary fat and obesity: a review of animal, clinical and epidemiological studies. Physiol Behav. 2004 Dec 30;83(4):549-55.)

Dietary energy density can also be increased by the addition of sugars to foods, and a high regular sugar consumption with food and drinks may also lead to excessive weight gain (Fig. 5).

With regard to the quality of fats in foods, high dietary intakes of saturated fatty acids and trans-fatty acids was shown to have untoward effects on plasma lipoprotein profiles associated with increased cardiovascular risks, which is the case not only in adults but also in children (ESPGAN Committee on Nutrition: Aggett PJ, Haschke F, Heine W, Hernell O, Koletzko B, Lafeber H, Ormisson A, Rey J, Tormo R. Comment on childhood diet and prevention of coronary heart disease. J Pediatr Gastroenterol Nutr 1994;19:261-269).

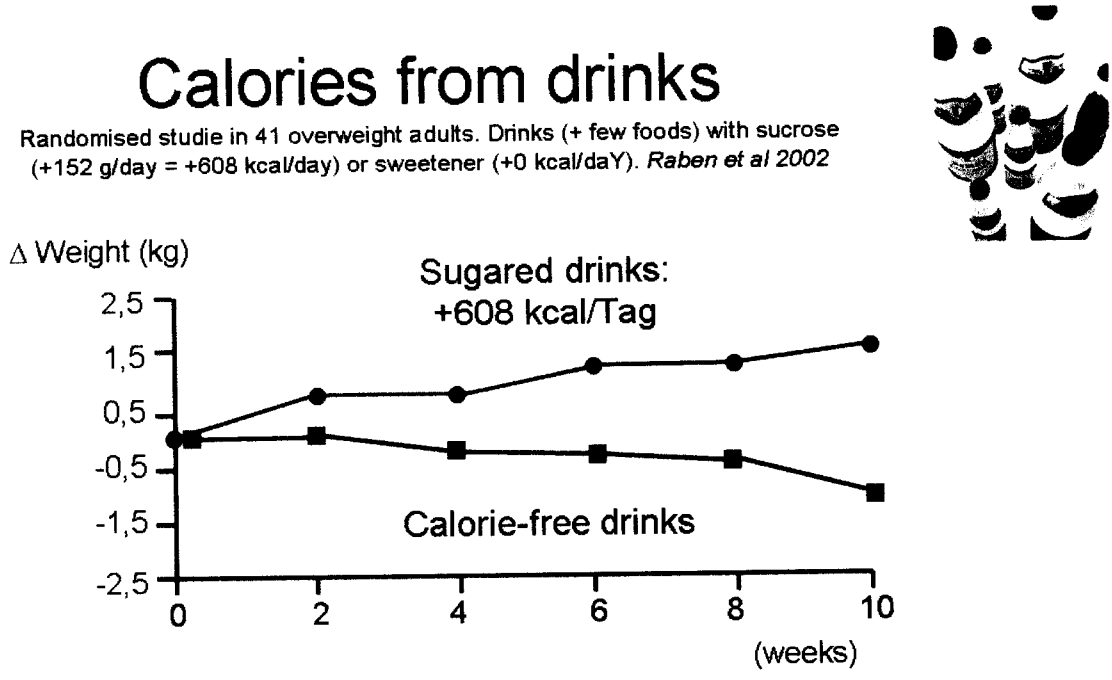

Figure 5: The addition of large amounts of sugars to foods and drinks can contribute to a high dietary energy density and to an increased energy intake. Thereby, the regular consumption of foods and drinks with high sugar contents may contribute to energy imbalance and weight gain

Diets with a high salt content that exceeds metabolic requirements induce thirst and compensatory fluid intake to allow for the renal excretion of excessive sodium. In European children a considerable proportion of this additional fluid consumption will not be water but by provided by energy containing drinks, including for example juices and soft drinks. Hence the consumption of diets with a high salt content can contribute to an increased energy intake. Moreover, diets with a high salt content were shown to have a long-lasting increasing effect on children's blood pressure.

Therefore, diets providing very high amounts of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium are not desirable for children, and paediatric organisations in Europe advocate dietary intakes for children with limited amounts only of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium. Numerical data have been provided as reference intake values for children, such as a dietary fat intake not exceed 35 % of energy and an intake of saturated fatty acids not exceeding 10 % of energy by the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN, www.espghan.org) and the UK Dept. of Health (www.eatwell.gov.uk).Obviously, these goals can and should be achieved by the overall balance of the diet, whereas the composition of a single food consumed may be of limited relevance only for total nutrient intake. However, foods with high amounts of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium, if consumed on a regular basis, will contribute to an undesirably high intake of such nutrients.

The definition of nutritional profiles for foods for children requires agreed dietary reference values for children. Such dietary reference values for children have been established for most EU member states and in 1993 for the European Community (The Scientific Committee for Food. Nutrient and energy intakes for the European Community (Opinion expressed on 11 December 1992). Luxembourg, Office for Official Publications of the European Communities.

Reports of the Scientific Committee for Food (Thirty-first series) 1993, pp 1-248 (http://europa.eu.int/comm/ food/fs/sc/scf/out89.pdf). Moreover, a target age group must be agreed on for which such nutritional profiles for foods for children are developed. However, if these prerequisites are fulfilled, nutritional profiles can be developed and have indeed been developed and applied.

For example, in their regulations on healthy snacks and foods provided in vending machines and school stores, the US Dept. of Health (2001) defined as criteria for healthy foods for children a content of total fat less than 35 % of energy content, a content of saturated fat less than 10 % of energy content, and a content of sugar less than 35 % of product weight.

In Canada, foods containing less than 5 % of the dietary reference values of fat or sodium and less than 10 % of the dietary reference values of saturated + trans fatty acids, respectively, are rated as providing a low content of these respective nutrients (Health Canada 2004).

In Scotland, standards for the nutrient composition of school meals have been established that also provide specifications for nutrient contents of food products (http://www.scotland.gov.uk/library5/education/niss-00.asp).

While nutrient profiles may and have been established based only on the food contents of fat, saturated fatty acids, trans-fatty acids, sugars, and salt/sodium, there are also scoring systems that take into account both the food contents of such nutrient considered undesirable in high amounts as well as desirable food components. Such scoring systems for nutritional profiling of foods which have also been introduced for children score both undesirable compositional criteria, such as the contents of fat, saturated and trans fatty acids, sugars, salt and high energy density, as well as desirable compositional criteria such as the contents of calcium, certain vitamins and micronutrients, or dietary fibre. Such scores have been developed, for example, by the American School Food Service Association (www.asfsa.org) and by a working group of the British Heart Foundation Health Promotion Research Group and the Dept. of Public Health, Univ. of Oxford (www.bhf.org.uk). Important variables that must be fully considered in the stages of developing nutrient profiles of foods include the age range and possibly gender of children for which a score is developed, the choices of nutrients and food components that are to be used in the score, the choice of food unit to which the

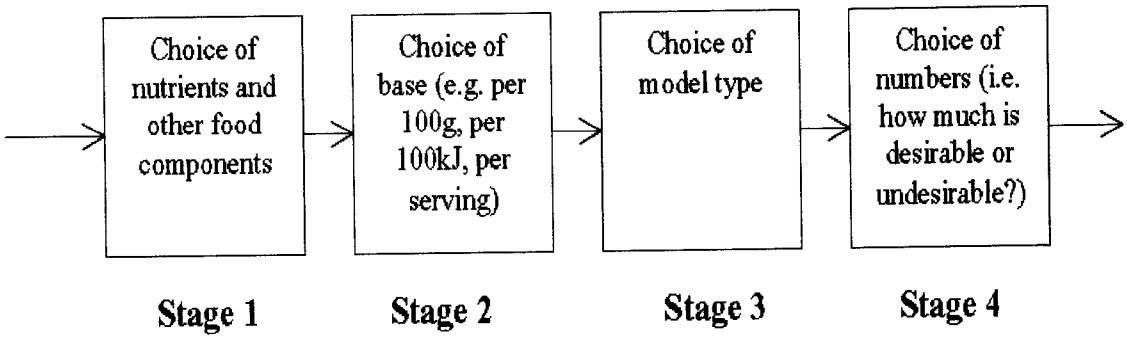

Figure 6: Stages in the development of nutrient profiles of foods. From: Rayner M, Sacrborough P, Stockley L. Nutrient profiles. Options for definitions for use in relation to food promotion and children's diets. Oxford, British Heart Foundation Health Promotion Research Group, 2004.

score refers (e.g. 100 g, 100 kcal, or an average portion size say of a 10 year old child), the choice of the model used for developing nutrient profiles, and an agreement of the desirable quantity of nutrient intake for the target group (Fig. 6). Given that these factors are defined, the development of nutritional profiling of foods for children based on scores considering nutrient contents is feasible.

When establishing nutritional profiles of foodstuffs intended for use by children, it is clearly preferable to base nutritional profiles not only on a small number of 1-3 nutrients with largely undesirable effects, but rather to also take into account the content of major nutrients both with largely undesirable as well as largely desirable physiological effects, which will better reflect the actual nutritional value that a foodstuff may contribute to typical dietary intakes.

3.2 What are the implications of use of health claims for children's food on a balanced diet and public health implications such as obesity/diseases.

It is widely appreciated that there is growing public interest in the relationship between diet and health, and that consumers generally give increasing attention to nutrition and health claims on foods (Hurt E. Nutrition labelling: European Union and United Kingdom perspectives. Asia Pac J Clin Nutr. 2002;11(2):S77-9),.

As a consequence, the number of foods labelled and advertised in the Community that bear nutrition and health claims is increasing [Council of the European Union, 2003/0165 (COD)]. Two concerted research activities funded by the 5th and 6th Framework Programmes, respectively, "Functional Food Science in Europe" (FUFOSE) and "Process for the Assessment of Scientific Support of Claims on Food" (PASSCLAIM) have evaluated the use and basis of nutrient content and health claims on foods, based on the mutual understanding and agreement of the EU, academia, consumer organisations and manufacturers and distributors of food products that nutrient content and health claims on foods are of great and increasing importance in influencing the choices that consumers make in selecting food products (Richardson DP, Affertsholt T, Asp NG, Bruce A, Grossklaus R, Howlett J, Pannemans D, Ross R, Verhagen H, Viechtbauer V. PASSCLAIM - Synthesis and review of existing processes. Eur J Nutr. 2003 Mar;42 Suppl 1:I96-111).

For nutrition and health claims to be effective, it is important that they are clearly understood by a larger proportion of consumers. While health claims for foods are permitted in an increasing number of countries and are in practical use in an even larger number of countries, there are only very few studies evaluating their effect on purchase behaviour and consumer health. Consumer science shows that while there are differences between countries, consumers generally see health claims as useful. Consumers prefer short, succinct wording rather than long and complex claims; and they believe that claims should be approved by the government. Consumers view a food as healthier if it carries a health claim and this may discourage them from seeking further nutrition information. Consumers do not clearly distinguish between nutrient content, structure-function, and health claims. There is evidence that the use of health claims does have an impact on dietary choices as well as on knowledge of diet-disease relationships (Williams P. Consumer understanding and use of health claims for foods. Nutr Rev. 2005 Jul;63(7):256-64).

Parents of young children are particular interested in and responsive to information on health effects of dietary choices for their children, and hence the impact of nutrition and health claims for children's foods is considerably greater that of those for other foods. For example, in a study including more than 1000 pairs of mothers and their children from a mixture of urban and rural areas in England representing a cross-section of socioeconomic groups and educational backgrounds, more than 80 % of mothers reported that for them a high fibre intake and a low fat intake was important or very important for their children, and they would preferentially choose respective food products. Also, most mothers considered a low sugar and salt intake to be important. These beliefs were representative of the sample population, irrespective of the socioeconomic group, location, age and education of the mother (Morgan JB, Kimber AC, Redfern AM, Stordy BJ. Healthy eating for infants - mothers' attitudes. Acta Paediatr. 1995 May;84(5):512-5).

No published scientific studies have been found that actually measured the quantitative impact of nutrition and health claims on purchase behaviour of foods for

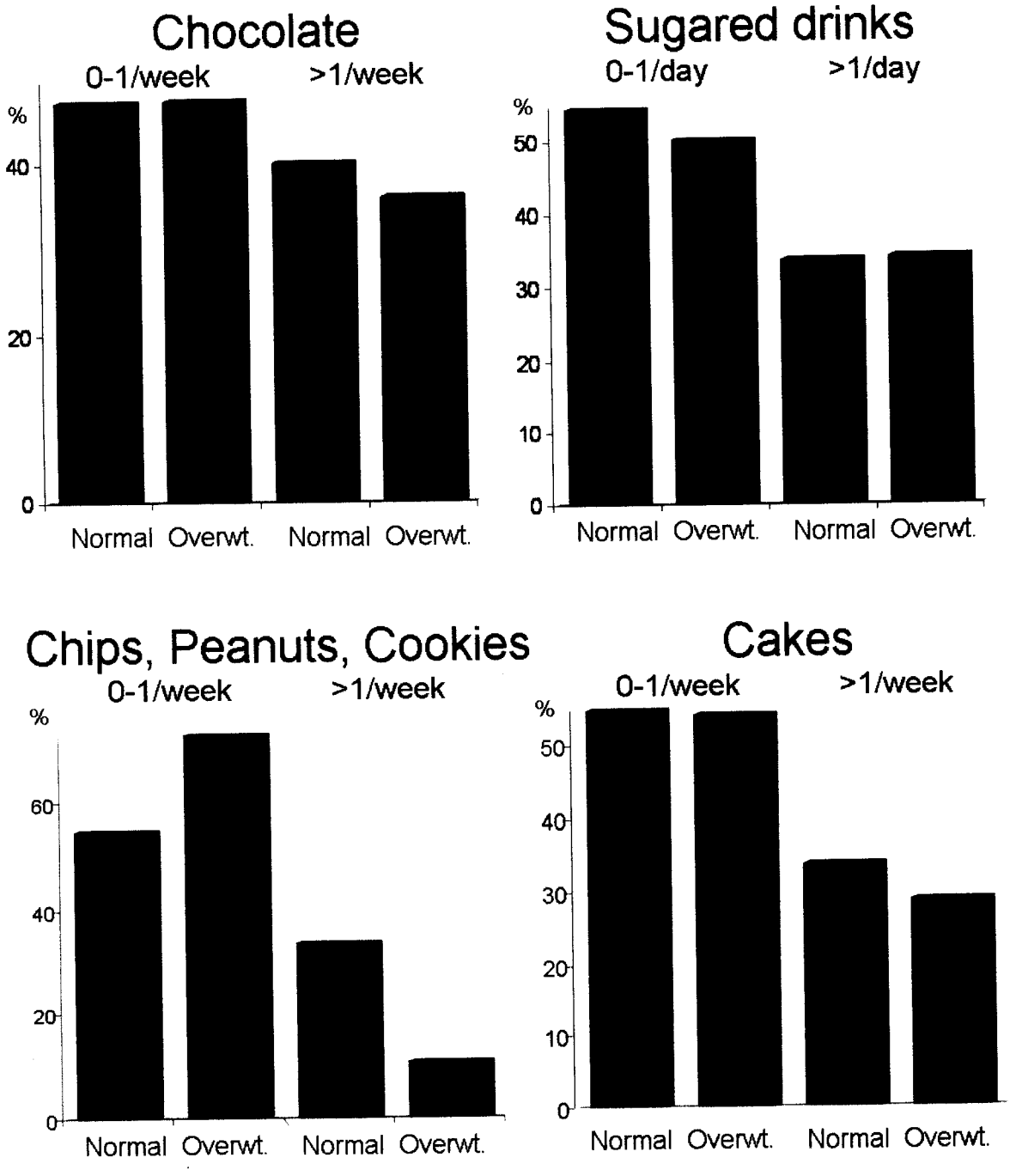

Figure 7: The frequency of consumption of chocolate, sugared drinks, chips peanuts and cookies, and of cakes, did not differ between children with normal body weight and those with overweight in a study on food habits performed in some 6862 children aged 5-6 years from Bavaria, southern Germany (Koletzko et al, Brit J Nutr 2004). These data point to a rather complex aetiology of childhood overweight, and thus the modification of consumption of single foods e.g. by labelling information and claims may have only a limited impact on rates of overweight children, and potential health outcomes.

With respect to the quantitatively most relevant diet related disorder in European children, overweight and obesity, there is no the evidence that the choice and consumption pattern of single food products would predict the occurrence of overweight. In a study on food habits performed in some 6862 children aged 5-6 years from Bavaria, southern Germany, the frequency of consumption of foods such as chocolate, sugared drinks, chips peanuts and cookies, and of cakes, did not differ between children with normal body weight and those with overweight (Fig. 7). (Koletzko B, de la Guéronnière V, Toschke AM, von Kries R. Nutrition in children and adolescents in Europe: what is the scientific basis? Brit J Nutr 2004;92,suppl 2:S67-73)

However, experience with the introduction of easily understandable consumer information on health aspects of food shows that this can markedly influence the product choices of consumers, and in particular of young families with children. An impressive example is the experience of the Swedish supermarket chain ICA, which has introduced since several years a keyhole symbol placed on those foods which are low in fat and/or rich in fibre, in accordance with the preferred choices following the Nordic Nutrient Recommendations (www.ica.se). The introduction of the keyhole symbol has indeed resulted in market proportional increase of sales of those foods that carry the symbol, within the respective food categories, and parents appear to be especially responsive to this type of labelling information.

Such labelling information and claims, however, appear to have a lesser effect in low socioeconomic groups of the population. A recent study from Canada examined the relationship between the price and amounts of saturated and trans fats in margarines and oils, and the relationship between price and the presence of nutrient content claims such as 'low in saturated fat'. Price and label information were recorded for margarines (n=229) and oils (n=342) sold in the major supermarkets within the greater Toronto area. The study revealed a negative relationship between the price of margarines and the amounts of saturated fat and of trans fats contained in them, while there was no such relationship in oils. Of importance, margarines with a nutrient content claim were significantly more expensive than were those without a claim. These findings for margarines are of particular concern for lower income groups for whom budgetary constraints result in the purchase of lower priced foods, and also raise important questions about the usefulness of nutrient content claims in guiding food selections in such lower socioeconomic groups (Ricciuto L, Ip H, Tarasuk V. The relationship between price, amounts of saturated and trans fats, and nutrient content claims on margarines and oils. Can J Diet Pract Res. 2005 Winter;66(4):252-5).

Thus, one can conclude from the available data that appropriate and easily understandable nutrition claims have the potential to provide a relevant contribution to improving food choices for children. Thereby, appropriate nutrition claims may contribute to enhancing dietary quality and health, but they must be expected not to reach all segments of the population to a similar degree. In contrast to nutrition claims, there are no indications of benefits of the use of reduction of disease risk claims directed specifically to children.

3.3 *Does the regular consumption of products chosen according to health claims lead to a balanced diet? Can nutritional/health claims be responsible for the failure of achieving a balanced diet?*

Appropriate nutrition claims may enhance the ability of consumers to make healthier dietary choices, including choices that parents make for their children. This might also apply to health claims, particularly if such health claims are linked to desirable nutrient profiles of the respective products.

For example, claims indicating products that contain lower amounts of sodium/salt can help enhancing consumer choices for food products with low salt content, which is of considerable public health relevance. The present average dietary sodium intakes of adults are in the order of 3000-4500 mg/day and thus 2-3-fold higher that current recommended intakes or population reference intakes, and they also markedly exceed the level of 2500 mg recently given as the maximum level of daily intake that is likely to pose no risk of adverse effects on blood pressure or otherwise (Karppanen H, Karppanen P, Mervaala E. Why and how to implement sodium, potassium, calcium, and magnesium changes in food items and diets? J Hum Hypertens. 2005 Dec;19 Suppl 3:S10-9). Decreasing the dietary intakes of sodium has been shown to reduce elevated blood pressure. This blood pressure lowering effect is further enhanced by increasing intakes of potassium, calcium, and magnesium each of which can contribute further. In fact, the combination of all these factors has an excellent blood pressure lowering effect. Thus, the introduction of well understandable nutrition and health claims which support the preferential choice of food products with a desirable mineral nutrient composition is likely to be effective in producing immediate beneficial effects.

Consumers responses and attitudes to claims on fat contents in foods were recently studied in Australia. Awareness of claims about fat was high, and study participants admitted that these claims did indeed influence their purchase decisions. Claims were considered most useful on foods that were high in fat. However, there was considerable scepticism about all nutrient claims, and consumers preferred to check claims about fat against the values in the nutrition information panel. Many claims were seen as advertising that could be misleading, deceptive or confusing. While claims about fat might prompt product trial, factors such as price, taste, naturalness, as well as other nutritional factors, also influenced purchase decisions (Chan C, Patch C, Williams P. Australian consumers are sceptical about but influenced by claims about fat on food labels. Eur J Clin Nutr. 2005 Jan;59(1):148-51).

The information available thus suggests that the introduction and promotion of tempting nutrition and health claims on food packages may help the consumers to choose healthier food alternatives for themselves and for their children, and make composition improvements tempting also for the food industry, with great potential for improving public health.

However, the use of claims, and particularly an inappropriate use of claims, may also lead to undesirable effects. For example, a large number of products marketed to young children in Europe with a less than desirable nutrient composition, such as sweet foods and snacks with high energy density but low contents of essential and micronutrients, are labelled and advertised with reference to extra contents of nutrients such as vitamins, calcium, or other minerals. Such claims can make those products appear to parents as more healthy and desirable choices, while there actual nutritional composition is often such that one would rather not have them consumed by children on a regular basis. It must also be emphasized that claims are usually made for industrially processed foods, whereas they are not applied to products that are presented and sold loose, for example bread, vegetables and fruits which are recommended to be consumed in large amounts as desirable basic components of a healthy diet. Therefore, health conscious parents that are particularly concerned about providing nutritious products to their children might be mislead by to consider bread, vegetables and fruits less valuable and desirable components of their children's diets than processed foods with some added nutrients that bear claims. These concerns lead to the conclusion that the use of specific claims for children's foods should be avoided.

3.4 What is the current availability of data and what are the accepted methodologies for scientific substitution of health claims?

In the USA, the Nutrition Labelling and Education Act of 1990 states that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition (health claim), unless the claim is made in accordance with Food and Drug Administration (FDA) regulations. Thus, the FDA promulgated regulations that described general requirements for health claims on foods in conventional food forms and specific requirements for seven authorized health claim topics. Three authorized claims are related to heart disease: dietary saturated fat and cholesterol and coronary heart disease; fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease and sodium and hypertension.

The general requirements regulation specifies the scientific standard for assessing the validity of claims, criteria for the qualification of claims, conditions for disqualification and general labelling requirements for health claims. The basis for approving a health claim is the totality of publicly available scientific evidence and significant agreement among experts qualified by scientific training and experience to evaluate the relationship (Yetley EA, Park YK. Diet and heart disease: health claims. J Nutr. 1995 Mar;125(3 Suppl):679S-685S).

In the EU, the project on The Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) evaluated existing schemes which assess scientific substantiation, produced a generic tool for assessing the scientific support for health claims for foods, and established criteria for markers which can be used to explore the links between diet and health. PASSCLAIM, which involved more than 160 experts from academia, industry, public interest groups and the regulatory environment and was supported by the Fifth European Community Framework Programme for Research and Technological Development, developed criteria for the scientific substantiation of claims (Table 2) (Aggett PJ, Antoine JM, Asp NG, Bellisle F, Contor L, Cummings JH, Howlett J, Müller DJG, Persin C, Pijls LTJ, Rechkemmer G, Tuijtelaars S, Verhagen H. Passclaim. Process for the Asessment of Scientific Support of Claims on Food. Consensus on Criteria. Eur J Nutr 2005;44;Suppl 1:1-30).

Table 2: Criteria for the scientific substantiation of claims that were agreed by the participants of the PASSCLAIM project

1. The food or food component to which the claimed effect is attributed should be characterised.

2. Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:

   2(a) Study groups that are representative of the target group.

   2(b) Appropriate controls.

   2(c) An adequate duration of exposure and follow up to demonstrate the intended effect.

   2(d) Characterisation of the study groups' background diet and other relevant aspects of lifestyle.

   2(e) An amount of the food or food component consistent with its intended pattern of consumption.

   2(f) The influence of the food matrix and dietary context on the functional effect of the component.

   2(g) Monitoring of subjects' compliance concerning intake of food or food component under test.

   2(h) The statistical power to test the hypothesis.

3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.

4. Markers should be:

   4(a) biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;

   4(b) methodologically valid with respect to their analytical characteristics.

5. Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.

6. A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

Based on these criteria, proposed claims need to be and can be evaluated by a science based approach, on a case by case basis, by an independent scientific expert body, for example the European Food Safety Authority (EFSA). Such an evaluation would be based on the submission of appropriate documentation of available scientific knowledge and research results. However, there are no agreed concepts on criteria for health claims specifically addressing children.

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