

ILSI Europe
Report Series

CONSUMER UNDERSTANDING OF HEALTH CLAIMS



SUMMARY REPORT OF A WORKSHOP HELD IN MAY 2006

Organised by the
ILSI Europe Consumer Science Task Force

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By Peter Leathwood, Hal MacFie and Hans van Trijp

SUMMARY REPORT OF A WORKSHOP HELD IN MAY 2006 IN FLORENCE, ITALY
ORGANISED BY THE ILSI EUROPE CONSUMER SCIENCE TASK FORCE

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FOREWORD

Provided that they are scientifically substantiated, nutrition and health claims linked to food products can help consumers make well-informed food choices. The new European legislation on nutrition and health claims made on foods was published on 30 December 2006 (with a corrigendum published on 18 January 2007). This law sets out conditions for their use, establishes a system for their scientific evaluation and will create European lists of authorised claims. An important aspect of this legislation is that it states (Article 5.2) “the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim”.

In anticipation of this legislation coming into force, the ILSI Europe Consumer Science Task Force set up an expert group activity and prepared a paper to address the issues that will be faced by legislators and producers in implementing this legislation. The paper also summarises some of the scientific approaches and decision-making frameworks that could be used to provide and assess the evidence of consumers’ understanding of health claims to support submissions for new claims. The Task Force also convened a workshop on “Consumer Understanding of Health Claims” in Florence on 17–19 May 2006 to comment on the draft of the paper and to stimulate the debate on methodologies that need to be developed to assess consumer understanding of nutrition and health claims. The timing of this workshop was particularly appropriate as the voting on the second reading of the law took place on 16 May 2006. The format of the workshop was a series of presentations to inform the participants about the current state of the development of the legislation, the problems that are likely to be faced in implementing it and the science that could be used to support submissions. Participants then joined one of four working groups to debate specific aspects and make recommendations.

This report summarises the results of that workshop and makes recommendations on the evidence and research that is needed to support the practical application of the legislation. It also gives guidance to producers about consumer research that should be used to support submissions.

OBJECTIVES OF THE WORKSHOP

The goals of the workshop were to:

- Review the meaning of consumer understanding of nutrition and health claims in the new regulatory context
- Consider the implications for consumer science and market research of nutrition and health claims
- Illustrate the use of nutrition and health claims in the market place
- Review methodologies for consumer research on understanding health claims, including qualitative and quantitative approaches, heuristics and data on purchase and consumption
- Recommend appropriate methodological approaches to demonstrate adequate consumer understanding proportionate to the nature of the claim
- Stimulate the debate and identify gaps and research needs

The new legislation identifies four types of claim:

- (1) Content claims
- (2) Health claims based on generally accepted evidence
- (3) Health claims based on new evidence
- (4) Health claims related to reduction of disease risk or children's development or health

It also specifies that claims will only be permitted if the average consumer can be expected to understand the beneficial effect as expressed in the claim and, if a claim is aimed at a particular group of consumers, that the impact of the claim can be assessed on average members of that group.

The workshop addressed the question of how to assess consumer understanding of nutrition and health claims as required by the legislation. It began by exploring the processes involved in consumer understanding (and misunderstanding) and the methodologies most appropriate to study them. This was followed by an outline of the practical experiences of regulators, which indicated that consumers do have difficulty understanding some claims and may in some circumstances over-interpret them. The third session used three case studies from industry to illustrate the methods used and the problems encountered in assessing consumer understanding of the claimed benefits. In the fourth session a representative from a consumer research company outlined the methods used to assess consumer understanding of claims in the full context of the product, the packaging and the advertising.

The participants then split into four working groups to discuss different aspects of the problem of assessing consumer understanding of nutrition and health claims and to develop recommendations.

REGULATORY FRAMEWORK

David Richardson (DPR Nutrition, United Kingdom) gave an overview of the new European legislation. The new European legislation on nutrition and health claims made on food (published in December 2006) sets out conditions for their use, establishes a system for scientific evaluation of the claims and will create European Community lists of authorised claims. The new law emphasises that claims on foods will only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim and that it is appropriate to protect all consumers from misleading claims.

Claims will be broadly classified into four groups and each group will have a specific authorisation procedure.

The first group concerns “content” claims for nutrients and “other substances” that influence growth, development or the functions of the body. Many nutrition claims are listed already, such as low energy, fat-free, high fibre, source of vitamin (e.g. vitamin C), etc., and each has specific conditions applying to it. Comparative claims can also be made if they relate to the same quantity of food and between foods of the same category. Other substance content claims such as omega-3, prebiotics, probiotics etc. can be added to the list by a Committee Procedure described in Article 25 (2). The Commission will involve, where appropriate, interested parties, in particular food business operators and consumer groups, to evaluate the perception and understanding of the claims in question.

The second group comprises health claims¹, based on generally accepted scientific evidence under Article 13.1, that describe or refer to any of the following:

- The role of a nutrient or other substance in growth, development and the functions of the body.
- Psychological and behavioural functions.
- Slimming, weight control, a sense of hunger or satiety, or a reduction of available energy from the diet.

The new law requires this list of generally accepted claims to be compiled by Member States by the last day of the month of entry into force of the regulation plus one year (i.e., January 2008). Then, after consulting the European Food Safety Authority (EFSA), the Commission shall adopt, in accordance with the procedure referred to in Article 25 (2), a Community list of permitted claims. This Community list will be developed by the last day of January 2010.

The third group concerns health claims based on newly developed scientific evidence and/or those claims that include a request for the protection of proprietary data. The procedure for these claims is set out in Article 18 and requires evidence of understanding by the “average consumer”.

The fourth group of claims relates to reduction of disease risk² and to those referring to child development and health and must be authorised in accordance with procedures laid down in Articles 15, 16, 17 and 19 of the regulation for inclusion in a Community list. The requirements of the procedures include a proposal for the wording of the claim as part of the application for authorisation, verification by EFSA that the wording of the health claim complies with the criteria laid down in the regulation and an EFSA proposal for the wording of the claim, as well as the basic requirements for demonstrating scientific substantiation and consumer understanding.

The burden of measuring consumer understanding of claims falls mainly on the food business operator.

1. Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

2. Reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

The consumer and the new legislation

Recital 15 of the preamble to the new regulation helps define the notion of the average consumer and states:

“It is important that claims on foods can be understood by the consumer and it is appropriate to protect all consumers from misleading claims. However, since the enactment of Council Directive 84/450/EEC of 10 September 1984 concerning misleading and comparative advertising, the Court of Justice of the European Communities has found it necessary in adjudicating on advertising cases to examine the effect on a notional, typical consumer. In line with the principle of proportionality, and to enable the effective application of the protective measures contained in it, this Regulation takes as a benchmark the average consumer, who is reasonably well-informed, observant and circumspect, taking into account social, cultural and linguistic factors, as interpreted by the Court of Justice, but makes provision to prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims. Where a claim is specifically aimed at a particular group of consumers, such as children, it is desirable that the impact of the claim be assessed from the perspective of the average member of that group. The average consumer test is not a statistical test. National Courts and Authorities will have to exercise their own faculty of judgment, having regard to the case-law of the Court of Justice, to determine the typical reaction of the average consumer in a given case.”

The legislation does not describe in detail what level and format of evidence needs to be submitted as proof that the average consumer can be expected to understand the beneficial effects as expressed in the claim. But the conclusions are justified that:

- Some level of evidence to illustrate consumer understanding will be required in the claim approval process.
- The details of what this level of evidence requires are still to be defined.

Specifically, there are four key issues in the area of consumer understanding of nutrition and health claims regulation that seem key challenges for the consumer science community:

- (1) How is consumer understanding of nutrition and health claims to be defined?
- (2) How is the concept of the average consumer to be operationalised?
- (3) What methodology is required to deliver evidence for consumer understanding?
- (4) How can the consumer understanding part of the new legislation be made practical?

These issues were addressed in the working groups that followed the scientific presentations.

SESSION 1: REVIEW OF THE EXPERT GROUP WORKING PAPER

Peter Leathwood (Nestlé, Switzerland) summarised the ILSI Europe Consumer Task Force's Expert Group working paper (Leathwood *et al.*, 2007) and presented an outline of the qualitative methodologies that could be used to explore consumer understanding of health claims (see also Williams, 2005). He underlined the importance of the processes that people use to understand and interpret claims, considering especially how the reader's own knowledge may be used to go beyond what is actually stated in the claim, and the different ways consumers can misunderstand health claims. This led to the conclusions that:

- Adequate understanding implies that the consumer makes inferences that are justified by the objective content of the claim without significant embellishment or exaggeration.
- These inferences may be influenced by other communication elements, so understanding of the claim needs to be tested in context.
- No criterion (in terms of the proportion of consumers demonstrating understanding) is available, even for current claims.

Participants pointed out that with regard to the idea of a criterion, one should be very cautious about setting numerical targets; levels of understanding are likely to vary across the member states and according to whether the science is well known or emerging. A case-by-case procedure is likely to be more appropriate.

Qualitative approaches

Qualitative methods cover a wide range of approaches including in-depth interviews (focus groups, etc.), observation linguistic analysis, semiotics, role-playing and many others. The aim is to understand the meaning of claims to consumers in a given culture, explore the logic(s) used to interpret them, identify aids and obstacles to understanding, create links between food and claim (appropriate combinations), identify meanings that are universal (shared by all), local (different between cultures) or individual (different within cultures) and finally, to explore, with consumers, how best to communicate different claims. Qualitative approaches provide insights into why people believe certain claims and not others, and importantly provide a valuable source of data to enable quantitative studies to be designed that are relevant and comprehensive.

Some participants felt that, as the qualitative work indicates that understanding is often influenced by consumers' pre-existing beliefs, it is difficult to get an independent measure of understanding a claim. One approach to resolve this problem is to explore consumers' understanding of the intended meaning of the claim. A second point raised was that, although the speaker proposed that qualitative work needs to be followed up by quantitative work, there are situations (e.g., for commonly and widely shared beliefs) where qualitative work alone is sufficient.

Quantitative approaches to health claims research

Hans van Trijp (Wageningen University and Unilever, the Netherlands) underlined that, when preparing a dossier to support a submission for a claim, quantitative research is essential but that little consensus exists as to how best this should be carried out. In general, consumers seem to prefer shorter health claims, expressed in normal language, rather than long, complex claims in scientific language, and consider that governments should approve claims. Also, consumers do not seem to differentiate between nutrient content, structure–function and health claims. Finally, there is some evidence that health claims on the front of the pack may reduce some consumers' search for back-of-pack information.

Participants agreed that the advantage of the quantitative approach is the numerical format of the results. However, this type of testing usually involves forced reading of the claim in an artificial environment. As the proposed definition of the average consumer (one who is reasonably well-informed and reasonably observant and circumspect) suggests that the claim would be read by such a consumer, forced reading is not unreasonable.

The decision heuristic approach

Peter Todd (University of Indiana, USA) noted that most studies of decision making in psychology and economics reflect a traditional definition of human rationality: the idea that people behaving rationally (should) use optimal decision-making strategies that assume unlimited knowledge, time and information-processing power. But, to understand the way that humans make decisions in everyday life, a more psychologically plausible perspective is required. Heuristics provides a useful approach for defining the sets of rules that people may adopt. Each heuristic specifies the order in which to search for information, indicates when enough information has been found so that search can be stopped and determines how the information found will be processed to make a final decision. The application of this approach to understanding how people understand health claims involves knowing how they process them to make decisions. These kinds of questions can be addressed through laboratory studies, including ones that track where people are looking for information about a product (on a label or on a web page description, for instance), or perhaps preferably in a more naturalistic shopping situation, though there the information search steps will be difficult to monitor.

Participants were interested in the various heuristics proposed, speculating on which might be involved in processing health claims. The simplifying strategies proposed emphasise that many consumers will not read the claims and may infer many things from a single cue (e.g., a front of pack symbol).

Purchase and consumption data: collection, analysis and utilisation

Peter Sträter (Südzucker, Germany) pointed out that purchase and consumption data contain information about observed purchase or reported use of consumer goods and services. Purchase data are collected at the point of sale, usually without the interaction of the shopper, who often purchases for a number of consumers. Consumption data originate in households and other sites of consumption. The data are mostly reported by the consumers themselves, either on an ad hoc basis or, in the case of panel data, as an activity that can go on for many years, with a slowly changing group of participants. Often, structural characteristics such as income, education, age and health are documented and it is possible to correlate the consumption data with these characteristics. With the help of econometric models it is possible to quantify relationships within the data to evaluate, for example, the impact of prices and advertising of goods, the roles of income, socio-economic status of consumers, or consumption patterns on the development of markets and segments thereof. Using information on individual packages it may be possible to estimate the impact that products with new claims might have.

Participants agreed that this methodology might be used to monitor the purchase of products containing health claims, with the possibility of analysing specific demographic segments.

SESSION 2: PRACTICAL EXPERIENCES FROM REGULATORY INSTITUTIONS

The Food Standards Agency (United Kingdom)

The challenge of checking and reversing the rise of obesity and diet-related disease is a key driver of nutrition policy in the UK. It is being addressed in many ways, such as providing consumers with information about nutrition, and through labelling that helps inform healthy eating choices. British consumers are increasingly conscious of the need to improve their diets and many are taking action. They are demanding more and better information to help them make informed choices. Gill Fine (Food Standards Agency, FSA, UK) presented consumer research carried out by the FSA into nutrition and health claims, which underlined that consumers have different expectations and different levels of understanding, and that there is a range of factors involved. The initiative on signpost labelling rests on extensive consumer research into how such labelling is understood and used, and the FSA considers this work provides a useful model for the study of consumer understanding.

Participants were interested in the FSA's work on signposts and traffic lights, asking if traffic lights had been tested for categories where the alternatives are only red or green? The FSA found that consumers expect there to be several colours and they do not see red as "never eat" but as "be cautious". In addition, any new system needs to be accompanied by a good information and communication campaign.

The US experience with health claims

Robert Earl (Food Products Association, USA) addressed the similarities and differences between the US and EU regulatory systems, arguing that in the USA there is a shortage of studies on consumer perceptions and understanding of nutrition and health claims. In the USA, on-pack health claims are regulated through the Food and Drug Administration (FDA) and advertising through the Federal Trade Commission (FTC), whereas in the EU both product claims and advertising fall under the new legislation. In the USA, the burden of proof for health claims is with the Government as it is essentially a post-market assessment of new health claims. In the EU, the burden of proof for new health claims is on the food industry as pre-market authorisation is required. The USA has 12 so-called unqualified health claims, (nine from Significant Scientific Agreement (SSA) and three from the FDA Modification Act (FDAMA)) that are based on a consensus level of high scientific substantiation. However, all of these claims have qualified wordings that include "may" and "reduce the risk of". For these 12 claims, FDA has predefined the wording that can be used.

Participants asked if there was any evidence that this has contributed to healthier eating patterns. This is not yet known because there has been little specific research into this issue.

Health claims in Sweden

Anita Laser Reuterswård (National Food Administration, Sweden) outlined current practice in Sweden concerning the code of practice for health claims, in use since August 1990. According to the Code, generic reduction of disease risk claims must be based on well-established connections between diet-related diseases (or risk factors for these) and diet. Originally eight such connections were included. In 2003 a ninth (the connection between heart disease and whole grain) was added. The organisations responsible for the programme are the Swedish Food Federation and Swedish Food Retailers. The Swedish Nutrition Foundation (SNF) has an advisory role. Documentation submitted in support of a product-specific physiological claim is evaluated by an independent panel of experts appointed by the SNF Research Committee.

Participants noted that the speaker had observed considerable heterogeneity among consumers; some saying they need more information, others not; some need more education, others not; and that this will be very important for the working group discussions.

SESSION 3: PRACTICAL EXAMPLES FROM THE FOOD INDUSTRY

Spreads with plant sterols

René Lion (Unilever, the Netherlands) presented a case study on Becel/Flora ProActiv. The health claim for plant sterols is “clinically proven to actively reduce LDL cholesterol” and is based on the observation that, with appropriate intake of Becel, LDL reductions of around 10–15% are obtained within 3 weeks. The problems that arose in the EU regulatory process were:

- There was no consistent view in EU states on functional foods.
- Handling of claims was neither transparent nor predictable.
- Dialogue with regulators was sometimes difficult.

The problems with the claim approval process arose because:

- The process was still local and differed widely from country to country, ranging from total ban, pre-market approval, to voluntary schemes.
- Communications via pack, print, TV and other means were often regulated/monitored by different authorities.
- There was little clarity as to the criteria for scientific substantiation. There were no guidelines from EFSA at the time of the workshop³, but PASSCLAIM (Aggett *et al.*, 2005) work on the judgement of the evidence has been published. Consumer tests were and are needed to understand how best to communicate the new ingredient, its effectiveness and the new positioning.

Participants noted that in future there would be more pre-testing of understanding before launch and this could include presenting the pre-education material to the European Commission.

Whole grains

Clare Chapman (Cereal Partners Worldwide, United Kingdom) showed that whole grain claims pose an interesting example of messages that are scientifically recognised as relevant to the majority of the population (in a similar way to “5 a day” fruit and vegetable messages) but which lack the recognition of regulatory authorities or governments in many countries. Epidemiological studies support the conclusion that whole grains protect against cardiovascular disease, diabetes, obesity and cancer, but around 90% of the population (in the UK and USA) do not eat enough whole grains. In order to encourage people to choose whole grain foods it is important to have authoritative messages and recognised, consistent claims. The USA has issued dietary guidelines to Americans to encourage increased consumption, but this has not yet been followed by other countries. In Europe there is an opportunity with the new health claims legislation to get whole grain claims on the generic list, and thus work towards consistent claims, which should help consumer understanding and recognition of such claims.

3. The guidance document has been published by EFSA afterwards and at the time of the publication consumer understanding of claims is not a concern of EFSA but rather the concern of the Commission and National Authorities:
http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

Participants speculated that perhaps “made with whole grain” claims might produce halo effects so that the content claim would be interpreted as a health claim. Another point was that consuming a single serving a day was not sufficient and so a specific health claim would relate to at least three servings of whole grain per day. Participants wondered about disclosures for other ingredients in the product (mainly sugar). In these products, lowering the sugar level would almost certainly compromise consumer acceptance. If disclosures and additional nutrition information are required, they will be put on the product, consistent with any legislative requirements.

Probiotics

Michel Rogeaux (Groupe Danone, France) showed how both science and culture are involved in defining appropriate health claims. Science provides the factual basis for the claim, but claims are only useful if they are meaningful to consumers. This requires “understanding”, combined with “attractiveness” (personal interest) and “exposure” (experience), each of the three dimensions supporting the others. This case study examined the launch of a probiotic fermented milk from Danone (Activia). The health claim is that “Activia helps to improve intestinal transit when it is slow”. The case study showed that exact consumer wording about intestinal transit needed to be carefully adjusted to each culture. A combination of qualitative and quantitative approaches, with consumers, health professionals and communicators, was used to define the wording of the claim. Post-launch analysis of motivations for consumption also shed light on the progression of health claim understanding.

Participants were interested to understand the role of focus groups in the process. These were used to understand the interpretations on the part of the consumer on the possible consumer wordings. This was an interesting application because the basic message (improve intestinal transit) was delicate to communicate and difficult for many consumers to understand.

SESSION 4: CONSUMER PERSPECTIVES

A consumer research agency point of view

Benoit Tranzer (IPSOS, France) provided a consumer research company view, pointing out that for any research on health claims:

- The information collected must be reliable.
- Individual levels of understanding of the claim need to be assessed.
- Research must assess the consistency between the claim and the brand, and the potential influence of perception and attractiveness of the brand.
- The brand-behaviour effect (i.e., the ability of the claim to be persuasive in the context of the specific brand) must be evaluated.

To achieve these goals IPSOS uses methodology based on the following elements:

- The claim is tested both with and without the advertising.
- After screening for suitability, the spontaneous reaction of each respondent on being exposed to a picture of the product or the advertisement, the level of understanding of the claim, and opinions about how the brand will affect health and about the credibility, relevance, and differentiation of the brand are collected.
- Analysis of the perception of the product compared to the understanding of the claim (on its own), with and without the claim inserted in the advertisement, is evaluated.

Participants were interested in the concept of the efficiency of a claim and how this is related to understanding. They are different things. Claims can be well understood but have no efficiency in influencing consumer behaviour.

WORKING GROUPS

Working Group A: Impact of the regulation on market research and consumer science needs

The following topics were considered by the participants of Working Group A:

Implications of the new regulations for the design of studies, including the appropriate stimuli to use, and interpretation of results

Studies to investigate consumer understanding may use labels, shelf tests, product-related promotional websites, examples of endorsement of medical, nutrition or dietetic professional associations, and also adverts and other means used to promote the product in question by using claims. It was felt that the decision as to whether consumer research should be repeated in each country where the product is intended to be marketed should lie with the producer in considering the submission.

Practical concerns and benefits

In relation to the list of claims under Article 13 it seems that, for well-established claims, additional consumer research should not be necessary. This is important for small and medium enterprises (SMEs), who are less likely to initiate specific claim-related research.

Opportunities for consumer science and market research

The group concluded that more meaningful and rigorous approaches in consumer science and market research are possible based on the principles that have been described by the ILSI Europe Expert Group. These would ultimately lead to improved cross-functional interactions between different scientific disciplines as well as science and marketing.

Participants suggested that the variation in understanding that will be observed may be a problem. What happens if most respondents understand the claim but a substantial subgroup is misled? They also suggested that, with regard to the question as to whether it is necessary to provide evidence from all countries where the product will be launched or just in one country, the studies carried out will depend on the category of claim. Only for emerging science will there be a need to go through the full procedure.

Working Group B: Description of the average consumer and the intended consumer

The following topics were considered by the participants of Working Group B:

The implications of the new legislation for recruitment of appropriate consumers to take part in studies on understanding of health claims.

The influences of cultural and personal background and nutritional knowledge on consumers' understanding of health claims.

The consequences of the new definition of the average consumer on recruitment criteria for studies evaluating consumer understanding of health claims.

Proportionality

The working group first examined how, according to the type of claim, the definition of the average consumer and/or the required depth of understanding might vary. With the help of its legal members, the group concluded that proof should not be needed for all types of claim, and that more novel or serious claims will need more detailed evidence of consumer understanding.

Type of claim	Who?	Demonstration of understanding required?
Content claims	–	No
Closed positive list (health claims)	Member states, with the European Commission	No
Additions to list	Will depend on novelty?	Will depend on novelty?
Novel claims (reduced risk claims and novel health claims)	Food companies, directly with the European Commission	Yes

Details of the way a benefit is expressed are likely to vary over time because marketing strategy aims to keep brands alive and in the minds of consumers. For the European Commission to re-evaluate every new variant seems neither feasible nor useful. The working group concluded that the focus should be on the diet and health relationship. Core elements of the benefit translated into consumer language should be submitted to regulatory authorities and, when approved, used in all subsequent claim executions.

There is considerable variability among countries and regions across the European Union, thus “average consumer” in the regulation does not mean average European consumer, but average consumer in each of the countries involved. Since social, cultural and linguistic factors are important and country-specific, the working group agreed that member states should be responsible for examining the definition of average consumer used by the food industry in claim dossiers.

The group tried to draw up a list of average consumer characteristics. They agreed that the consumers participating in a test of understanding must be functionally literate in the language of the claim. There was, however, disagreement as to other characteristics. Some favoured using a representative sample of the adult population weighted towards intended consumers, buyers of the product category or household purchasers, according to the type of product and type of claim. Others proposed a focus on health-aware consumers. The group did agree that while it is essential to target intended users as outlined in the legislation, other consumers, also exposed to the claim, should be protected against being misled.

During the discussion it was pointed out that it is possible that the intention of the definition of the average consumer in the legislation was aimed at excluding some extreme consumers. A majority of participants were in favour of testing understanding with intended users rather than average consumers, but agreed that this depends on the claim.

Working Groups C and D: Identification of the strengths and weaknesses of each proposed methodology/ Definition of consumer understanding

As both groups reached the same conclusions, they are summarised together in this section. Both groups considered that a combination of qualitative and quantitative approaches is likely to be needed when testing consumer understanding of health claims, while purchase/consumption data and heuristic approaches may be useful to address special questions.

A health claim can be understood as a speech act within the context of discourse between originators of the health claim (e.g., the food company) and consumers. The communication can thus be evaluated using the conversational maxims outlined by Grice (1975).

Evaluation of understanding should focus on “circumspect” consumers, who at least pay some attention to nutritional information, and should involve a two-step approach, starting with a small-scale qualitative study and following up with larger-scale quantitative research. This has the advantage that even small companies can afford the testing.

An example of the two-step approach

Small-scale qualitative study: The product with the health claim, together with a concept board of the planned advertising, is presented to focus groups or in individual interviews to generate interpretations of the health claim. A set of these interpretations are then selected to be used as statements in a large-scale quantitative study.

Large-scale quantitative study: The product with the health claim, along with a concept board of the planned advertising campaign, is presented to about 100 consumers together with a list of statements gathered in the qualitative study. They are asked to indicate which of the statements on the list they believe to be true about the product.

A control group of another 100 consumers answer the same questions, but are presented with the product and the advertising, without the health claim. This two-group design allows differences between groups to be attributed to the health claim.

To determine if a particular health claim is understood well enough, comparison with some benchmark is required. Unfortunately no benchmarks exist.

The output of the study will be the prevalence of agreement with different interpretations of the health claim, in comparison to inferences about the product without the health claim, and ideally, in comparison to some benchmark. At the time the dossier is submitted, results from a few key countries should be sufficient, but the dossier should include an outline of the kind of testing that will be conducted before the roll-out in the other countries.

One drawback of this methodology is the artificial study context, with forced exposure to the health claim. This is at least partially counteracted by presenting the health claim in the context of the product and the concept of the planned advertising campaign. Additionally, while acknowledging that many consumers might not read health claims very carefully when shopping, a circumspect consumer can be expected to pay sufficient attention to information on the package to generalise the results of the proposed study to a real-world shopping environment.

When designing studies to provide evidence for consumers' understanding of health claims, the following criteria need to be kept in mind:

- An experimental approach helps to disentangle inferences due to the health claim from inferences due to other information about the product.
- In quantitative studies, consumer-generated interpretations of the health claim should be used rather than interpretations proposed by the producer.
- One should provide as realistic a context as possible given the study design (e.g., advertising campaign concept boards).
- A benchmark (not yet available) is necessary to judge if a particular health claim is understood well enough.

Other methodologies

In some cases, post-marketing surveillance may be needed. For example, it can be used to test if the intended target group of consumers has been reached.

The heuristics approach is well suited to assess the effects of health claims on consumers' decision-making processes. An important question in this context is whether health claims induce some consumers to ignore other information on the pack.

Participants agreed that the distinction between literal meaning, intended meaning and realised meaning is extremely helpful as it allows the study to measure both understanding and absence of misunderstanding. They also agreed that there is an urgent need for more research to establish the proportions of consumers demonstrating understanding that one might expect to achieve in the various member states.

Some felt that the group's proposals focused too much on misunderstanding/misleading, whereas the regulatory text asks for evidence of understanding. Participants agreed that the spirit of the legislation was to focus on not misleading the reasonably circumspect consumer.

A minority of participants considered ingredient knowledge may be important, especially if several foods contain the ingredient.

CONCLUSIONS AND RECOMMENDATIONS

Accurately translating the scientifically measured benefit into consumer language

Participants agreed on the importance of accurately translating the claimed benefit from scientific to consumer language. As illustrated by the presentations in this meeting, this involves a careful balance between keeping it simple and understandable vs. keeping it serious and scientific.

Who is an average consumer?

A unique feature of this legislation is that the average consumer is defined as being “reasonably well informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors”. However, it is emphasised that this is not to be taken as a statistical test and that it is appropriate to protect all consumers from misleading claims. This generated a lot of discussion in the workshop and participants were left somewhat puzzled on how this would materialise in practice.

There was consensus that understanding by the intended consumer is essential in the provision of evidence. The problem is that other consumers will also be exposed to the claim so understanding among a broader group of consumers may also be needed to ensure protection of all consumers.

What proportion of consumers can be expected to understand a given claim?

There is very little information published on this point and there was a strong consensus on the urgent need for more research to establish the proportions of consumers demonstrating understanding that one might expect to achieve for existing claims in the various member states. Some suggested that if food companies agreed to release some of their findings into the public domain this would help establish realistic expectations in terms of the proportions of consumers understanding different claims.

Consumer understanding of new claims

Understanding by consumers of a really new claim is likely to be low at first, but can be expected to increase over time with repeated exposure to the information. Thus, for some new health claims, it is not very realistic to expect that full understanding can be developed before the claim is permitted in the market. This could be an added complication to the development of new health claims. A potential solution that participants suggested was an increased effort in education together with critical exposure to new health claims before they actually reach the market.

Methodology to deliver evidence for consumer understanding

The ILSI Europe Consumer Science Expert Group discussed four approaches used in marketing and consumer research for nutrition and health claims: qualitative, quantitative, heuristics and analysis of purchase/consumption data. It was recognised that, for providing evidence of consumer understanding as requested in the new legislation, a two-phase procedure will usually be sufficient. The first phase is based on spontaneous articulation of the associations that consumers have with the health claim. This identifies the range of inferences (correct and inappropriate) drawn by consumers. The second phase quantifies consumer responses on the most important inferences (some coded positive, some negative). It was felt that the scale of work required by this approach was within the grasp of SMEs. It was also suggested that for widely shared beliefs, qualitative work alone may sometimes be sufficient. Evidence obtained from heuristics research (to understand some of the psychological mechanisms) and analysis of purchase and consumption data (relevant to post-launch monitoring) were not felt to be essential to pre-launch authorisation.

There was a consensus that, although the idea of establishing norms for understanding and making invalid inferences was attractive, it would not help in practice as there is just too much variation between claims in terms of familiarity, complexity etc.

The workshop participants agreed on the following recommendations:

Recommendation 1

The proposed two-stage qualitative/quantitative testing methodology is a realistic vehicle for both SMEs and large companies. However, the actual methods used will depend on:

- The level of detail requested by the Commission and the European Food Safety Authority (particularly with respect to multi-country roll-outs).
- Agreement on a more formal definition of what is meant by “evidence that the average consumer can be expected to understand”.

Recommendation 2

For competitiveness of the European food industry it is important that:

- What is needed for authorisation is defined precisely so that it can be incorporated in the food business operators’ internal business case evidence.
- It remains practical not only for multinational companies but also for SMEs seeking approval for health claims.

Recommendation 3

The food business should take a lead in pro-actively clarifying (together with other stakeholders) the criteria and level of evidence required. Food companies already collect a lot of this type of information for building the health claim business case internally and it is important that these processes are optimally aligned to European requirements in terms of level and format of evidence.

Final conclusion

The final conclusion from this ILSI Europe workshop is that food business operators face the challenge of submitting pre-market authorisation evidence on consumer understanding of (new) nutrition and health claims. Such evidence should be scientifically convincing, yet practical, and at the same time must sufficiently protect their intellectual property. It is therefore important that all stakeholders (the European Commission, the European Food Safety Authority, the Member States, consumer representatives, the market research and consumer science communities, the food business operators) work together to clarify further the consequences of this new legislation on research concerning consumer understanding of nutrition and health claims. This will aid practical application of the legislation and avoid complex trial-and-error that could disadvantage the competitive position of the European food industry.

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